



ICS STANDARDS 2020 - 2021



 Las Vegas, United States of America

The 2020 - 2021 compilation of the
**International Continence Society Standardisations, Consensus statements,
Educational modules, Terminology and Fundamentals documents,
with the International Consultation on Incontinence algorithms**



ICS STANDARDS 2020-2021

ICS Standards 2020-2021 brings together many of the major initiatives of the International Continence Society in its role of supporting healthcare professionals to deliver care and develop knowledge.

Contained here are the current documents developed by the organisation. These include the rapid response initiatives for adjusting our practice with the new healthcare challenges brought by the Covid-19 pandemic. As previously, we provide the ICS Consensus Statements, which reflect leading opinion in challenging areas of practice. The Fundamentals of Assessment section is a compilation of succinct reviews setting out the most important components for acquiring or consolidating clinical knowledge, with examples, in lower urinary tract symptoms, incontinence and prolapse. The Standardisations are the state-of-the-art reference sources for the specialist professional, developed by expert working groups overseen by the ICS Standardisation Steering Committee. The International Consultation on Incontinence algorithms are therapy pathways derived by expert committees responsible for detailed literature review and interpretation as part of the regular Consultations process- published most recently in 2017. These documents are a powerful resource intended to help all healthcare professionals dealing with the broad scope of this clinical area.



David Castro-Diaz
ICS General Secretary

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1. ICS STANDARDISATIONS

The Standardisations are flagship ICS documents that are the reference point for all terminology and practice in the relevant clinical areas, developed by the ICS, often in partnership with other professional bodies. They ensure that the term for a symptom, condition or disease has the same meaning for all healthcare professionals. They are a series of evidence-based pragmatic documents, developed by experts following a defined process (1), and covering the substantial majority of all relevant areas. Such terminology strength underpins the advancement of research and clinical practice. This compilation incorporates the current ICS Standardisations applicable in 2020. For a quick search on individual terms, the ICS also has a searchable glossary: www.ics.org/glossary

The ICS also has a historical compilation of older Standardisations that have been superseded.



Marcus Drake
ICS Trustee



REVIEW ARTICLE

The International Continence Society (ICS) report on the terminology for male lower urinary tract surgery

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Abstract

Introduction: In the development of terminology of the lower urinary tract (LUT), due to its increasing complexity, the terminology for male LUT surgery needs to be updated using a male-specific approach and via a clinically-based consensus report.

Methods: This report combines the input of members of the Standardization Committee of the International Continence Society in a Working Group with recognized experts in the field, assisted by many external referees. Appropriate core clinical categories and a subclassification were developed to give a numeric coding to each definition. An extensive process of 14 rounds of internal and external review was developed to exhaustively examine each definition, with decision-making by collective opinion (consensus).

Results: A Terminology Report for male LUT and pelvic floor surgery, encompassing 149 separate definitions/descriptors, has been developed. It is clinically-based with the most common diagnoses defined. Clarity and user-friendliness have been key aims to make it interpretable by practitioners and trainees in male LUT surgery. Figures have not been included to avoid any preference or bias towards a specific procedure.

Conclusions: A consensus-based Terminology Report for male LUT surgery has been produced aimed at being a significant aid to clinical practice and a stimulus for research.

KEYWORDS

lower urinary tract dysfunction, male surgery, terminology

On behalf of the Standardization Steering Committees ICS and the ICS Working Group on the Terminology for Male Lower Urinary Tract Surgery

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1 | INTRODUCTION

The surgical procedures for the lower urinary tract (LUT) vary widely in indications. Even surgeries intended for the treatment of oncological and stone diseases have functional implications that can lead to the need for additional surgeries. Prostate surgeries and other therapies applied to prostate disease have been subject to recent developments and multiple variations with local preferences in technical details and terminologies.

Some procedures have their rationale and origins decades ago, with subtle differences among them. Traditional names and definitions were adopted long before current standardization approaches, leading to historical, conceptual, and practical puzzles and misunderstandings. For many years, a number of different terms have been used to describe surgical procedures even within the same surgical teams in a hospital.

With a plethora of new techniques being introduced the terminology for standardization of names for surgical procedures is becoming more important to facilitate clear communication amongst professionals. Most of these procedures are undertaken by urologists who have their own jargon with imprecise but widely accepted terms. However, nowadays, LUT dysfunctions are treated by various other professionals, so a standardized terminology is required for effective communication and research. Invasive procedures may have a diagnostic or therapeutic intention and often, the same procedure can aim both objectives simultaneously.

No document is available to standardize these terms in a comprehensive methodology encompassing open, laparoscopic and robotic, endoscopic surgeries, and minimally invasive therapeutic options. In general, LUT male surgery classification can be based on etiologies: oncologic, stone disease, and functional procedures. The latter is the focus of this report.

The International Continence Society (ICS) has provided leadership in terminology for LUT dysfunction over decades employing combined or generic reports.

The current report acknowledges that a male-specific terminology for invasive LUT procedures is required for surgical procedures in functional urology. It is envisaged that this report will result in

- (i) greater coherency and user-friendliness,
- (ii) greater specificity of surgical procedures,
- (iii) more accurate communication for clinical and research purposes.

Hence, in a functional and anatomical classification it will be divided into the following sections:

- I. urethra
- II. prostate
- III. bladder neck
- IV. bladder
- V. urinary diversions and reconstructions
- VI. vesico-ureteric junction and ureter

Some procedures involving the lower ureter will also be discussed as they happen to have an effect on LUT (dys)function.

The document reviews old but still existing procedures and also the latest approaches with clear worldwide acceptance. Historical practices and methods are defined for the sake of completeness and also because patients may present persistent complaints following historical treatments. Regular updates will be needed and considered in the initial document structure. The report is definitional with additional explanation when judged necessary.

The description of the procedure will be limited to the relevance of terms and expressions. Whenever possible, aliases and synonyms will be commented, and an historical explanation will be given. For example, Millin's prostatectomy versus retropubic transcapsular prostate adenectomy. Terminology is aligned with previous ICS definitions.

TABLE 1 Total, new, and changed definitions (compared with previous male-inclusive Reports)^{1,2}

Section	New definitions/ descriptors	Changed definitions/ descriptors	Total
I. Urethra	29	0	29
II. Prostate	36	0	36
III. Bladder Neck	5	0	5
IV. Bladder	23	0	23
V. Urinary Diversion/reconstruction	34	0	34
VI. Vesicoureteric junction/ureter	22	0	22

Origin: Where a term's existing definition (from one of multiple sources used) is deemed appropriate, that definition will be included and duly referenced. A large number of terms in male LUT invasive procedures, because of their long-term use, have now become generic, as apparent by their listing in medical dictionaries (Table 1).

Able to provide explanations: Where a specific explanation is deemed appropriate to explain a change from earlier definitions or to qualify the current definition, this will be included as an addendum to this paper (*Footnote [FN] 1,2,3...*). Wherever possible, evidence-based medical principles will be followed.

2 | SECTION I: URETHRA PROCEDURES

2.1 | Urethral assessment or enlargement

2.1.1 | Urethral calibration

Measurement of the diameter of the (distal) urethral lumen with special urethral sounds. **NEW**

2.1.2 | Urethral dilatation

Distension of a stenotic segment with semi-rigid, rigid dilators, or balloon distention. **NEW**

2.1.3 | Urethroscopy

Endoscopic visualization of the inner wall of the urethra (mucosa), usually done with a flexible or rigid cystoscope. **NEW**

2.1.4 | Meatotomy

Incision of the meatus to enlarge the distal urethra to the caliber of the urethral lumen. **NEW**

2.1.5 | Meatal skin flap technique

After meatotomy, a flap is mobilized from the prepuce or distal penile skin and sutured to the edge of the opened *fossa navicularis*. **NEW**

Graft technique

After meatotomy, skin, buccal mucosa, or any other suitable tissue is used as a free patch or a tube and sutured into the edge of the *fossa navicularis* or to substitute the urethra at this level. **NEW**

2.1.6 | Meatoplasty

Reconstruction of the meatal segment of the urethra for cosmetic or functional purpose. **NEW**

2.2 | Urethral incision

2.2.1 | Urethrotomy

Incision of an urethral stricture.

Blind urethrotomy

(without visual guidance): Opening of the stricture with the use of a special instrument (Otis urethrotome) to perform the incision without direct visualization. **NEW**

Endoscopic urethrotomy

(direct vision): Opening of the stricture with a cold incision (Sachse urethrotome using mechanical effect) or energy (LASER) under urethroscopy. **NEW**

2.3 | Transurethral resection of the urethra

Mono- or bipolar electric ablation of intraluminal tissue of the penile or bulbar urethra using a resectoscope and a resection loop or LASER, mostly done for urethral tumors. **NEW**

2.4 | Sphincterotomy

Transurethral incision of the external urethral sphincter with a mono- or bipolar electric hook or a LASER in patients with fibrotic sphincter stenosis or patients with detrusor-sphincter-dyssynergia. **NEW**

2.5 | Urethroplasty

Open surgical reconstruction of the posterior (proximal to the external urethral sphincter) or anterior (distal to the external urethral sphincter) urethra. This involves

incision/removal or substitution of the strictured part of the urethral segment followed by urethral reconstruction. **NEW**

2.5.1 | End-to-end repair

Open surgery for reconstruction of the urethra. After excision of the fibrotic urethral segment, the healthy proximal and distal urethra ends are reconnected by a primary tension-free anastomosis. **NEW**

2.5.2 | Substitution urethroplasty

Open surgery usually done for the reconstruction of bulbar urethral strictures with a stricture length ≥ 1.5 cm or penile urethral strictures. After incision of the fibrotic urethral segment, tissue from another part of the body, for example, buccal mucosa, lingual mucosa, or skin (graft/local flap/free flap—see below) are used to cover the incised area. The tissue may be placed dorsally/ventrally or combined (ventral and dorsal grafts). Substitution urethroplasty may be accomplished as a single-stage or as part of a multi (usually two-) stage procedure. **NEW**

Urethroplasty with graft

The use of free graft for urethral reconstruction usually in urethral stricture disease, in any part of the urethra. **NEW**

Urethroplasty with flap

The use of flaps for urethral reconstruction of penile urethra stricture disease, local rotational flaps such as preputial skin or local genital skin (e.g., Orandi flap). Flaps are often used in recurrent urethral stricture disease involving the penile urethra and navicular fossa. **NEW**

Staged urethroplasty

Usually two stage but occasionally additional stages are required in the treatment of urethral stricture. ^{FN 1}**NEW**

2.6 | Perineal urethrostomy

Surgical creation of a neomeatus in the perineum. ^{FN 2}**NEW**

2.7 | Sling surgery

A synthetic, biological, or composite sling placed ventrally of the urethra to treat stress urinary incontinence. **NEW** (*sling already defined*)

2.7.1 | Reposition sling

The sling pulls in and up the bulbous urethra. **NEW**

2.7.2 | Compressive sling

The sling compresses the urethra against the pubis. **NEW**

Adjustable slings

The pressure on the urethra can be readjusted over time. **NEW**

Non-adjustable slings

These cannot be adjusted once inserted in place. **NEW**

2.8 | Artificial urinary sphincter

Use of a prosthetic device, encircling the urethra which creates occlusion to restore continence. The cuff can be placed in the bulbar urethra or in the bladder neck to restore continence.^{3,4} There are a number of different devices available using two or three components with different techniques of implantation. **NEW**

2.9 | Bulking agents

Endoscopic injection of inert substance into proximal urethral wall to achieve continence by coaptation. **NEW**

2.10 | Botulinum toxin to external sphincter

Endoscopic injection of toxin into the external sphincter complex. **NEW**

2.11 | Urethral diverticulectomy

Excision of a pseudo diverticulum (out-pocketing) of urethral mucosa. **NEW**

2.12 | Urethral prosthesis or stent

Placement of a temporary or permanent synthetic tube splint device in a stenotic urethral segment to avoid restenosis of the urethra or to keep the external sphincter open in detrusor-external sphincter dyssynergia.^{5,6} **NEW**

2.13 | Urethral fistulectomy

Excision of a fistulous segment between the urethral lumen and the exit of the fistula (skin, bowel) and repair/reconstruction of the fistula openings. **NEW**

3 | SECTION II: PROSTATE PROCEDURES

Partial removal of the prostate (transition zone) for the treatment of benign diseases (e.g., benign prostatic obstruction) or complete removal of the prostate and adjacent tissues for the treatment of malignant diseases (e.g., prostate cancer). The routes to the prostate may be through the urethra, abdomen (transperitoneal), retroperitoneal space (extraperitoneal), perineum or vessels (arteries). The systematics of prostate operations is shown in Figure 1.

3.1 | Transurethral procedures of the prostate

Various prostate operations through the urethra to widen the proximal prostatic urethra by removal or compression of the transition zone. Tissue removal may be immediate or delayed. **NEW**

3.1.1 | Transurethral procedures with immediate tissue ablation

Transurethral operations with removal of prostate tissue during the operation using different energy sources (electric current, LASERS,⁷ or highly focused waterjet) and tissue removal techniques (fragmented, en bloc, or by vaporization), with or without suprapubic trocar to aid bladder irrigation. The resection is limited to the proximal prostatic urethra (resection margin: verumontanum). ^{FN 3}**NEW**

3.1.2 | Transurethral resection procedures

Usually done in small to intermediate volume prostates but can be dependent on the experience and resection speed of the operating surgeon.

Transurethral resection of the prostate (TURP)

Fragmented prostate tissue removal using a resection loop and monopolar (m-TURP) or bipolar electric current (b-TURP).⁸ **NEW**

Holmium LASER resection of the prostate (HoLRP). Fragmented prostate tissue removal by using the pulsed 2140 nm wavelength holmium LASER. **NEW**

Thulium LASER resection of the prostate (ThuRP or TmLRP). Fragmented prostate tissue removal by using the continuous wave thulium LASER with a wavelength between 1940 and 2013 nm. **NEW**

Aquablation of the prostate. Robot-assisted, fragmented prostate tissue removal by using a powerful waterjet stream (hydrodissection) under transrectal ultrasound control of the prostate.⁹ **NEW**

3.1.3 | Transurethral vaporization procedures

Usually done in small to intermediate volume prostates ($\leq 80 \text{ cm}^3$).

Bipolar transurethral electrovaporization of the prostate (B-TUVP)

Prostate tissue removal by vaporization using high-frequency bipolar electric current.¹⁰ **NEW**

“GreenLight” LASER vaporization of the prostate (GreenLight-VAP). Prostate tissue removal by vaporization using the 532 nm wavelength KTP (kalium [potassium] titanyl phosphate) or LBO (lithium borat) LASER.¹¹ **NEW**

Holmium LASER vaporization of the prostate (HoLAP).

Prostate tissue removal by vaporization using the pulsed 2140 nm wavelength holmium LASER. **NEW**

Thulium LASER vaporization of the prostate (ThuVAP).

Prostate tissue removal by vaporization using the continuous wave thulium LASER with a wavelength between 1940 and 2013 nm. **NEW**

Diode LASER vaporization of prostate (D-VAP).

Prostate tissue removal by vaporization using the diode LASER with a wavelength of 940, 980, 1318, or 1470 nm (depending of the used semiconductor).⁸ **NEW**

3.1.4 | Transurethral vaporesection procedures

Usually done in small to intermediate volume prostates ($\leq 80 \text{ cm}^3$).

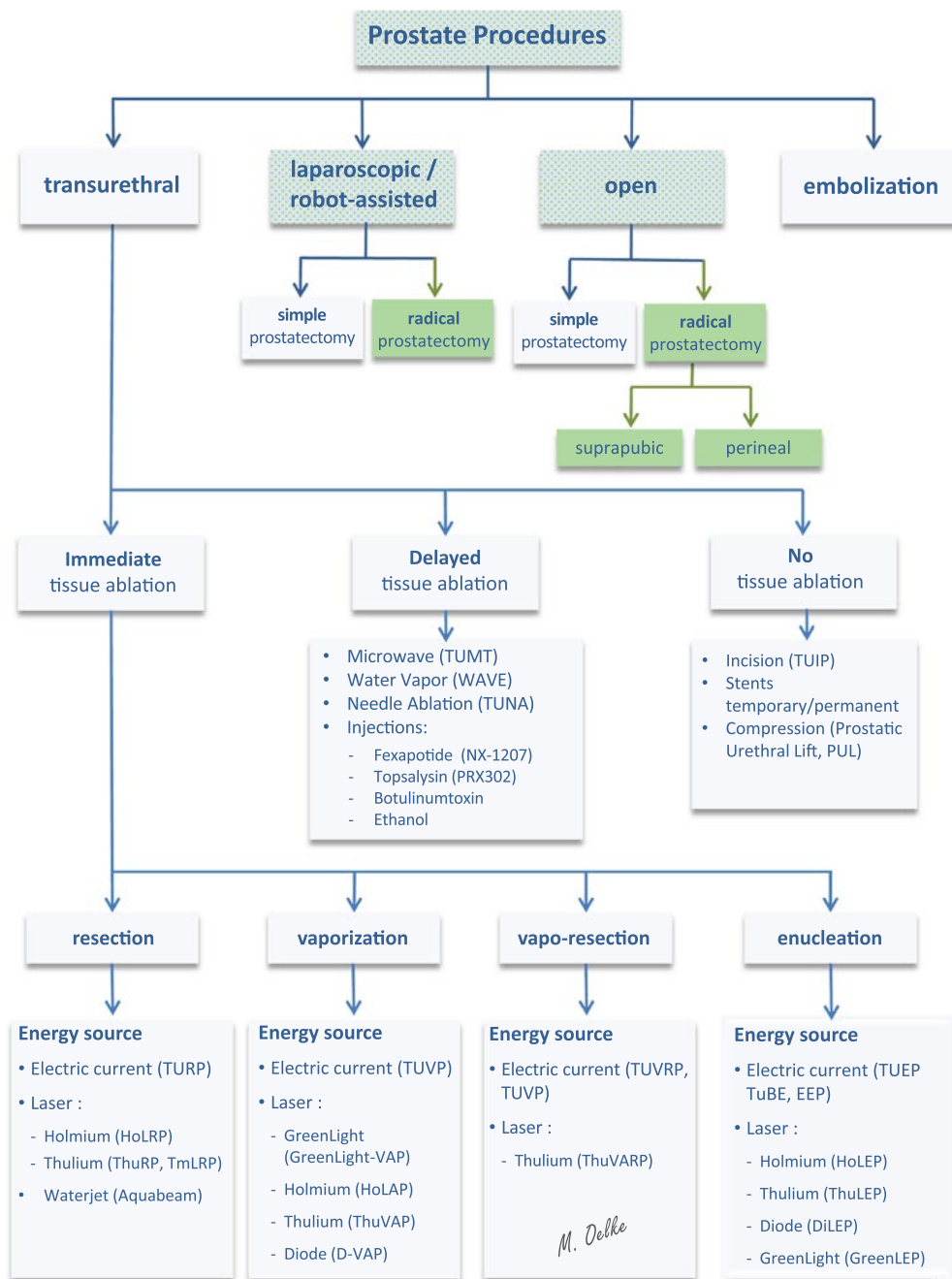


FIGURE 1 Classification of prostate operations for benign (blue) or malignant diseases (green). Abbreviations and systematics are explained in the text

Transurethral vaporesction of prostate (TUVRP, TUVP)

Fragmented prostate tissue removal by electric resection and simultaneous vaporization using a broad resection loop (combination of TURP and b-TUVP). **NEW**

Thulium vaporesction of the prostate (ThuVARP)

Fragmented prostate tissue removal by resection and simultaneous vaporization using the continuous wave Thulium LASER with a wavelength between 1940 and 2013 nm. **NEW**

3.1.5 | Transurethral enucleation procedures

Usually done in large volume prostates (>80 cm³) but can also be done in small or intermediate volume prostates.

Transurethral enucleation of prostate (TUEP, TUBE, or EEP)

En bloc removal of the transition zone by using monopolar or bipolar electric current and specifically designed hooks or loops to approach the surgical capsule and blunt peeling of the prostatic adenoma with the shaft of the resectoscope afterwards. **NEW**

Holmium LASER enucleation of the prostate (HoLEP). En bloc removal of the transition zone and separation of the tissue between the adenoma and surgical capsule by using the pulsed 2100 nm wavelength holmium LASER.^{12,13} **NEW**

Thulium LASER enucleation of the prostate (ThuLEP). En bloc removal of transition zone by using the thulium LASER with a wavelength between 1940 and 2013 nm to approach the surgical capsule and blunt peeling of the prostatic adenoma. The thulium LASER vapo-enucleation (ThuVEP) technique is identical.¹⁴ **NEW**

Diode LASER enucleation of prostate (DiLEP). En bloc removal of transition zone by using the diode LASER with a wavelength of 940, 980, 1318, or 1470 nm (depending of the used semiconductor) to approach the surgical capsule and blunt peeling of the prostatic adenoma with the shaft of the resectoscope.¹⁵ **NEW**

“GreenLight” LASER enucleation of the prostate (GreenLEP). En bloc removal of the transition zone using the 532 nm wavelength KTP (kalium [potassium] titanyl phosphate) or LBO (lithium borat) LASER to approach

the surgical capsule and blunt peeling of the prostatic adenoma with the shaft of the resectoscope. **NEW**

3.1.6 | Transurethral procedures with delayed tissue removal

Transurethral prostate operations using different energy sources or molecules which cause tissue damage during the operation and delayed desquamation (sloughing) of prostatic tissue during the next weeks or months, thereby reducing benign prostatic obstruction over time. ^{FN 4} **NEW**

Transurethral microwave therapy (TUMT)

Destruction and secondary ablation of prostate tissue by transurethral delivery of high-energy microwaves through an intraurethral antenna. Tissue is destroyed by being heated up to temperatures above cytotoxic thresholds (>45°) causing coagulation necrosis.¹⁶ **NEW**

Convective water vapor energy (WAVE) ablation of the prostate

Destruction and secondary ablation of tissue by transurethral application of water vapor thermal energy injected into the prostate by needles.¹⁷ **NEW**

NX-1207 injections of the prostate

Destruction and secondary ablation of prostate tissue by transurethral (or transrectal) injection of fexapotide triflate (NX-1207).¹⁸ ^{FN 5} **NEW**

PRX302 injections of the prostate

Destruction and secondary ablation of prostate tissue by transurethral (or transrectal) injection of topsalsyn (PRX302).¹⁹ ^{FN 6} **NEW**

Transurethral needle ablation of the prostate (TUNA)

Destruction and secondary ablation of prostate tissue by insertion of needles into the prostate and application of radiofrequency thermal energy causing a coagulation necrosis.²⁰ ^{FN 7} **NEW**

Botulinum toxin injections of the prostate

Destruction and secondary ablation of prostate tissue by transurethral (transrectal, transperineal) injection of 100–300 U onabotulinumtoxinA (Botox) or 300–600 U abobotulinumtoxinA (Dysport).²¹ ^{FN 8} **NEW**

Ethanol injections of the prostate

Destruction and secondary ablation of prostate tissue by transurethral injection of dehydrated 95–98% ethanol.^{22,23} ^{FN 9} **NEW**

3.1.7 | Transurethral procedures without tissue removal

Immediate relief of benign prostatic obstruction by incision or compression of prostatic tissue without tissue removal. Minimally-invasive procedures aim to reduce morbidity compared with operations with immediate tissue removal (see Section 1.1). **NEW**

Transurethral incision of the prostate (TUIP)

Diathermic incision of the transition zone at the 5 and 7 o'clock positions until the prostate capsule from the ureteral orifices until the verumontanum. TUIP works best in small volume prostates ($\leq 30 \text{ cm}^3$). Some surgeons incise unilaterally to reduce the risk of retrograde ejaculation. **NEW**

Prostatic stents

Transurethral implantation of metallic prostate stents of different shapes and materials. Prostate stents may be implanted temporarily (removable) or permanently (non-removable). The latest development is the iTIND system made out of nitinol which is transurethrally inserted into the prostatic urethra where it expands and incises the prostatic tissue at the 5 and 7 o'clock positions, similar to TUIP. The iTind device is removed 5 days later.²⁴ FN 10 **NEW**

Prostatic urethral lift (PUL)

Transurethral implantation of small anchors (made of nitinol, stainless steel, and a polyester suture) through the entire anterior prostate which compress prostatic tissue against the anatomic prostate capsule to widen the proximal anterior prostatic urethra. PUL works best in small to intermediate volume prostates ($60\text{--}80 \text{ cm}^3$).²⁵ **NEW**

3.2 | Open or laparoscopic/robot-assisted procedures of the prostate

3.2.1 | Suprapubic open prostatectomy (prostate adenomectomy, open enucleation of prostate)

Removal of the prostatic adenoma (transitional zone) after lower abdominal wall incision, either through the bladder (Freyer; Hryntschak)^{26,27,28} or anterior prostatic capsule (Millin). These operations are usually done in large volume prostates ($>80 \text{ cm}^3$). FN 11 **NEW**

3.2.2 | Laparoscopic/robot-assisted adenomectomy (enucleation of prostate)

Extraperitoneal or transperitoneal enucleation of prostate with laparoscopic or robotic armamentarium. The enucleation of the prostate adenoma is similar to open enucleation of the prostate and can be done by the transvesical (Freyer; Hryntschak) or transcapsular approach (Millin). These operations are usually done in large volume prostates ($>80 \text{ cm}^3$). **NEW**

Open suprapubic radical prostatectomy

Radical removal of the entire prostate and seminal vesicles via an open, extraperitoneal approach for the treatment of prostate cancer. **NEW**

Open perineal radical prostatectomy

Radical removal of the entire prostate and seminal vesicles via a perineal approach for the treatment of prostate cancer. **NEW**

Laparoscopic radical prostatectomy (LRP) or robot-assisted radical prostatectomy (RARP)

Radical removal of the entire prostate and seminal vesicles via a minimally-invasive abdominal extraperitoneal or transperitoneal or even transperineal approach by using trocars and laparoscopic armamentarium for the treatment of prostate cancer. **NEW**

3.3 | Prostatic artery embolization (PAE)

Destruction and secondary ablation of prostate tissue by uni- or bilateral embolization of prostatic arteries with microspheres. Tissue damage is done during the operation but desquamation (sloughing) of prostatic tissue occurs only during the next weeks or months, thereby reducing benign prostatic obstruction over time. PAE belongs to the secondary ablative procedures, is performed in local anesthesia and is a minimally-invasive procedure which aims to reduce morbidity compared to operations with immediate tissue removal (see Section 1.1).²⁹ **NEW**

4 | SECTION III: BLADDER NECK PROCEDURES

Widening of the bladder neck with the intent of relieving bladder outlet obstruction, usually caused by primary bladder neck hypertrophy or secondary neck stenosis.¹

4.1 | Endoscopic bladder neck incision

Transurethral incisions of bladder neck tissue at the 5 and/or 7 o'clock positions using a metal hook with electric current or a LASER beam. An additional incision can be made at the 12 o'clock position if the bladder neck is still incompletely opened. Some surgeons only incise unilaterally to reduce the risk of retrograde ejaculation. *NEW*

4.2 | Endoscopic bladder neck resection

Transurethral resection of bladder neck tissue using a metal loop with electric current. *NEW*

4.3 | Open/laparoscopic/robot-assisted bladder neck incision with Y-V plasty

Complete incision through the anterior bladder neck tissue in Y-shape and resuturing the tissue in V-shape after open or laparoscopic approach of the retropubic space.² *NEW*

4.4 | Open/laparoscopic/robot-assisted bladder neck resection

Complete removal of the entire bladder neck via an open or laparoscopic approach and reconnection of the prostatic urethra to the bladder. *NEW*

4.5 | Botulinum toxin to bladder neck

This involves injection of botulinum toxin mixed with normal saline to the bladder neck for relief of functional obstruction. FN 12 *NEW*

5 | SECTION IV: BLADDER PROCEDURES

5.1 | Urethrocystoscopy

Direct visualization of the inner wall (mucosa) of urethra and bladder. It implies a form of endoscopic method. *NEW*

5.1.1 | Flexible urethrocystoscopy

Direct visualization of the bladder and urethra using a hand operated flexible scope, a thumb lever allows the scope to be deflected as required to visualize the entire bladder. Can be performed under local or general

anaesthesia predominantly for diagnostic purposes or can be combined with tissue ablation. *NEW*

5.1.2 | Rigid urethrocystoscopy

Direct visualization of the bladder and urethra using a rod-lens telescope optical system as well as a rigid sheath. Usually performed under local, regional, or general anaesthesia for diagnostic or therapeutic purposes. *NEW*

5.2 | Transurethral bladder biopsy

Removal of sample of bladder tissue or lesion by the endoscopic, transurethral route, by means of mechanical or diathermic instrument with diagnostic intent. *NEW*

5.3 | Transurethral resection of the bladder

Removal of bladder tissue or lesion by endoscopic transurethral route with both, diagnostic and therapeutic intent. Different energy sources can be used (electric energy, LASER). *NEW*

5.4 | Cystodiathermy

Selective cauterization of areas of the bladder using different energy sources through an endoscope with therapeutic intent. *NEW*

5.5 | Bladder distension

Infusion of fluid usually saline, under anaesthesia with the intent to stretch or distend the bladder walls in excess of usual physiological capacity. *NEW*

5.6 | Bladder wall injections

Injection of a pharmaceutical agent into the bladder wall (to the suburothelial space or detrusor), using a needle inserted through the endoscope. *NEW*

5.7 | Bladder instillations

This involves instillation of a chemical substance via a urethral catheter mostly under local anaesthesia. Usually there are multiple instillations spread over a period of

time. EMDA treatment (electromotive drug administration) aims to increase drug concentration in the vesical wall by iontophoresis and electrophoresis to overcome the urothelial barrier. *NEW*

5.8 | Cystectomy

Removal of the urinary bladder using a transabdominal open/laparoscopic/robot-assisted approach. Cystectomies are most frequently done for the treatment of bladder cancer but can also be a valid option for treatment resistant bladder pain syndromes or small capacity bladder where minimally invasive treatments have failed. *NEW*

5.9 | Partial cystectomy

A segment of urinary bladder (e.g., bladder dome) is excised. *NEW*

5.9.1 | Supratrigonal cystectomy

The entire bladder except the trigone and bladder neck is excised. *NEW*

5.9.2 | Total cystectomy

The entirety of the organ (urinary bladder) is removed. Usually for benign conditions. *NEW*

5.9.3 | Radical cystectomy

The entirety of the urinary bladder is removed along with adjacent organs or structures (prostate/seminal vesicles). *NEW*

5.10 | Bladder diverticulectomy

Excision of a bladder pseudodiverticulum using a transvesical or extra vesical approach, by abdominal open, laparoscopic or robotic assisted techniques. *NEW*

5.11 | Bladder psoas-hitch

Fixation of bladder wall to the psoas muscle aponeurosis with the intent of reducing tension of a ureter to bladder

anastomosis in case of shortened/strictured distal ureter.³⁰ *NEW*

5.12 | Boari flap

Use of a segment of bladder wall to create a tube, which is then anastomosed to the remaining ureter with the intent of substituting the terminal ureter in case of shortened/strictured distal ureter.³⁰ *NEW*

5.13 | Cystolithotomy

Surgical removal of a bladder stone through the abdomen and the bladder wall. *NEW*

5.13.1 | Percutaneous cystolithotripsy/cystolitholapaxy

Minimally invasive fragmentation of the bladder stone by ultrasonic or pneumatic lithotripsy or LASER and removal of the stone fragments via a thin suprapubic channel and an abdominal access sheath. *NEW*

5.13.2 | Transurethral cystolithotripsy/cystolitholapaxy

Fragmentation of a bladder stone via the transurethral route with urethral removal of fragments. Different energy sources can be used, from direct mechanical to LASER impulses. *NEW*

5.13.3 | Open, laparoscopic, or robot-assisted bladder stone removal

Complete removal of a bladder stone (without fragmentation) by a suprapubic open or laparoscopic or robotic approach. *NEW*

5.14 | Fistula repair

Excision and closure of an abnormal passage between two epithelial surfaces.

5.14.1 | Vesico-cutaneous fistula repair

Excision of a fistula between bladder and skin. *NEW*

5.14.2 | Enterovesical fistula repair

Excision of a fistula between the bladder and an intestinal segment, usually with reconstruction of the intestinal tube and bladder wall. **NEW**

5.14.3 | Rectourethral fistula repair

Excision of a fistula between the rectum and (prostatic) urethra, often associated with prostatectomy and temporary artificial anus. **NEW**

5.15 | Cystorrhaphy

Suture of a laceration, injury, or rupture in the urinary bladder. **NEW**

6 | SECTION V: URINARY DIVERSIONS AND RECONSTRUCTIONS

Urinary diversion is any surgical procedure that alters the usual passage of urine from the kidneys. It may or may not involve the addition of bowel into the urinary tract, either to reroute the urine or replace/augment the native urinary tract. All urinary diversions and reconstructions can be done as an open procedure, laparoscopically, or robot-assisted. **NEW**

6.1 | Incontinent diversion

Rerouting of the urine from the urinary bladder, with or without removal of all or part of the urinary bladder. Reconstruction often involves addition of an isolated intestinal segment (stomach/small intestine/colon). Egress of urine is cutaneous and requires containment. Common incontinent diversions include ileal/colonic conduits, ileovesicostomy and ureterostomy. **NEW**

6.1.1 | Ileal conduit

A rerouting of the urine from the ureters through an isolated segment of terminal ileum to a premarked site on the skin. It is in most parts of the world the most common diversion performed after cystectomy. **NEW**

6.1.2 | Sigmoid or colon conduit

A segment of sigmoid or colon is used for the urinary diversion where the ileum cannot be used or its appearance as a stoma onto healthy skin in the usual position is not possible. It is usually performed in cases of pelvic irradiation, regional enteritis, or short bowel syndrome. **NEW**

6.1.3 | Vesicostomy

A method of creating a communication between the bladder and the skin. This procedure is indicated in children with vesicourethral dysfunction (myelomeningocele, posterior urethral valve) who are unable to void or cannot catheterize through the urethra. **NEW**

6.1.4 | Ileovesicostomy

A communication from the bladder through an isolated segment the ileum to the skin. This method is typically employed with high spinal lesion patients who cannot perform intermittent catheterization. **NEW**

6.1.5 | Cutaneous ureterostomy

Direct anastomosis of the ureter to the skin. Can be loop or end cutaneous ureterostomy. **NEW**

6.2 | Continent urinary diversion

Re-routing of the urine from the urinary bladder. Reconstruction usually involves an isolated intestinal segment (stomach/small intestine/colon). Continence mechanisms may utilize existing sphincters (anal, urethral or ileocaecal valve) or be created by tunneling a bowel segment through the bladder/neobladder which requires catheterization. Egress of urine can therefore be via the anus (ureterosigmoidostomy) via the urethra (neobladder) or via a continent catheterisable channel (e.g. Mitrofanoff, Kock pouch, Mainz I). **NEW**

6.2.1 | Orthotopic

Reconstructed bladder reservoir (entirely or partially constructed from bowel; usually terminal ileum) anastomosed to

the native urethra, usually utilizing the urethral sphincter as a continence mechanism. Diversion may be supratrigonal or total substitution—See 3.2 for more details on bladder substitution reconstructions.³¹ **NEW**

6.2.2 | Heterotopic

Reconstructed urine storage organ (neobladder), which is attached directly to the ureter(s). Created entirely from bowel (usually terminal ileum), this neobladder resides outside the pelvis, and requires a catheterisable continent channel to the skin. **NEW**

Ileal reservoir

This neo-bladder is made entirely of ileum. It is opened at the anti-mesenteric border and stitched back in a detubularised manner. **NEW**

Ileocaecal reservoir

This neo-bladder is constructed from terminal ileum and caecum incorporating the ileo-caecal valve. Again, this isolated piece is de-tubularized to be stitched back together to decrease the peristalsis and increase capacity of the reservoir. **NEW**

Pouches using large bowel

Indiana pouch. Utilizes a segment of terminal ileum, caecum, and ascending colon. The ureteric implantation along the tinae coli and plication sutures of the ileal stoma conduit for improvement of continence. **NEW**

Charleston pouch. Utilizes the same bowel segments of Indiana pouch with the addition of the appendix as the cutaneous catheterisable stoma. **NEW**

Mainz II pouch. Also known as sigma-rectum pouch. Hence the pouch is created from a segment of rectum and sigmoid colon. The Mainz-II can also be utilized to convert a uretero-sigmoidostomy or colonic conduit. **NEW**

Lundiana pouch. Utilizes the ileocaecal segment with an instussuscepted ileal nipple, including the ileocaecal valve as efferent segment. **NEW**

Small bowel pouches

Studer pouch. Utilizes a segment of terminal ileum of approximately 54 cm length 25 cm proximal from the ileocaecal valve. The ureteric implantation site is

located at the proximal end of a closed ileum segment (chimney usually at the right side with a length of 14 cm), whereas the rest of the ileum is opened at the anti-mesenteric border and stitched back to a plate which is then formed to a neobladder and anastomized to the urethra. **NEW**

Mansoura pouch. Construction of a detubularized W-shaped ileal reservoir in which two serous lined troughs and two tapered ileal segments are used, one for reflux prevention and the other as a continent outlet. **NEW**

6.3 | Cystoplasty

A reconstructive procedure involving the addition of a detubularized bowel segment usually to the native bladder. The bladder is bivalved (as a clam) and the isolated piece of bowel is interposed between with the intention of increasing capacity, reducing bladder pressure or treating refractory detrusor overactivity. The outlet of this may be the native urethra (utilizing the intrinsic continence of the external urethral sphincter) or a created abdominal stoma (emptied via catheterization). **NEW**

6.3.1 | Ileocystoplasty

The piece of bowel used is terminal ileum at least 30 cm from ileo-caecal junction. **NEW**

6.3.2 | Gastrocystoplasty

An isolated piece of stomach is utilized to fashion an augmented bladder. **NEW**

6.3.3 | Colocystoplasty

Generally, sigmoid colon is used. **NEW**

6.3.4 | Ureterocystoplasty

The ureter is used to bridge the gap in a clammed bladder. This is only used if there is a mega ureter post severe long-standing dilatation of the upper tract with the ipsilateral non functioning kidney that will be removed at the same time or previously has been removed. This is mainly utilized in pediatric population. **NEW**

6.3.5 | Bladder auto-augmentation

Removal or incision of a portion of the detrusor leaving behind the exposed mucosa which bulges out, with the aim of reducing bladder pressures. *NEW*

6.4 | Supratrigonal/substitutional reconstruction

If an adequate reservoir capacity cannot be obtained using a bowel patch, then a substitution procedure is required. This reconstruction can include the trigone of the native urinary tract or consist of a reservoir created entirely from autologous tissue. These are described separately below. *NEW*

6.4.1 | Supratrigonal

The dome of the bladder is excised leaving the trigonal plate/bladder base, with attached ureters, to the native urethra. A reservoir (created from an isolated bowel segment) is then fashioned and anastomosed to the trigone. Although a number of bowel segments can be utilized, distal ileum is most commonly selected for reconstruction. A continent catheterisable stoma (usually catheterized via the anterior abdominal wall) can also be used in addition to this reconstructive technique. This technique usually spares the nerves maintaining sexual function. *NEW*

6.4.2 | Substitutional

This reconstruction does not utilize any part of the native bladder. Following cystectomy, a reservoir is constructed from bowel (usually terminal ileum) and the ureters are anastomosed to this, that is, orthotopic neobladder. The reservoir is then, in turn, anastomosed to the native urethra. *NEW*

6.5 | Continent stoma

6.5.1 | Appendicovesicostomy (Mitrofanoff)

Use of an isolated appendix on a vascularized pedicle as a catheterizable route of access to the bladder from the skin as an alternative to the urethra. *NEW*

6.5.2 | Yang–Monti catheterizable channel

A variant of the Mitrofanoff procedure in which a short segment of bowel is reconfigured into a long tube positioned between bladder and skin to permit intermittent catheterization. *NEW*

6.5.3 | Stapled continent conduit (Bejany and Politano)

A continent colonic urinary reservoir with a tapered distal ileal segment with a gastrointestinal anastomosis stapler with a catheterizable abdominal stoma. *NEW*

6.5.4 | The gastroileal reservoir (Lockhart)

A continent urinary diversion where segment of stomach and proximal ileum is used to construct the reservoir. *NEW*

6.6 | Continent heterotopic urinary diversion

6.6.1 | Ureterosigmoidostomy—Sigma rectum pouch (Mainz pouch II)

Modification that involves detubularizing the recto-sigmoid colon and reconfiguring the detubularized segment into a spherical shape, while maintaining bowel continuity.³² *NEW*

6.7 | Suprapubic catheter

This involves insertion of a catheter via suprapubic route.

6.7.1 | Seldinger technique

The catheter is inserted into the bladder from the suprapubic route by seldinger technique through a specially designed kit. After ensuring the bladder is full a needle is inserted from suprapubic skin directly into the bladder. Once aspiration of urine is confirmed the tract is dilated with a trocar and the catheter is inserted via a specially designed sheath. This process can be aided by

direct endoscopic visualization or under ultrasound guidance. **NEW**

6.7.2 | Open/laparoscopic/robot-assisted technique

This involves insertion of a catheter into bladder via the suprapubic route under direct visualization of the bladder puncture. This entails incising skin, subcutaneous tissues, and sheath of the anterior abdominal wall. It is ensured the bladder is as full as possible and under direct vision the catheter is inserted into the bladder. **NEW**

6.7.3 | Button cystostomy

This procedure involves insertion of a gastrostomy button normally used for enteral nutrition into the bladder, using an endoscopic technique. Button cystostomy results in a continent device that permits urine drainage by suprapubic route, as well as suprapubic catheter, resulting more cosmetically acceptable, with less obstacles for sports activities, swimming, improving quality of life especially in children and young adults. **NEW**

7 | SECTION VI: VESICO-URETERIC JUNCTION AND URETER PROCEDURES

7.1 | Vesicoureteric junction operations

7.1.1 | Ureteral reimplants

Ureteroneocystostomy

Direct reimplantation of the ureter into the bladder, primarily for disease involving the lower third portion of the ureter. **NEW**

Intravesical (Politano-Leadbetter) technique. A ureteroneocystostomy in which the ureter is excised from its attachment to the bladder and reattached intravesically in a more medial and superior position with a new submucosal tunnel.³³ **NEW**

Extravesical (Lich-Gregoir) techniques. An ureteroneocystostomy where the ureter is mobilized extravesically along the course of the ureter and the detrusor and then divided in the direction of the ureter. The ureter is then anastomosed to the bladder mucosa and the divided detrusor sutured to cover the ureter, creating a submucosal ureteral tunnel.³⁴ **NEW**

Ureteral advancement (Glenn-Anderson) reimplantation technique. The submucosal tunnel is made from the original ureteral meatus to the bladder neck—with or without incision of detrusor proximally from the original ureteral orifice—allowing the ureter to follow its natural course without the risk of folding or obstruction of the ureter.³⁵ **NEW**

Cross-trigonal (Cohen) technique. A submucosal ureteral tunnel is created transtrigonally, allowing the new ureteral orifice to be created around the contralateral ureteral orifice. **NEW**

Intra-extra vesical technique (Paquin). A type of ureteroneocystostomy in which the ureter is excised from its attachment to the bladder and reattached in a more posteromedial position. **NEW**

7.1.2 | Ureterocele incision/resection

This involves endoscopic resection/incision of the ureterocele. **NEW**

7.1.3 | STING (subtrigonal injection of inert substance) procedure

This entails injection of an inert substance via endoscopic technique at the vesico-uretric junction to treat reflux. Teflon was initially used but other inert substances can be used alternatively. **NEW**

7.1.4 | Ureter procedures

Ureteroscopy

Upper urinary tract endoscopy performed with a semi rigid or flexible endoscope passed through the urethra, bladder, and then directly into the upper urinary tract. **NEW**

Unilateral/bilateral retrograde pyelography

Evaluation of the ureter by injection contrast on either side and undertaking live fluoroscopy to delineate the anatomy of the ureter. **NEW**

Endoluminal stents (ureteral stenting)

Threading a thin tubular catheter into segments of the ureter, either down into the bladder internally, or to an external collection system, through the skin (percutaneously), or through the bladder via a cystoscope. Stents consist of an elongated body portion and a retention module. **NEW**

Ureterolysis

Mobilization and freeing of the ureter by surgical displacement of the ureters from the surrounding disease/adhesions, or from retroperitoneal fibrosis process with lateral/intraperitoneal transposition and/or omental wrapping of the involved ureter. **NEW**

Ureterolithotomy

Open, laparoscopic or robot-assisted removal of a calculus lodged in the ureter through a direct incision of ureter over the calculus. **NEW**

Endoureterotomy

Endoscopic incision of a benign ureteral lesion or ureteroenteric strictures. **NEW**

Ureteroureterostomy

An end-to-end anastomosis of the segments of the same ureter, with excision of the intervening injured, tumor, or scarred ureter. Transperitoneal ureteroureterostomy is a special urinary reconstruction with side-to-end anastomosis of the injured ureter from one side across the peritoneal cavity under the mesentery of the intestine to the healthy ureter on the opposite side. **NEW**

7.1.5 | Ureteroplasty

Any surgical reconstruction of the ureter. **NEW**

Graft ureteroplasty

Use of buccal mucosa, preputial skin, and bladder mucosa to graft partially obliterated or defective ureter. **NEW**

Flap ureteroplasty

Use of bladder mucosa or bowel to substitute partially obliterated or strictured ureter. **NEW**

Ileal ureteric replacement

A segment of ileum is used to replace the damaged ureter. **NEW**

7.1.6 | Anastomosis to a bowel segment*The Bricker technique*

Spatulating and anastomosing each ureter to the serosa of the bowel segment separately. **NEW**

Wallace I (66) surgical technique

Both ureters are spatulated to the same length. Their medial walls are anastomosed together, and the free

edges of the newly conjoined ureters are then anastomosed to the proximal end of an open bowel segment. **NEW**

Wallace II (69) technique

Head-to-tail anastomosis: Blood supply is protected by suturing the apex of one ureter to the end of the other. The posterior medial walls are sutured together, and then the ends and lateral walls are sutured to the bowel segment. **NEW**

FOOTNOTES

FN 1: The first stage involves incising the penile urethra ventrally, excising the stricture segment completely and applying an inlay graft (often oral mucosa graft). A period of at least 4–6 months is required to allow adequate vascularization of the graft before the final stage of the repair requiring tubularisation of the graft. Occasionally an intermediate stage is required with additional graft inlay.

FN 2: The word boutonnière is frequently used as a synonym.

FN 3: LASER energy aims to reduce the intra- and postoperative blood loss, even in larger prostates. Different LASER wavelengths are available, producing an array of resection, thermal vaporization, or enucleation of prostatic tissue. Enucleation techniques are a combination of blunt dissection and judicious use of electric or LASER energy to separate the prostate adenoma from the underlying surgical capsule. The adenoma tissue is pushed into the bladder and has to be retrieved by morcellation/resection at the end of the procedure.

FN 4: These procedures are also known as secondary ablative procedures, are minimally-invasive and aim to reduce morbidity compared to operations with immediate tissue removal (see Section 3.1.1). These procedures are usually done in small to intermediate volume prostates ($\leq 60\text{--}80\text{ cm}^3$).

FN 5: The procedure is currently under clinical evaluation.

FN 6: The procedure is currently under clinical evaluation.

FN 7: The procedure is not in routine use anymore in most parts of the world.

FN 8: The procedure is no longer recommended because of the poor outcome results

FN 9: The procedure is no longer recommended because of the poor outcome results.

FN 10: Elderly men with multiple comorbidities may be unfit to undergo surgical management of benign prostatic obstruction and, therefore, are only suitable for minimal-invasive procedures without anesthesia.

FN 11: While the term “simple prostatectomy” has been used synonymously for open adenectomy or open enucleation of the prostate, it is misleading because only the hyperplastic adenomatous and not the entire prostate are removed. The nonhyperplastic peripheral and central prostatic zones as well as the anterior fibromuscular stroma are not removed and the prostatic capsule and seminal vesicles are also left in situ. In the era of prostatectomy for prostatic malignancy, use of the term “simple prostatectomy” should be discouraged to avoid confusion.

FN 12: This is still an experimental technique.

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No discussion on terminology should fail to acknowledge the fine leadership shown by the ICS over many years. The legacy of that work by many dedicated clinicians and scientists is present in all the reports by the different Standardization Committees. It is pleasing that the ICS leadership has accepted the need for this project.



This document was initiated at ICS Tokyo (BH, LA-M, RH—September 2016) and formalized in London (June 2017—LA-M, RH Co-Chairs). Working Group (WG) live meetings have been held in Florence (September 2017), Philadelphia (August 2018) and Gothenburg (September 2019). It has involved 14 rounds of full review, by coauthors, of an initial draft (LA-M, RH). Formal editing and formatting then occurred (December 2019, January 2020—MO, BH) to create Version 12. Following external review (four experts—Ricardo Pereira, Rui Almeida Pinto, Howard Goldman, and Tufan Tarcan). There have been a further two rounds to review the comments made. We thank the other colleagues who have provided comments on the website reviews. Sign-off has included Standardization Steering Committee (V14) and the ICS Board (V15). The document (V16) will be published in *Neurourology and Urodynamics*.

This document and all the **NEW** definitions will be uploaded to the **ICS GLOSSARY** (www.ics.org/glossary) where immediate electronic access to definitions and document download is available.

AREAS FOR FURTHER RESEARCH

As this document was prepared, some difficulties arose on classifying the latest advances on prostatic procedures as they belong to entirely new approaches.

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An International Continence Society (ICS) report on the terminology for single-use body worn absorbent incontinence products

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Abstract

Aims: In 2016, the International Continence Society (ICS) Standardization Steering Committee appointed a working group to address the confusing plethora of synonyms currently used to describe single-use body worn absorbent incontinence products by recommending preferred terminology.

Methods: An online questionnaire was posted in 2016/17 inviting input from stakeholders internationally. The data were analyzed and conclusions progressively refined through working group discussions, an open meeting at the 2017 annual ICS conference, and a review of further iterations—including from the parent ICS Standardization Committee—until consensus was reached. Partway in, the International Organization for Standardization started

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Bernard Haylen is Chair ICS Standardization Steering Committee.

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a project with similar scope and the two organizations liaised to harmonize their conclusions while respecting each other's processes.

Results: A hundred people from 18 countries responded to the questionnaire. About a third (32.2%) of those declaring their nationality were from the UK and a further third (34.5%) from other English-speaking countries. Two-thirds (67.8%) lived in Europe; around a quarter (23%) in North America; and 9.2% in Australasia. Seven main design categories of products were identified and, while clear consensus was readily achieved in naming some of them, others required more work to determine the best term among multiple contenders.

Conclusions: The working group concluded that the seven product design categories should be called: (a) pads; (b) unbacked pads; (c) male pads; (d) male pouches; (e) pull-on pads (protective underwear); (f) all-in-ones (wrap-around pads, adult briefs); and (g) belted pads (belted products), in which the bracketed terms are judged acceptable (though not preferred) alternatives.

1 | INTRODUCTION

Not all bladder or bowel incontinence problems can be completely and permanently cured. The challenge for those whose symptoms persist is to discover how to deal with their incontinence to minimize its impact on their health and quality of life (QoL). And this usually includes managing urine and stool leakage using continence products. Even those whose incontinence is ultimately treated successfully may have to live with symptoms for a time—for example, while waiting for surgery, or for pelvic floor muscle training to yield its benefits—and they may use continence products temporarily during this waiting period. Others may use them as an adjunct to a treatment that reduces their leakage (eg, bladder training, toileting programs) without eliminating it. Still, others may use products intermittently, limiting their use to particular timeframes or activities associated with troublesome leakage. However, some use products permanently, either following treatment that has not been (completely) successful or because—depending on their frailty, severity of symptoms, and personal priorities—they are not candidates for treatment.

Successful management of incontinence with products is often referred to as “*contained incontinence*” and can bring substantial benefits to QoL even though a cure has not been achieved.¹ A wide variety of such products exists but by far the most common are *single-use* (as opposed to reusable/washable) *body worn* (that is, worn on the body as opposed to bed and chair protectors) *absorbent products*. The ICS defines absorbent products as “... those that have been specifically developed to help manage leakage or soiling,

such as absorbent pads and pants, absorbent bed sheets and chair covers”² and they come in a range of different designs. The purpose of this report is to recommend terms for single-use body worn absorbent products. The primary purpose of such products is to absorb and thereby contain urine, however, some designs may also be used to contain faeces either alone or in combination with urine. There are a very small number of products made from absorbent materials that are designed specifically to contain faeces alone; these are not included within the scope of this report.

The names used to describe absorbent products can vary considerably among—and even within—countries and cultures. This has resulted in a confusing plethora of synonyms in the clinical/academic literature,^{3–14} as well as the literature provided by product suppliers, and information available on the internet or through other media such as magazines. Standardized terminology, providing preferred terms that all are encouraged to use, would facilitate understanding and communication among users, caregivers, clinicians, researchers manufacturers, and government agencies. To that end, the ICS appointed an international working group of experts in the field of containment with continence products to consult widely across the international community of people concerned with these products to establish a standard terminology that enjoys widespread support. The guiding principles were to identify—and recommend—for each product design category, that term most widely acceptable internationally, favoring—where possible—terms which are most helpfully descriptive of a design's characteristic features and avoiding terms with child/toddler/baby connotations.

This report summarizes the recommendations of the working group. Further, detailed Supporting Information is available on-line on the ICS website (URL to be

determined), describing: the on-line questionnaire that was used to solicit the views of stakeholders internationally (Supporting Information, Appendix A, ICS website); the key characteristics and views of the respondents (Supporting Information, Appendices B and C, ICS website); and an International Continence Society members' consultation meeting on the topic at the 2017 annual ICS conference (Supporting Information, Appendix D, ICS website).

2 | METHODOLOGY

Drawing on their collective experience and the literature review conducted for the absorbent products section of the sixth International Consultation on Incontinence,¹ the working group created an online questionnaire (Supporting Information, Appendix A, ICS website) to solicit the opinions of stakeholders internationally. The questionnaire invited respondents to identify their interest in these products (such as product user, healthcare professional, or product manufacturer) and their nationality; express their preferences for a range of offered alternative names for each of seven different categories of single-use body worn absorbent incontinence products identified by the working group; suggest—with reasons—any other alternative names worthy of consideration; and comment on proposed descriptions for the defining features and main variant features for each of the seven design categories. The final questionnaire was posted on 12 December 2016 and closed for participation on 7 March 2017, by which time 100 people from 18 countries had responded. Almost a third (32.2%) of respondents who declared their nationality were from the UK and about a further third (34.5%) were from other English-speaking countries. Two-thirds (67.8%) lived in Europe; around a quarter (23%) in North America; and 9.2% in Australasia. Details of the characteristics and views of the respondents are given in Appendices B and C (Supporting Information, ICS website).

Drawing on the survey findings, the working group drafted a set of recommendations which were presented at an open meeting at the 2017 annual conference of the International Continence Society in Florence attended by 12 experts. This meeting focused on reaching agreement on rival terms when a clear consensus was not apparent, and a report of the meeting is provided in Appendix D (Supporting Information, ICS website). Part way into this project the International Organization for Standardization (ISO) embarked on a parallel project to standardize nomenclature relating to single-use absorbent body worn products for incontinence. ICS and ISO working groups shared their draft reports and recommendations to achieve as much alignment as they could while respecting each other's processes. The

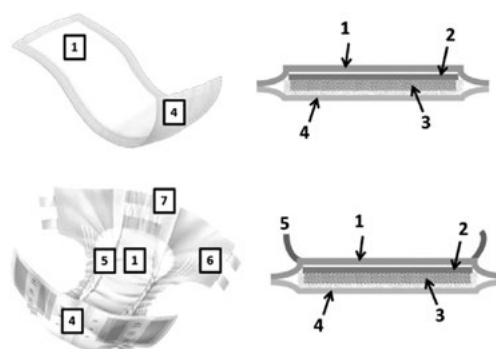


FIGURE 1 A (top), The design of a simple pad (left) and a transverse section through it (right) to show the layered construction. B (bottom), The design of a typical all-in-one product (left) and a transverse section through it (right) to show the layered construction. 1: Topsheet; 2: Backsheet; 3: Absorbent core; 4: Acquisition and distribution layer (ADL); 5: Standing gathers (leg cuffs); 6: Fasteners; and 7: Elastication

terminology adopted in the ISO standard currently under preparation is expected to be very similar to that described here. To complete the ICS project, working group members were invited to comment on drafts of the final report before it was deemed completed.

3 | PRODUCT DESIGN FEATURES

Although single-use (disposable) body worn absorbent incontinence products come in a variety of generic designs, they share many design features in common, as illustrated in Figure 1 and described in the following sections. These terms were used in describing the various proposed product categories in the on-line questionnaire (Supporting Information, Appendix A, ICS website), along with an invitation to respondents to identify any omissions, errors, or preferences for changes. In fact, terms and descriptions for design features turned out to be far less contentious than those for product categories, necessitating only very minor changes to draft text to arrive at the wording below.

3.1 | Topsheet

The *topsheet* in an absorbent incontinence product is the layer of fabric which lies against the wearer's skin. It is made from a water-permeable material that allows urine to pass readily through to the acquisition and distribution layer (ADL) and the absorbent core beneath.



FIGURE 2 Examples of pads

3.2 | Acquisition and distribution layer

Absorbent incontinence products often have an ADL between the topsheet (above) and the absorbent core (below). The ADL is designed to allow urine to enter the product rapidly, and spread it over a large area of absorbent core. It is not intended to absorb urine itself.

3.3 | Absorbent core

The *absorbent core* of an absorbent incontinence product is where urine is captured and stored. It is made from (a) material(s) which absorb(s) urine readily and retains it under pressure, such as when the wearer changes posture or position.

TABLE 1 Total, new, and changed definitions (from those currently in the ICS Glossary)

Section	New definitions/descriptors	Changed definitions/descriptors	Total
Introduction & methodology	4	0	4
Product design features	7	0	7
Terms for product design categories	7	0	7
Total	18	0	18

Abbreviation: ICS, International Continence Society.

TABLE 2 The defining features and main variant features of pads

Defining features	Waterproof-backed absorbent products that are held in place using separate, close-fitting (regular or specially designed) underwear
Main variant features	<ul style="list-style-type: none"> • Products may be used by either sex, but some are intended (by their color, style, shape, or the placing of absorbent material, for example) just for men or just for women. • Products come with different absorption capacities. • Longitudinal elastic side barriers and leg cuffs on either side of the crotch may be included to improve fit, comfort, and prevent leakage. • Products may have an adhesive strip on the back or adhesive wings to the sides to help secure them in underwear. • Products may have a wetness indicator. • Products may or may not be suitable for containing fecal incontinence (FI) as well as urinary incontinence (UI).



FIGURE 3 An example of an unbacked pad

3.4 | Backsheet

The *backsheet* in an absorbent incontinence product is a layer of waterproof material which forms the outside surface of the product, away from the wearer's body. It may be breathable.

3.5 | Fasteners

Fasteners (Tabs) enable the front and back regions of all-in-ones and belted pads to be secured to one another, helping to hold the product in the intended shape and enable a close fit to the wearer. Fasteners/tabs are most commonly faced with an adhesive (which usually allows them to be undone and refastened to achieve the desired fit) or a hook and loop fastening system.

TABLE 3 The defining features and main variant features of unbacked pads

Defining features	Absorbent products without a waterproof backing used either (a) inside another product such as a category 6 product to supplement its absorption capacity or to reduce the frequency with which it needs to be changed (the unbacked pad may be changed with relative ease, without necessarily needing to also change the outer product), or (b) on its own, secured using separate, close-fitting, underwear which itself includes waterproofing in the pad area
Main variant features	<ul style="list-style-type: none"> • Products may be used by either sex. • Products may be rectangular or contoured to better fit the wearer. • Products come with different absorption capacities. • Products may or may not be suitable for containing FI as well as UI.

**FIGURE 4** Examples of *male pads***FIGURE 5** An example of a *male pouch*

3.6 | Elastication

Elastication is often used to give an incontinence product the desired shape and to achieve a close fit with the wearer. It is commonly used in the waist belts of all-in-ones (wrap-arounds, adult briefs), pull-on pads (protective underwear), and belted pads (belted products). In pull-on pads, it may be used across much of the area of the product. It is used along the edges of the crotch region in many different designs.

3.7 | Leg cuffs

Leg cuffs (standing gathers) refer to a particular kind of elasticsation which may be used longitudinally on a

product near the edges of the crotch region to promote close contact with the groin on either side of the body.

4 | RECOMMENDED TERMS FOR PRODUCT DESIGN CATEGORIES

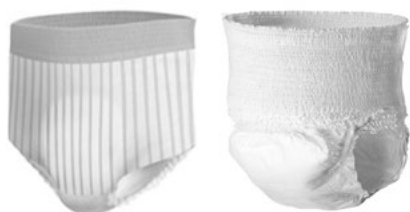
Single-use body worn absorbent products can be divided into seven distinct categories according to their main (defining) features. A recommended name for each design category is given below, along with descriptions of its defining—and main variant—features.

TABLE 4 The defining features and main variant features of *male pads*

Defining features	Waterproof-backed absorbent products for men that are designed to cover the penis and scrotum, and are held in place using separate, close-fitting (regular or specially designed) underwear
Main variant features	<ul style="list-style-type: none"> • Products come with different absorption capacities. • Longitudinal elastic side barriers and leg cuffs at the sides may be included to improve fit and comfort and prevent leakage. • Products may have an adhesive strip on the back to help secure them in underwear.

TABLE 5 The defining features and main variant features of *male pouches*

Defining features	Waterproof-backed absorbent products for men, fashioned into a pocket into which the penis—and sometimes the scrotum, too—is placed. They are held in place using separate, close-fitting (regular or specially designed) underwear
Main variant features	<ul style="list-style-type: none"> • Products come with different absorption capacities. • Products may have an adhesive strip on the back to help secure them in underwear. • Products may have a hook and loop fastening system or adhesive tape to secure the product round the penis.

**FIGURE 6** Examples of *pull-on pads* (protective underwear)**FIGURE 7** Examples of *all-in-ones* (wrap-around pads, adult briefs)

4.1 | Pads

We recommend that products of the kind shown in Figure 2 should be called *pads*—waterproof-backed absorbent products that are held in place using separate, close-fitting (regular or specially designed) underwear. The defining features of pads and the main variant features are described in Table 1, while the construction of a simple variant is shown in Figure 1A. Although the online questionnaire found clear international consensus in favor of pad, two alternative names (insert and liner) were popular in some countries, but never more popular than pad (Supporting Information, Appendix C: Figure C-1 and Table C-1, ICS website). Accordingly, use of these two terms—and others favored by small groups of respondents—is discouraged Table 2.

4.2 | Unbacked pads

We recommend that products of the kind shown in Figure 3 should be called *unbacked pads*—absorbent products without a waterproof backing. They comprise an absorbent core held in an envelope of water-permeable material and their defining features and main variant features are described in Table 3. The online questionnaire found clear international consensus in favor of booster pad. However, in Asia, it is common to use such pads, not so much to boost the absorption capacity of another product as to reduce the frequency with which it needs to be changed. An unbacked pad may be changed relatively easily without the need to also change the outer product. It is also known that pads (Section 4.1) may be used as “booster” pads and this term may, therefore, be confusing. Accordingly, unbacked pads are favored, a term which was also accepted

TABLE 6 The defining features and main variant features of *pull-on pads* (protective underwear)

Defining features	Products in which the absorbent core, waterproof backing, and the means to hold it in place are combined in a single design resembling regular underwear. Elastic linings around the waist and hips help give a close fit
Main variant features	<ul style="list-style-type: none"> • Products may be used by either sex, but some are intended (by their color, style, or the placing of absorbent material, for example) just for men or just for women. • Products come with different absorption capacities, and fit different body sizes. • Longitudinal elastic side barriers and leg cuffs on either side of the crotch may be included to improve fit and comfort and prevent leakage. • In some designs, side seams can be torn away for easy removal. • Products may have wetness indicators. • Products may or may not be suitable for containing FI as well as UI.

TABLE 7 The defining features and main variant features of *all-in-ones* (wrap-around pads, adult briefs)

Defining features	One-piece products in which the absorbent core and the means to hold it in place are combined in a single design, secured using adjustable adhesive tabs or a hook and loop fastening system at the sides
Main variant features	<ul style="list-style-type: none"> • Products may be used by either sex, but some are intended (by their color, style, or the placing of absorbent material, for example) just for men or just for women. • Products come with different absorption capacities, and to fit different body sizes. • Longitudinal elastic side barriers and leg cuffs on either side of the crotch may be included to improve fit and comfort and prevent leakage. • Products may have wetness indicators. • Products may or may not be suitable for containing FI as well as UI.

**FIGURE 8** Example of a *belted pad* (belted product)

internationally (Supporting Information, Appendix C: Figure C-2 and Table C-2, ICS website).

4.3 | Male pads

We recommend that products of the kind shown in Figure 4 should be called *male pads*—waterproof-backed absorbent products for men that are designed to cover the penis and scrotum, and are held in place using separate, close-fitting (regular or specially designed) underwear. Although they are shaped differently, they generally include a series of material layers similar to those shown in the pad in Figure 1A. The defining features of male pads and the main variant features are described in Table 4. The online

questionnaire found a clear international consensus in favor of male pad. Guard pad was quite a popular alternative in some countries but it was more popular than male pad in only one (Canada), though only marginally (Supporting Information, Appendix C: Figure C-3 and Table C-3, ICS website) Accordingly, the use of the term guard pad for men—and others favored by small groups of respondents—is discouraged.

4.4 | Male pouches

We recommend that products of the kind shown in Figure 5 should be called *male pouches*—waterproof-backed absorbent products for men, fashioned into a pocket into which the penis—and sometimes the scrotum, too—is placed. Although they are shaped differently, they generally include a series of material layers similar to those shown in the pad in Figure 1A. The defining features of male pouches and the main variant features are described in Table 5. The online questionnaire found clear international consensus in favor of pouch and no other term emerged as a popular alternative (Supporting Information, Appendix C: Figure C-4 and Table C-4, ICS website). We subsequently made the minor modification of “pouch” to “male pouch” to improve alignment with the conclusions of the parallel ISO project.

TABLE 8 The defining features and main variant features of *belted pads* (belted products)

Defining features	One-piece products in which the absorbent core, waterproof backing, and the means to hold it in place are combined in a single design, secured by means of an adjustable belt with adhesive tabs or a hook and loop fastening system
Main variant features	<ul style="list-style-type: none"> • Products may be used by either sex, but some are intended (by their color, style, or the placing of absorbent material, for example) just for men or just for women. • Products come with different absorption capacities, and to fit different body sizes. • Longitudinal elastic side barriers and leg cuffs on either side of the crotch may be included to improve fit and comfort and prevent leakage. • Products may have wetness indicators. • Products may or may not be suitable for containing FI as well as UI.

TABLE 9 Recommended, acceptable alternative and “retired” terms for the seven categories of single-use body worn absorbent products for incontinence

Design category #	Recommended term	Acceptable alternative term(s)	“Retired “ term(s)
1	Pads	...	Inserts, liners, shields, slips
2	Unbacked pads	...	Booster pads
3	Male pads	...	Guard pads for men; shields, leafs
4	Male pouches
5	Pull-on pads	Protective underwear	Pant-designs, pull-ups, underwear designs, up-and-gos
6	All-in-ones ^a	Wrap-around pads ^a , adult briefs	Briefs, diapers, slips
7	Belted pads	Belted products	Flexes, undergarments

^aAll-in-one is not a helpfully descriptive term but is in common use. The use of the term Wrap-around pad (currently uncommon) is encouraged.

4.5 | Pull-on pads (protective underwear)

We recommend that products of the kind shown in Figure 6 should be called *pull-on pads*—products in which the absorbent core, waterproof backing, and the means to hold it in place are combined in a single design resembling regular underwear, with protective underwear as an acceptable alternative. Although they are shaped differently and have no need of fasteners, they generally include a series of material layers similar to those shown in the all-in-one in Figure 1B. The defining features of pull-on pads (protective underwear) and the main variant features are described in Table 6. The terms protective underwear and pull-up were each supported by about the same number of respondents in the questionnaire, but protective underwear was favored over pull-up (or equal to it) in all countries except the UK and Ireland (Supporting Information, Appendix C: Figure C-5 and Table C-5, ICS website). However, protective underwear is not a usefully descriptive term, and pull-up has child/toddler connotations. Thus, the term, Pull-on pads, is proposed as being descriptive of the key characteristic of the design while avoiding child/toddler connotations, with protective underwear as an acceptable alternative.

4.6 | All-in-ones (wrap-around pads, adult briefs)

We recommend that products of the kind shown in Figure 7 should be called *all-in-ones*—one-piece products in which the absorbent core and the means to hold it in place are combined in a single design, secured using adjustable adhesive tabs or a hook and loop fastening system

at the sides, for the time being. Although in common use this term does not provide a helpful description of the product and we, therefore, encourage the use of the alternative more descriptive term, *wrap-around pads*. *Adult brief* is also an acceptable alternative but lacks helpful description and is, therefore, not encouraged. The construction of a typical all-in-one product is shown in Figure 1B, while the defining features of all-in-ones and their main variant features are described in Table 7. The online questionnaire revealed a diversity of views on what category 6 products should be called. Respondents from four countries favored diaper, but many others were against the term because of its connotations to infants. Slip and wrap-around were favored in the Netherlands but enjoyed little support elsewhere. Adult brief was favored by Canada, the United States, and Norway but, again, there was little support elsewhere. All-in-one was favored by Australia, Belgium, and the UK and had the highest number of respondents favoring it (note: the UK was strongly represented—about a third of respondents) (Supporting Information, Appendix C: Figure C-6 and Table C-6, ICS website). In conclusion, we recommend that these products should be called *all-in-ones*. However wrap-around pads and adult briefs are acceptable as alternatives.

4.7 | Belted pads (belted products)

We recommend that products of the kind shown in Figure 8 should be called *belted pads*—one-piece products in which the absorbent core, waterproof backing, and the means to hold it in place are combined in a single design, secured by means of an adjustable belt with adhesive tabs or a hook and loop fastening system, with belted products as an acceptable alternative. Although they are shaped and secured differently, belted pads generally include a series

of material layers similar to those shown in the all-in-one product in Figure 1B. The defining and main variant features of belted pads (belted products) are described in Table 7. The online questionnaire found clear international consensus in favor of belted products, which was the (joint) top choice in most countries (Supporting Information, Appendix C: Figure C-7 and Table C-7, ICS website). However, “product” is rather vague, and we recommend that “pad” should be used instead, with belted product as an acceptable alternative Table 8.

4.8 | Summary

The recommended terms for the seven categories of single-use body worn absorbent products for incontinence are gathered in Table 9, along with acceptable alternatives and retired terms; that is, terms recommended for discontinuation.

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An International Urogynecological Association (IUGA) / International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Organ Prolapse (POP)

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Introduction: The terminology for female pelvic floor prolapse (POP) should be defined and organized in a clinically-based consensus Report. **Methods:** This Report combines the input of members of two International Organizations, the International Urogynecological Association (IUGA) and the International Continence Society (ICS), assisted at intervals by external referees. Appropriate core clinical categories and a sub-classification were developed to give a coding to definitions. An extensive process of fourteen rounds of internal and external review was involved to exhaustively examine each definition, with decision-making by collective opinion (consensus). **Results:** A Terminology Report for female POP, encompassing over 230 separate definitions, has been developed. It is clinically-based with the most common diagnoses defined. Clarity and user-friendliness have been key aims to make it interpretable by practitioners and trainees in all the different specialty groups involved in female pelvic floor dysfunction and POP. Female-specific imaging (ultrasound, radiology and MRI) and conservative and surgical managements are major additions and appropriate figures have been included to supplement and clarify the text. Emerging concepts and measurements, in use in the literature and offering further research potential, but requiring further validation, have been included as an appendix. Interval (5-10 year) review is anticipated to keep the document updated and as widely acceptable as possible. **Conclusion:** A consensus-based Terminology Report for female POP has been produced to aid clinical practice and research. *NeuroUrol. Urodynam.* 35:137–168, 2016. © 2016 Wiley Periodicals, Inc., and The International Urogynecological Association

Key words: female; pelvic organ prolapse; standardization report; terminology report

INTRODUCTION

Prolapse (Latin: *Prolapsus* – “a slipping forth”) refers to a falling, slipping or downward displacement of a part or organ. **Pelvic organ** refers most commonly to the uterus and/or the different vaginal compartments and their neighboring organs such as bladder, rectum or bowel. **Pelvic organ prolapse (POP)** is thus, primarily, a definition of anatomical change. Some such changes may well be considered within the range of normality for certain women. A **diagnosis of POP** ideally demands clear clinical evidence, starting with a woman having symptoms related to the “downward displacement” of a pelvic organ.

There is currently no single document encompassing all elements required for diagnoses in the area of female POP. Such a report would require a full outline of the terminology for symptoms, signs, clinical assessments, functional investigations for female POP, the imaging associated with those investigations, the most common diagnoses and terminology for the different conservative and surgical treatment modalities.

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There will be a need to reference considerably the 2010 IUGA-ICS Joint Terminology Report on Female Pelvic Floor Dysfunction¹. An original aim of that report¹ had been to provide a general terminology, forming a “backbone” or “core” terminology to which more specific terminologies can be attached. Reference can also be made to three other published Standardization Reports²⁻⁴ and 6 joint IUGA-ICS Female Terminology Reports⁵⁻¹⁰ subsequent to the 2010 Report¹, three published⁵⁻⁷, three⁸⁻¹⁰ advanced in development.

In terms of the previous standardization document on female POP⁴, now 20 years old, there has been much discussion and debate¹¹⁻¹⁴ on the possible need to update its classification POP-Q, or at least to present it in a refreshed version. The POP Working Group has opted for the latter, with major upgrades to symptoms, signs, investigations and diagnoses, but a conservative approach to the classification itself (apart from adding a validated simplified version), due to the longevity of its use and the lack of any validated, clearly superior alternative classification. Female-specific imaging (ultrasound, radiology and MRI) and conservative and surgical managements are major additions and appropriate figures have been included to supplement and clarify the text. Emerging concepts and measurements, in use in the literature and offering further research potential, but requiring further validation, have been included as an Appendix. This Report acknowledges that POP is often not a diagnosis in isolation but may be associated with POP-related and unrelated voiding, defecatory and/or sexual dysfunctions and/or other diagnoses of pelvic floor dysfunction.

This Terminology Report is inherently and appropriately a definitional document, collating the definitions of those terms, i.e. “words used to express a defined concept in a particular branch of study”¹⁵, here POP. Emphasis has been on comprehensively including those terms in current use in the relevant peer-reviewed literature. The aim is to assist clinical practice and research. Some new and revised terms have been included. Explanatory notes on definitions have been referred, where possible, to the “Footnotes” section.

Like all the other joint IUGA-ICS female-specific terminology reports, every effort has been made to ensure this Report is:

(1) User-friendly: It should be able to be understood by all clinical and research users.

(2) Clinically-based: Symptoms, signs and validated assessments/investigations should be presented for use in forming workable diagnoses for POP and associated dysfunctions. Sections 1-5 will address symptoms, signs, POP quantification, investigations for associated dysfunctions and current POP imaging modalities that may be used to make those diagnoses. A number of related radiological investigations including Magnetic Resonance Imaging (MRI) and Computerized Tomography (CT) have also been incorporated. Section 6 will address POP diagnoses, possible POP-related diagnoses and co-existing diagnoses. The scope of the Report will exclude more invasive investigations requiring an anesthetic. Sections 7 and 8 will list the terminology for evidence-based conservative and surgical treatments for POP.

(3) Origin: Where a term's existing definition (from one of multiple sources used) is deemed appropriate, that definition will be included and duly referenced. A large number of terms in female pelvic floor prolapse and dysfunction, because of their long-term use, have now become generic, as apparent by their listing in medical dictionaries.

(4) Able to provide explanations: Where a specific explanation is deemed appropriate to describe a change from earlier definitions or to qualify the current definition, this will be included as an addendum to this paper (*Footnote [FN] 1,2,3...*). Wherever possible, evidence-based medical principles will be followed.

It is suggested that acknowledgement of these standards in written publications related to female POP, be indicated by a footnote to the section “Methods and Materials” or its equivalent, to read as follows: “Methods, definitions and units conform to the standards jointly recommended by the International Urogynecological Association and the International Continence Society except where specifically noted”.

SECTION 1: SYMPTOMS:

Symptom: Any morbid phenomenon or departure from the normal in structure, function or sensation, experienced by the woman and indicative of disease or a health problem¹⁶. Symptoms are either volunteered by, or elicited from the woman or may be described by the woman's caregiver¹⁻³.

¹: In the era of advanced cellphone camera technology, a woman, at times, will bring photographic evidence of the prolapse at its worst. This can add to other clinical evidence, particularly if there is a discrepancy between symptoms and signs.

²: The more formal classification of constipation is as follows:

Rome II diagnostic criteria for constipation:

- At least 12 weeks, which need not be consecutive, in the previous 12 months, of two or more of:
 - (i) Straining in > 1 in 4 defecations.
 - (ii) Lumpy or hard stools in > 1 in 4 defecations.
 - (iii) Sensation of incomplete evacuation in > 1 in 4 defecations.
 - (iv) Sensation of anorectal obstruction/ blockage in > 1 in 4 defecations.
 - (v) Manual manoeuvres to facilitate > 1 in 4 defecations (e.g. digital evacuation, support of the pelvic floor).
 - (vi) Less than 3 defecations per week.
- Loose stools are not present and there is insufficient evidence for IBS (irritable bowel syndrome)

³: A symptomatic-based subdivision of Stage II (see Appendix A) was overlooked at this time in favor of maintaining the current strictly anatomical definition of the “sign of POP”.

Pelvic Organ Prolapse (POP) Symptoms

Prolapse symptoms¹: A departure from normal sensation, structure or function, experienced by the woman in reference to the position of her pelvic organs. Symptoms are generally worse in situations when gravity might make the prolapse worse (e.g. after long periods of standing or exercise) and better when gravity is not a factor e.g. lying supine. Again symptoms may be more noticeable at times of abdominal straining e.g. defecation.

A: Vaginal Prolapse Symptoms

(i) Vaginal bulging¹: Complaint of a “bulge”, lump or “something coming down” or “falling out” through the vaginal introitus. The woman may state she can either feel the bulge by direct palpation or see it, perhaps aided with a mirror. FN1

(ii) Pelvic pressure¹: Complaint of increased heaviness or dragging (pain or discomfort) in the suprapubic area and/or pelvis.

(iii) Bleeding, discharge, infection¹: Complaint of abnormal vaginal bleeding, discharge or infection which may be related to ulceration of the prolapse.

(iv) Splinting / Digitation¹: Complaint of the need to digitally replace the prolapse or to otherwise apply manual pressure, e.g. to the vagina, perineum or perianal area (splinting), or rectally (digitation) to assist voiding or defecation.

(v) Low backache¹ (POP-related): Complaint of low, sacral (or “menstrual-like”) backache associated temporally with vaginal POP and relieved when prolapse is reduced.

B: Urinary Tract Prolapse Symptoms

(i) Urethral Prolapse: Complaint of a “lump” at the external urethral meatus.

C: Anorectal prolapse symptoms

(i) Anorectal prolapse: Complaint of a “bulge” or “something coming down” towards or through the anus/rectum. The woman may state she can either feel the bulge by direct palpation or see it perhaps aided with a mirror. FN1

(ii) Rectal prolapse: Complaint of external protrusion of the rectum.

Effects of Pelvic Organ Prolapse on Bladder, Bowel and Sexual Function.

As demonstrated in Figure 1, higher stage utero-vaginal prolapse will usually cause anatomical distortion to surrounding organs, bladder and rectum most commonly. This can lead to abnormal function, most commonly difficulty with bladder and bowel emptying. Commonly, symptoms related to those surrounding organs are the most bothersome leading to the eventual diagnosis of the POP.

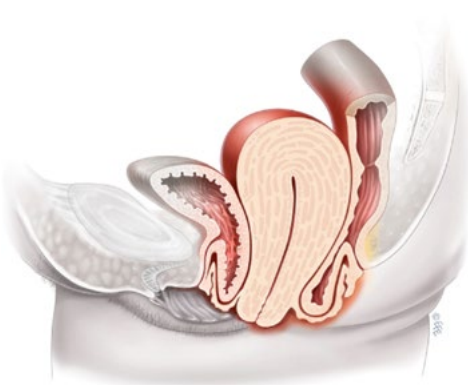


Figure 1. Utero-vaginal prolapse.

D: Potential prolapse-related lower urinary tract symptoms:

(i) Hesitancy¹: Complaint of a delay in initiating micturition.

(ii) Slow stream¹: Complaint of a urinary stream perceived as slower compared to previous performance (particularly prior to the development of POP) or in comparison with others.

(iii) Intermittency¹: Complaint of urine flow that stops and starts on one or more occasions during voiding.

(iv) Straining to void¹: Complaint of the need to make an intensive effort (by abdominal straining, Valsalva or suprapubic pressure) to either initiate, maintain or improve the urinary stream.

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(v) **Spraying (splitting) of urinary stream**¹: Complaint that the urine stream is a spray or split rather than a single discrete stream.

(vi) **Feeling of incomplete (bladder) emptying**¹: Complaint that the bladder does not feel empty after micturition.

(vii) **Need to immediately re-void**¹: Complaint that further micturition is necessary soon after passing urine.

(viii) **Post-micturition leakage**²: Complaint of a further involuntary passage of urine following the completion of micturition.

(ix) **Position-dependent micturition**¹: Complaint of having to take specific positions to be able to micturate spontaneously or to improve bladder emptying e.g. leaning forwards or backwards on the toilet seat or voiding in the semi-standing position.

(x) **Splinting to micturate**: as above A (iv).

(xi) **Dysuria**¹: Complaint of burning or other discomfort during micturition. Discomfort may be intrinsic to the lower urinary tract or external (vulvar dysuria).

(xii) **(Urinary) retention**¹: Complaint of the inability to pass urine despite persistent effort.

(xiii) **Increased daytime urinary frequency**¹: Complaint that micturition occurs more frequently during waking hours than previously deemed normal by the woman.

(xiv) **Urgency**¹: Complaint of a sudden, compelling desire to pass urine which is difficult to defer.

E: Potential prolapse-related anorectal dysfunction symptoms^{1,8}

(i) **Constipation**⁸: Complaint that bowel movements are infrequent and/or incomplete and/or there is a need for frequent straining or manual assistance to defecate. FN2

(ii) **Feeling of incomplete bowel evacuation**^{1,8}: Complaint that the rectum does not feel empty after defecation and may be accompanied by a desire to defecate again.

(iii) **Straining to defecate**^{1,8}: Complaint of the need to make an intensive effort (by abdominal straining or Valsalva) to either initiate, maintain or improve defecation.

(v) **Sensation of anorectal blockage**⁸: Complaint suggestive of anorectal obstruction.

(vi) **Splinting / Digitation**^{1,8}: Defined above in A (iv).

(vii) **Fecal (rectal) urgency**^{1,8}: Complaint of a sudden compelling desire to defecate that is difficult to defer.

(viii) **Post-defecatory soiling (NEW)**: Soiling occurring after defecation.

F: Potential prolapse-related Sexual dysfunction symptoms^{1,10,17}

(i) **Dyspareunia**: Complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration.

(ii) **Obstructed intercourse**: Complaint that vaginal penetration is impeded. Possible causes include narrowing or a bulge.

(iii) **Vaginal laxity**: Complaint of excessive vaginal looseness.

(iv) **Libido – loss or decrease**: Complaint of loss or decrease of sexual desire

G: Other Possible Associated Symptoms¹

(i) **Urinary incontinence symptoms**¹: Urinary incontinence (symptom); stress (urinary) incontinence; urgency (urinary) incontinence; postural (urinary) incontinence; nocturnal enuresis; mixed (urinary) incontinence; continuous (urinary) incontinence; insensible (urinary) incontinence; coital (urinary) incontinence.

(ii) **Bladder storage symptoms**¹: nocturia; overactive bladder syndrome.

(iii) **Bladder sensory symptoms**²: Increased bladder sensation; reduced bladder sensation; absent bladder sensation.

(iv) **Lower Urinary Tract Infection**¹: Urinary tract infection (UTI); recurrent urinary tract infections (UTIs); other related history.

H: More common POP-related symptoms: Table I gives a consensus view of the authors of the more common POP-related symptoms

TABLE I. The symptoms that women with POP would more* and most commonly** describe.

Potential prolapse-related symptoms	
<u>Vaginal prolapse</u>	Bulge sensation /visualization**, pelvic pressure**, low (sacral) backache*
<u>Urinary tract</u>	Frequency**, recurrent UTI**, incomplete emptying/urinary retention*, slow stream*
<u>Ano-rectal</u>	Incomplete defecation**, digitation/splinting*, rectal urgency*, post-defecatory soiling
<u>Sexual</u>	Dyspareunia*, vaginal laxity*
Other possible associated symptoms	
<u>Urinary incontinence**</u>	Stress, urge, postural, nocturnal, coital
<u>Bladder storage*</u>	Urgency, nocturia,

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SECTION 2: SIGNS

Sign: Any abnormality indicative of disease or a health problem, discoverable on examination of the patient; an objective indication of disease¹⁶ or a health problem.

A: Signs of Pelvic Organ Prolapse: All examinations for POP should be performed with the woman's bladder empty (and if possible an empty rectum). An increasing bladder volume has been shown to restrict the degree of descent of the prolapse¹⁶. The choice of the woman's position during examination, e.g. left lateral (Sims), supine, standing or lithotomy is that which can best demonstrate POP in that patient and which the woman can confirm as the maximal extent she has perceived e.g. by use of a mirror or digital palpation. The degree of prolapse may be worse after a lengthy time in the upright position. FN1

(i) Pelvic organ prolapse (anatomical definition of the sign of POP)¹: The descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy). **The presence of any such sign should be correlated with relevant POP symptoms^{13,19-21}**, i.e., patient report of maximal prolapse. More commonly, this correlation would occur at the level of the hymen or beyond¹⁹⁻²¹.

(ii) Pelvic organ prolapse – (POPQ) - (staging^{3,5,4}):

Stage 0: No prolapse is demonstrated.

Stage I: Most distal portion of the prolapse is more than 1cm above the level of the hymen.

Stage II: The most distal portion of the prolapse is situated between 1 cm above the hymen and 1cm below the hymen. FN3. See also Appendix.

Stage III: The most distal portion of the prolapse is more than 1cm beyond the plane of the hymen but everted at least 2cm less than the total vaginal length.

Stage IV: Complete eversion or eversion at least within 2 cm of the total length of the lower genital tract is demonstrated.

(iii) Uterine/ cervical prolapse: Observation of descent of the uterus or uterine cervix.

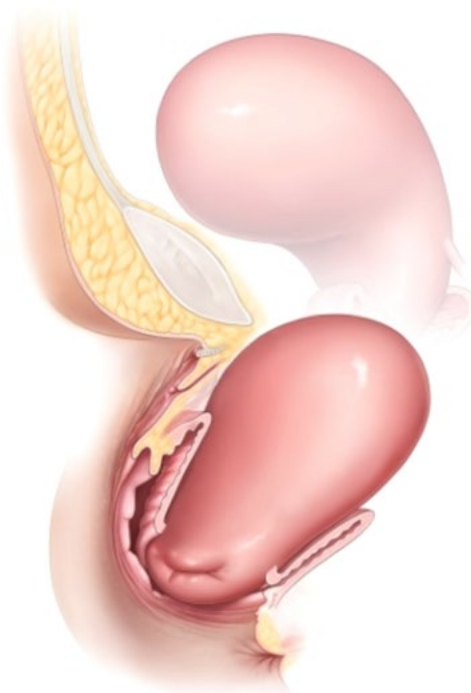


Figure 2. Uterine Prolapse.

(iv) Anterior vaginal wall (compartment) prolapse: Observation of descent of the anterior vaginal wall (compartment). Most commonly this might represent bladder prolapse (cystocele). Higher stage anterior vaginal wall prolapse will generally involve descent of uterus or vaginal vault (if uterus is absent). Occasionally, there might be an anterior enterocele (hernia of peritoneum and possibly abdominal contents), most commonly after prior reconstructive surgery.



Figure 3. Anterior vaginal wall (compartment) prolapse.

(v) Posterior vaginal wall (compartment) prolapse: Observation of descent of the posterior vaginal wall. Commonly, this would represent rectal protrusion into the vagina (rectocele). Higher stage posterior vaginal wall prolapse after prior hysterectomy will generally involve some vaginal vault (cuff scar) descent and possible enterocele formation. Enterocele formation can also occur in the presence of an intact uterus.

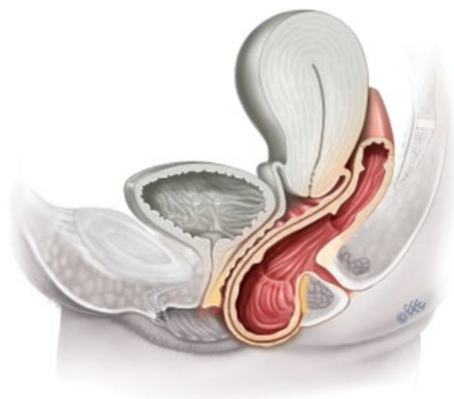


Figure 4. Posterior vaginal (compartment) wall prolapse.

(vi) Vaginal vault (cuff scar) prolapse: Observation of descent of the vaginal vault (cuff scar after hysterectomy).

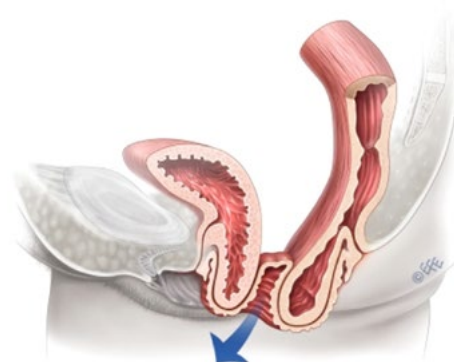


Figure 5. Vaginal vault prolapse.

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B: Clinical Staging⁴:

Each aspect of POP, uterine (cervical) prolapse, anterior vaginal wall (compartment), posterior vaginal wall (compartment), vaginal vault (cuff scar) prolapse can and should be subject to a clinical staging.

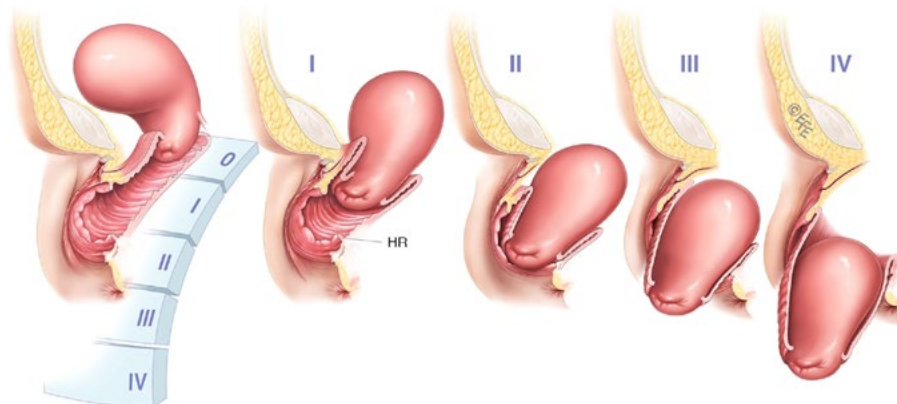


Figure 6. shows prolapse staging⁴ – 0, I, II, III, IV. (uterine – by the position of the leading edge of the cervix).

C: Supplementary Physical Examination Techniques

(i) **Digital rectal-vaginal examination⁴:** While the patient is straining and the prolapse is maximally developed. The aim is to try to differentiate between a high rectocele and an enterocele.

(ii) **Q-tip (urethral) testing⁴:** Measurement of urethral axial mobility at rest and straining to assess degree of mobility.

D: Clinical Assessment of Associations of POP

(i) **Levator Defects / Trauma²²:** Per-vaginal palpation for levator injury/defect/ “avulsion”.

(ii) **Uterine retroversion^{23,24}:** (Turning backward) The axis of the uterus is directed backwards towards the hollow of the sacrum, away from its anteverted position overlying the bladder. Cervix is noted in/ towards the anterior fornix with fundus perhaps palpable in the posterior fornix. FN4

E: Other Possible Signs.

(i) **Urinary incontinence signs¹:** Urinary incontinence; stress (urinary) incontinence; urgency (urinary) incontinence; extraurethral incontinence; stress incontinence on prolapse reduction (occult or latent stress incontinence)

(ii) **Other pelvic examinations/signs¹:** Vulvar examination; urethral inspection/palpation (urethral mucosal prolapse, urethral caruncle; urethral diverticulum); vaginal examination; bimanual pelvic examination; pelvic floor muscle function (normal pelvic floor muscles, overactive pelvic floor muscles, underactive pelvic floor muscles, non-functioning pelvic floor muscles); examination for levator (puborectalis) injury; perineal examination (perineal elevation, perineal descent); rectal examination (anal sphincter tone and strength, anal sphincter tear, fecal impaction present/absent, other rectal lesions, anal lesions, other perianal lesions), vaginal atrophy.

(iii) **Other relevant examinations/Signs¹:** Neurological signs, abdominal signs (bladder fullness/retention; abdominal masses or distension; scars from previous relevant surgery or trauma; renal tenderness or masses).

(iv) **Frequency volume chart / Bladder diary¹**

(v) **Pad testing¹**

SECTION 3: PROLAPSE QUANTIFICATION**A: Pelvic Organ Prolapse Quantification (POP-Q)⁴**

(i) **Fixed Point of Reference.** The hymen is the fixed point of reference used throughout the POP-Q system of quantitative prolapse description.

⁴: The axis of the retroverted uterus is parallel to that of the vaginal axis with less impediment to uterine (cervical) descent. In contrast, the anteverted uterus is perpendicular to the vaginal axis with impediment to descent by the posterior vaginal wall and behind that the rectum.

(ii) **Defined Points.** The anatomic position of the six defined points (two on the anterior vaginal wall, two in the superior vagina, and two on the posterior vaginal wall) for measurement should be centimeters (cm) above or proximal to the hymen (negative number) or cm below or distal to the hymen (positive number) with the plane of the hymen being defined as zero (0). For example, a cervix that protruded 3 cm distal to the hymen would be + 3 cm. All points are measured on maximal straining (except total vaginal length).

(iii) **Anterior Vaginal Wall.**

(a) **Point Aa.** A point located in the midline of the anterior vaginal wall three (3) cm proximal to the external urethral meatus. By definition, the range of position of Point Aa relative to the hymen is -3 to +3 cm.

(b) **Point Ba.** A point that represents the most distal (i.e., most dependent) position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to Point Aa. By definition, Point Ba is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff (Point C) in women with total uterine prolapse or post-hysterectomy vaginal eversion.

(iv) **Superior Vagina.** These points represent the most proximal locations of the normally positioned lower reproductive tract. The two superior sites are as follows:

(c) **Point C.** A point that represents either the most distal (i.e. most dependent) edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar) after total hysterectomy.

(d) **Point D.** A point that represents the location of the posterior fornix in a woman who still has a cervix. It is included as a point of measurement to differentiate suspensory failure of the uterosacral-cardinal ligament "complex" from cervical elongation. When the location of Point C is significantly more positive than the location of Point D, this is indicative of cervical elongation which may be symmetrical or eccentric. Point D is omitted in the absence of the cervix.

(v) **Posterior Vaginal Wall.**

(e) **Point Ap.** A point located in the midline of the posterior vaginal wall three (3) cm proximal to the hymen. By definition, the range of position of Point Ap relative to the hymen is -3 to +3 cm.

(f) **Point Bp.** A point that represents the most distal (i.e., most dependent) position of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to Point Ap. By definition, Point Bp is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in a women with total post-hysterectomy vaginal eversion.

(vii) **Other Landmarks and Measurements.**

(g) The *genital hiatus* (GH) is measured from the middle of the external urethral meatus to the posterior margin of the hymen.

(h) The *total vaginal length* (TVL) is the length of the vagina (cm) from posterior fornix to hymen when Point C or D is reduced to its full normal position. (See Figure 40 - Appendix).

(i) The *perineal body* (PB) is measured from the posterior margin of the hymen to the mid-anal opening.

(viii) **Recording Measurements:** (NB: Intraoperative measurements with traction can be quite different from measurements made during Valsalva in clinic, both in regards to cervical location and the vaginal walls). Measurements directly after removing a vaginal pessary are unreliable and will tend to understage the degree of POP.

The position of Points Aa, Ba, Ap, Bp, C, and (if applicable) D with reference to the hymen should be measured (cm) and recorded.

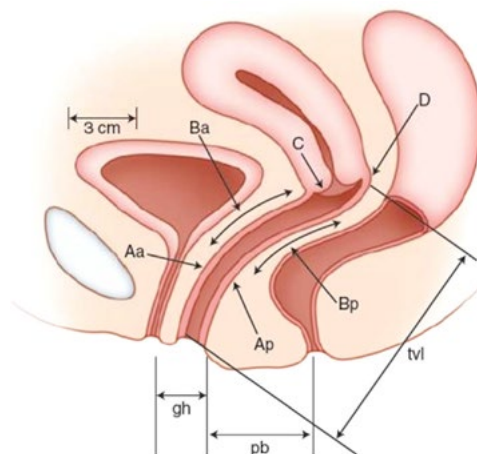


Figure 7. The six sites (Aa, Ba, C, D, Bp and Bp), the genital hiatus (gh), perineal body (pb) and total vaginal length (tv) used cm above or proximal to the hymen (negative number) or cm below or distal to the hymen (positive number) with the plane of the hymen being defined as zero (0). Alternatively, a three by three grid can be used to organize concisely the measurements as noted in Figure 8.

Anterior wall Aa	Anterior wall Ba	Cervix or Cuff C
Genital hiatus gH	Perineal Body pB	Total Vaginal Length TVL
Posterior wall Ap	Posterior wall Bp	Posterior Fornix D

Figure 8. Grid presentation of POP-Q measurements.

B: Simplified POP-Q^{25,26}

This is based on the POP-Q with similar ordinal staging but with only four points measured instead of nine. There is no Stage 0; it is combined with Stage 1. It is undertaken in the dorsal lithotomy position with patient forcefully bearing down, performing Valsalva or coughing.

(i) Four points used:

- . Anterior vaginal segment: point Ba (estimated around 3cm proximal to hymenal remnants).
- . Posterior vaginal segment: point Bp (estimated around 3cm proximal to hymenal remnants).
- . Cervix point C
- . Apex/posterior fornix: point D (non-hysterectomized); point C (hysterectomized)

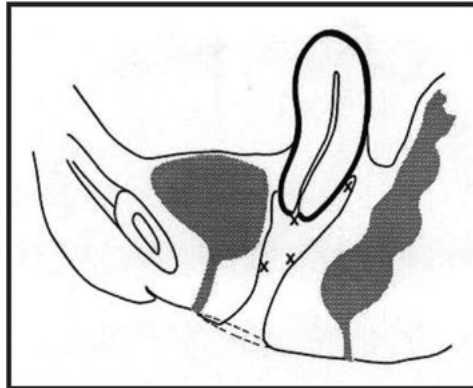


Figure 9. Simplified POP-Q.

(ii) Staging:

I, II, III, IV as for POP-Q above.

C: Additional available measurements awaiting further validation

These have been included as an Appendix after the References

(i): Vaginal Anatomical Levels and Lengths.

(ii): Perineal measurements.

(iii): Vaginal measurements.

SECTION 4: INVESTIGATIONS

Urodynamics¹: Functional study of the lower urinary tract.

Clinical sequence of testing¹: Urodynamic investigations generally involve a woman attending with a comfortably full bladder for free (no catheter) uroflowmetry and post void residual urine volume (PVR) measurement prior to filling and voiding (with catheter) cystometry.

A: Assessment of Impact of Prolapse on Voiding Function

POP can have a negative impact on voiding function, screening for which importantly involves a postvoid residual and ideally uroflowmetry. Voiding cystometry may clarify the cause of any voiding dysfunction.

(i) Postvoid Residual¹⁻³: Volume of urine left in the bladder at the completion of micturition. **Conditions for PVR measurement:** PVR reading is erroneously elevated by delayed measurement due to additional urine production (1-14 mls/min). Ultrasonic techniques (transvaginal, translabial most accurately) allow immediate²⁷ (within 60 seconds of micturition) measurement and possible repeat measurement (Figure 10). A short plastic female catheter provides the most effective bladder drainage for PVR measurement by catheterization.

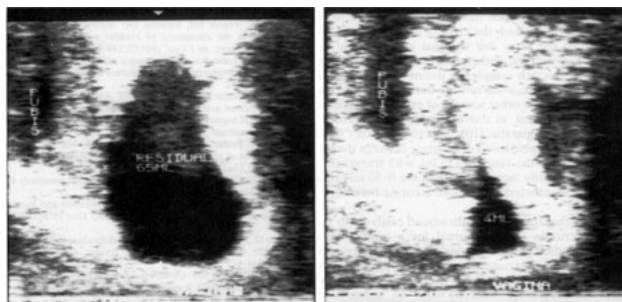


Figure 10. An image of postvoid residual of 65ml by transvaginal ultrasound, reducing to 4ml with a subsequent attempt at voiding.

(ii) Uroflowmetry¹⁻³: Measurement of urine flow rates during micturition¹⁶

- . **Flow rate:** Volume of urine expelled via the urethra per unit time. It is expressed in ml/sec.
- . **Voided volume (ml):** Total volume of urine expelled via the urethra.
- . **Maximum (urine) flow rate (MUFR - ml/sec) - Q_{max}:** Maximum measured value of the flow rate.
- . **Flow time (sec):** The time over which measurable flow actually occurs.
- . **Average (urine) flow rate (AUFR - ml/sec) - Q_{ave}:** Voided volume divided by the flow time.

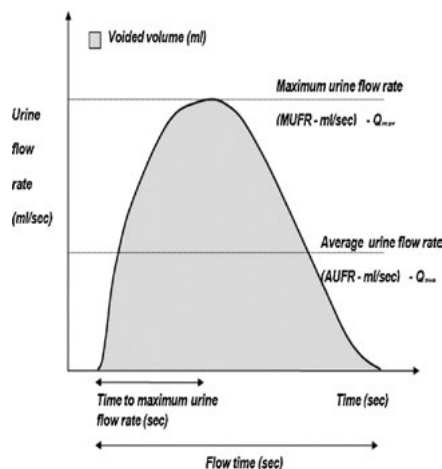


Figure 11. A schematic representation of urine flow over time.

The dependence of urine flow rates on voided volume²⁸ makes it desirable to reference raw urine flow rate data to established normative data.

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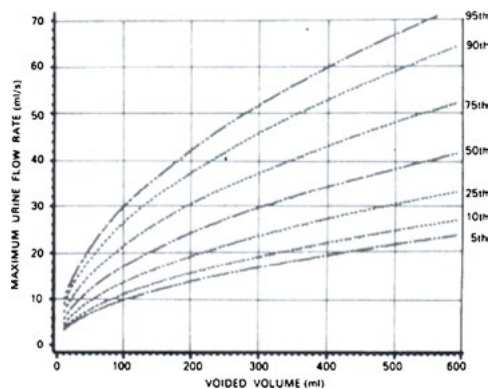


Figure 12. The Liverpool nomogram²⁹ for the maximum urine flow rate in women (under the 10th centile on repeat measurement can be regarded as abnormally slow³⁰).

(iii) **Pressure- Flow studies**^{1-3,31}

Cystometry: Measurement of the pressure/volume relationship of the bladder during filling and/or pressure flow study during voiding. Higher voiding detrusor pressures and slower urine flow during voiding may point an element of bladder outflow obstruction^{1-3,32}, though other patterns of pressure-flow data are possible.

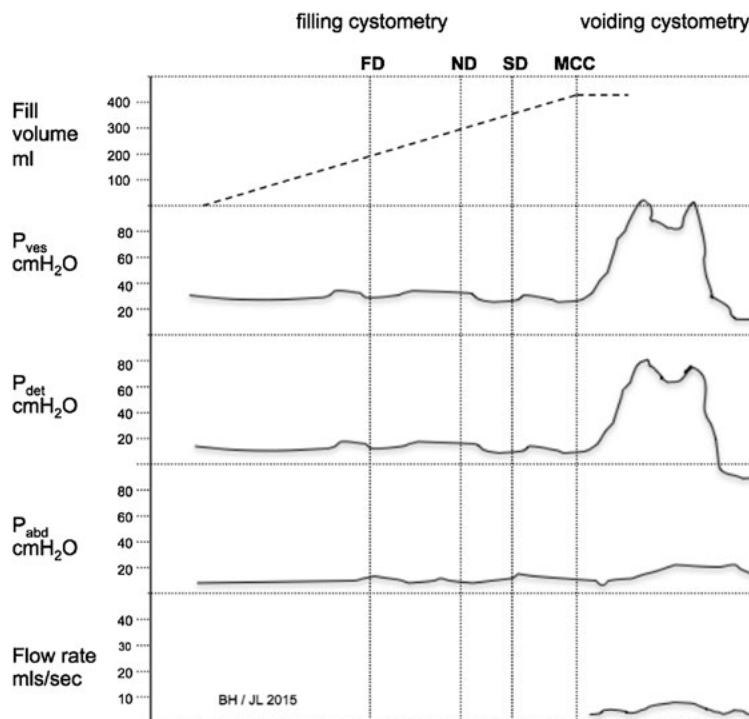


Figure 13. Filling and voiding cystometric trace, the latter part showing evidence of an element of bladder outflow obstruction. Normal bladder capacity, stable detrusor: no phasic activity seen. Voided with low urine flow rate and elevated detrusor pressure. Bladder outflow obstruction is thus demonstrated.

B: Assessment of Impact on Prolapse on Defecatory Function

(i) **Ultrasound Assessment:** See imaging section.

(ii) **Radiological Assessment:** See imaging section.

C: Other urodynamic investigations for intercurrent diagnoses^{1-3,31}

(i) **Filling cystometry:** The pressure/volume relationship of the bladder during filling can evaluate the presence of intercurrent diagnoses (ii-iv).

(ii) **Urodynamic stress incontinence¹:**

Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

(iii) **Detrusor Overactivity¹:**

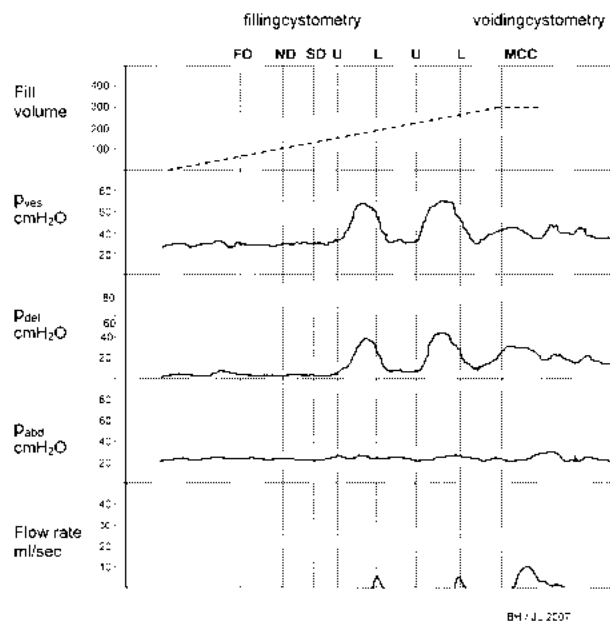
The occurrence of involuntary detrusor contractions during filling cystometry. These contractions, which may be spontaneous or provoked, produce a wave form on the cystometrogram, of variable duration and amplitude (Figure 14).

(iv) **Bladder Oversensitivity¹:**

Increased perceived bladder sensation during bladder filling with: an early first desire to void; an early strong desire to void, which occurs at a low bladder volume; a low maximum cystometric bladder capacity. No abnormal increases in detrusor pressure are noted.

(v) **Detrusor underactivity¹FN5 and Acontractile detrusor¹FN6**

Can also be diagnosed at voiding cystometry.



54 year old female with urgency and frequency. Phasic detrusor activity during filling. Leakage is associated with urgency and detrusor contractions. FD = First Desire to Void, ND = Normal desire to void, SD = Strong desire to void, U = Urgency, L = leakage, MCC = Maximum Cystometric Capacity.

Figure 14. Cystometric trace showing detrusor overactivity¹.

⁵: *Detrusor underactivity*: Detrusor contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span.

⁶: *Acontractile detrusor*: The detrusor cannot be observed to contract during urodynamic studies resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span. The term "areflexia" has been used where there is a neurological cause but should be replaced by *neurogenic acontractile detrusor*.

SECTION 5: PROLAPSE IMAGING

Imaging may assist the clinical assessment of POP or intercurrent pelvic floor diagnoses. Use of any of the different imaging modalities is, however, entirely optional.

A: Prolapse-related ultrasound imaging – 2-D

(i) Modalities

Transabdominal, perineal, introital and transvaginal ultrasound¹.

- Transabdominal (T-A): curvilinear scanning applied to the abdomen.
- Perineal: curved array probe applied to the perineum. This term incorporates transperineal and translabial ultrasound.
- Introital: sector probe applied to the vaginal introitus.
- Transvaginal (T-V): intravaginal curvilinear, linear array, or sector scanning.

(ii) Clinical applications:

- Bladder neck descent/mobility. The position of the bladder neck at rest and on Valsalva.
- Urethral funnelling: i.e., opening of the proximal third of the urethra during coughing or on Valsalva.
- Post void residual: Several formulas have been described in the literature to measure the bladder volume by ultrasound^{33–35}. An early formula $[(h \times d \times w) \times 0.7]$ has been demonstrated to give reproducible results with a percentage error of 21%³³ (see Figure 15 for definitions of h,d,w).
- Bladder abnormalities: e.g., tumor, foreign body.
- Urethral abnormality: e.g., diverticulum.
- Intercurrent uterine and/or pelvic abnormality: dependent on probe range.
- Postoperative findings: e.g., bladder neck position and mobility, position of meshes, tapes, or implants.
- Descent of pelvic organs: visualization of descent of the bladder, uterine cervix, and rectum during coughing or on Valsalva.
- Assessment of voluntary pelvic floor muscle contractility.
- Pelvic floor/levator ani muscle defect (“avulsion”) and hiatal ballooning³⁶.
- Ultrasound measurements of bladder and detrusor wall thickness, and ultrasound estimated bladder weight (UEBW) are potential noninvasive clinical tools for assessing the lower urinary tract. UEBW is higher in women with overactive bladder and detrusor overactivity^{37,38}. FN7.

Figures 16 and 17 show examples of 2-D introital ultrasound in patients with POP symptoms.

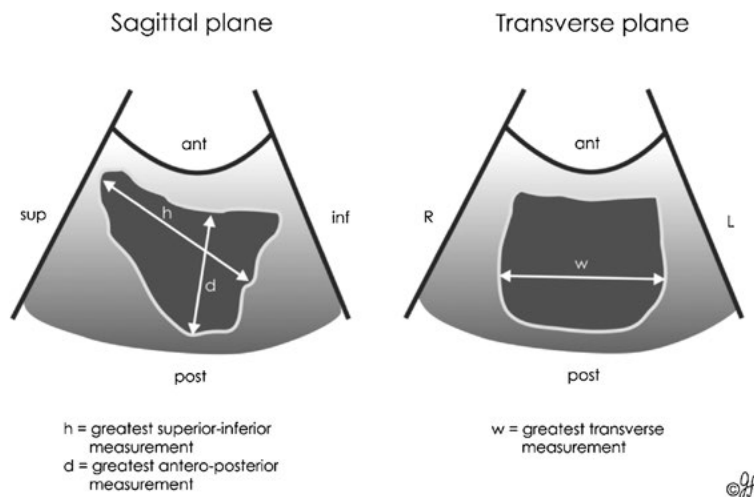


Figure 15. Ultrasound measurement of the bladder volume from Poston GJ et al. 1983³³(redrawn).

⁷: Women with detrusor overactivity have a median UEBW of 48.0 g (95% CI 46-51), with urodynamic stress incontinence a median UEBW of 30 g (95% CI 29-31) and those who have associated detrusor overactivity and urodynamic stress incontinence have a median UEBW of 37.3 g (95% CI 33-41) ($p < 0.001$)^{37,38}.

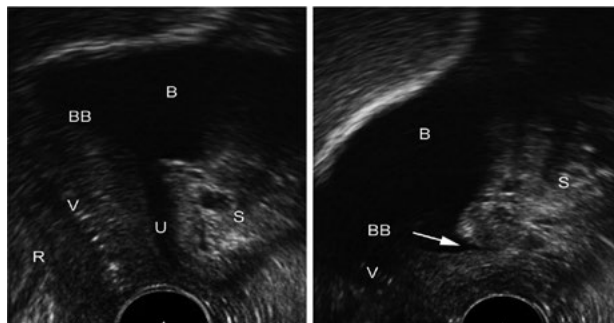


Figure 16. (above): 56 year old female with stage II cystocele and urodynamic stress incontinence. Left: at rest. Right: during Valsalva. B=Bladder, BB = bladder base, U = urethra, S = symphysis pubis, arrow = bladder neck during Valsalva, V = vagina, R = rectum. Arrow = bladder neck during Valsalva with bladder neck funneling as a sign of urethral incompetence.

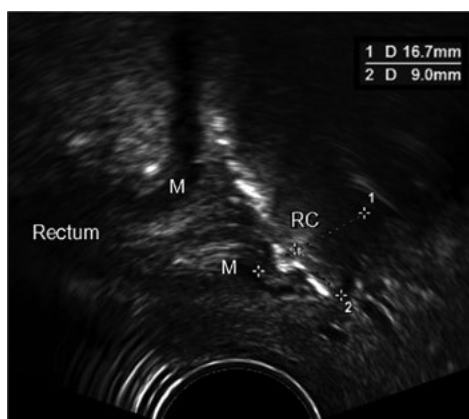


Figure 17. (above): 72 year old female with stage II rectocele. Measurement of rectocele (RC) width (1) and depth (2) during Valsalva. M = muscularis of rectum.

B: Prolapse-related ultrasound imaging – 3-D

(i) Modalities: Endovaginal, transanal, and translabial/transperineal

- Endovaginal ultrasound imaging may inadvertently compress tissues thus distorting the anatomy.
- Transanal ultrasound approach requires an expensive and dedicated transducer, and it is a more uncomfortable and embarrassing test for the woman. Its most common clinical indication is the assessment of sphincter integrity following obstetric trauma.
- Translabial/transperineal approach overcomes the limitations of endovaginal and transrectal techniques providing minimal pressure on local structures and it is least likely to alter surrounding anatomy.

(ii) Evaluations:

The following pelvic floor abnormalities/ surgical sequelae can be evaluated:

- (a) Trauma (injury/damage) of the levator ani muscle (LAM).
- (b) Excessive distensibility of the puborectalis muscle and levator hiatus (“ballooning”).
- (c) Pathologies of the anterior vaginal compartment like urethral diverticula.
- (d) Bladder tumours or foreign bodies (sling, mesh, bulking agents).
 - Polypropylene meshes: highly echogenic and thus easily identified in the coronal and axial plane, unless they are obscured by vaginal prolapse.
 - Periurethral bulking agents, used as a continence procedure, can also be depicted with 3D pelvic floor ultrasound. FN8

⁸: Synthetic implant such as macropastique, are hyperechogenic whereas collagen injections are hypoechoic and can be seen as spherical structures surrounding the bladder neck.

Figure 18 shows 3D ultrasound imaging of the pelvic floor anatomy.

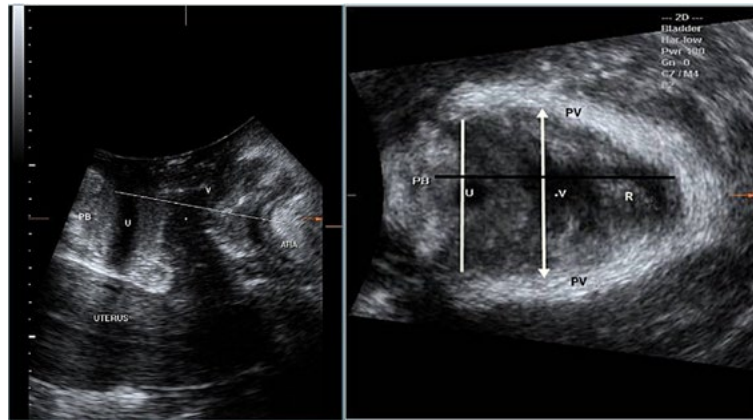


Figure 18. (above): 3D ultrasound image of levator ani muscle of an asymptomatic nulliparous woman at rest. 3D ultrasound image of the pelvic floor at rest showing the anatomy and the reference plane of measurements. Left: sagittal view; PB: pubic bone; U: urethra; V: vagina; ARA: anorectal angle; white line: plane of minimal hiatal dimensions (plane of all measurements). Right: axial view; PB: pubic bone; U: urethra; V: vagina; R: rectum; PV: pubovisceralis muscle; black line: antero-posterior diameter of the levator hiatus; white line: transverse diameter of the levator hiatus at the level of pubovaginalis, white double-headed arrowed line: transverse diameter of the levator hiatus at the level of pubourethralis.

(iii) 3D ultrasound imaging of the female urethra

3D ultrasound imaging of the rhabdosphincter overcomes the limits of MRI and two-dimensional (2D) ultrasound imaging that incorrectly measure the urethral sphincter volume using mathematical formulas based upon assumptions that the shape of the urethra is similar to that of an ellipse. Since the urethral shape is neither elliptical nor spherical, but rather an atypical geometric shape, equations should not be used³⁹. FN9. Figure 19 shows 3D ultrasound imaging of the urethral sphincter

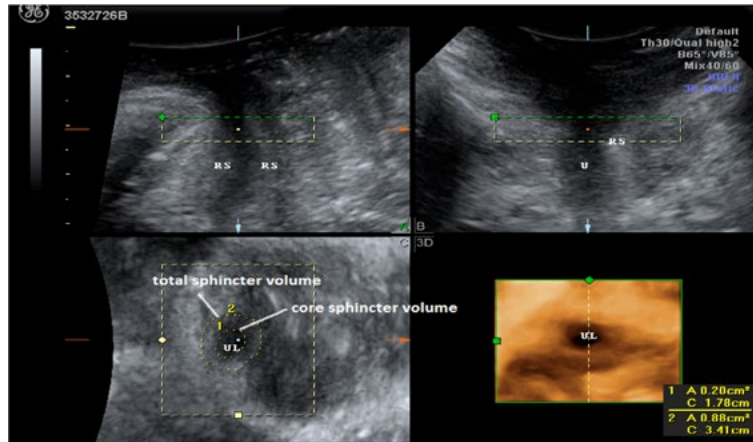


Figure 19. (above): 3D translabial image of the female urethra. The urethra lumen is shown clearly in the rendered volume image (bottom right). (U, urethra; UL, urethra lumen; RS, rhabdosphincter).

(iv) 3D ultrasound imaging of the levator ani trauma

The presence of levator ani trauma has been postulated to be associated to an increased risk of pelvic organ prolapse⁴⁰. This can be evaluated using a tomographic ultrasound imaging assessment of the levator ani muscles (Figure 20).

⁹: The importance of precise structural assessment of the urethral sphincter using multiple axial cross-sectional areas at set distances can assist the evaluation of women with stress urinary incontinence. It has been suggested that it may predict the severity of incontinence as well as the outcome of continence surgery since a weak sphincter will have a lower volume compared to a competent/continent urethral sphincter³⁹.

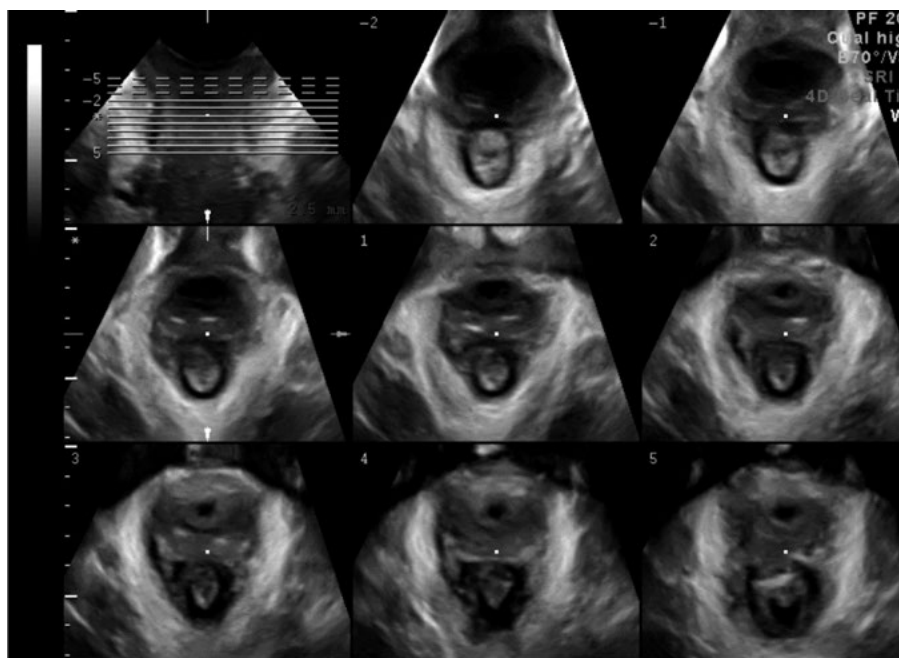


Figure 20. (above): Tomographic ultrasound imaging assessment of the levator ani muscles Intact LAM.

(v) 3D ultrasound imaging of ballooning of the genital hiatus

The presence of ballooning of the genital hiatus (= excessive distensibility of the levator hiatus) on Valsalva manoeuvre has also been associated to the severity of urogenital prolapse. An area of more than 25 cm², 30 cm², 35 cm² and 40 cm² has been defined as mild, moderate, marked and severe ballooning respectively (Figure 21)⁴¹.

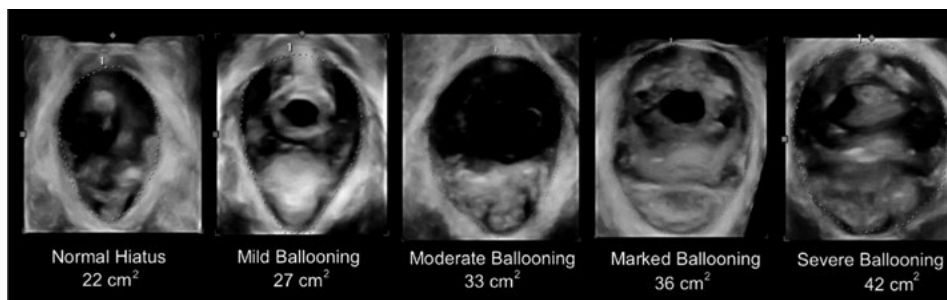


Figure 21. (above): Ballooning of the genital hiatus on Valsalva manoeuvre – levator defect.

C: Magnetic resonance imaging (MRI) of the pelvic floor

Magnetic resonance imaging (MRI) allows the detection of ligamentous and muscular pelvic floor structures in fine detail. Although it does not use ionising radiation, it is a high cost technique. Static MRI relies on static sequences and high spatial resolution images, to delineate the passive and active elements of the pelvic organ support system. Most commonly, images are acquired in axial, sagittal and coronal planes.

MRI has been proposed to be a useful method for diagnosing and staging POP. Several lines and levels of reference have been described in the literature. The most commonly used ones are either a line drawn from the inferior margin of the pubis symphysis to the last coccygeal joint (pubococcygeal line—PCL) or a line extending caudally along the longitudinal axis of the symphysis pubis in the sagittal plane, noted as midpubic line (MPL)^{42,43} (Figures 22 and 23).

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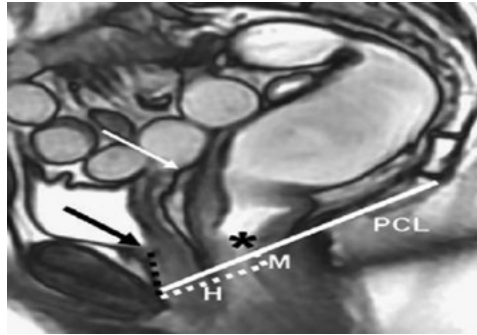


Figure 22. (above): Sagittal MRI image of the pelvic floor obtained at rest in a 50-year-old normal volunteer woman. The H line is drawn from the inferior border of the pubic symphysis to the posterior wall of the rectum at the level of the anorectal junction.

The M line is drawn perpendicularly from the PCL to the most posterior aspect of the H line. (PCL: pubococcygeal line, black arrow: bladder base, white arrow: vaginal vault, *: anorectal junction, from Colaiacomo MC⁴² et al. 2009).

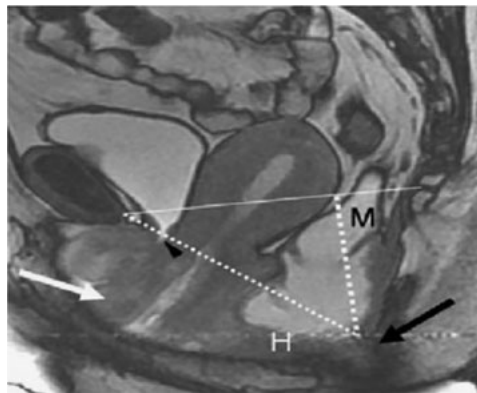


Figure 23. (above): Severe uterine prolapse in a 41-year-old woman. Sagittal function MRI image obtained during defaecation shows the uterus moving downward inside the vagina and the cervix exits the vaginal introitus (white arrow). H and M lines are abnormally elongated. Urethral funnelling without hypermobility (arrowhead) and severe posterior compartment descent (black arrow) are also noted (from Colaiacomo⁴² et al. 2009).

Other applications of MRI are the assessment of the LAM morphology (size, thickness volume) and detection of LAM injuries/defects/ (“avulsion”) (figure 24)⁴⁴⁻⁴⁶.

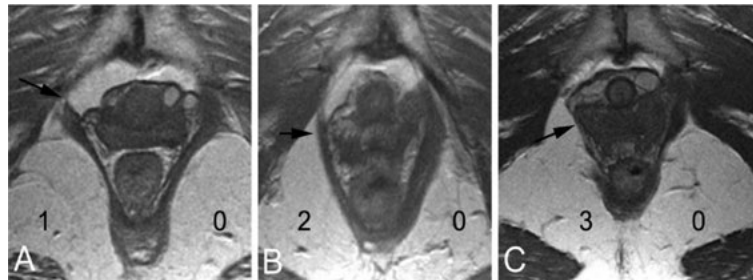


Figure 24. (above): Examples of grades of unilateral defects in the pubovisceral portion of the LAM in axial magnetic resonance images at the level of the mid-urethra. The score for each side is indicated on the figure, and the black arrows indicate the location of the missing muscle (A. grade 1 defect; B. grade 2 defect; and C. grade 3 defect, from DeLancey. *Levator Ani Impairment in Prolapse. Obstet Gynecol* 2007).

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The International Continence Society (ICS) report on the terminology for adult male lower urinary tract and pelvic floor symptoms and dysfunction

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Introduction: In the development of terminology of the lower urinary tract, due to its increasing complexity, the terminology for male lower urinary tract and pelvic floor symptoms and dysfunction needs to be updated using a male-specific approach and via a clinically-based consensus report.

Methods: This report combines the input of members of the Standardisation Committee of the International Continence Society (ICS) in a Working Group with recognized experts in the field, assisted by many external referees. Appropriate core clinical categories and a subclassification were developed to give a numeric coding to each definition. An extensive process of 22 rounds of internal and external review was developed to exhaustively examine each definition, with decision-making by collective opinion (consensus).

Results: A Terminology Report for male lower urinary tract and pelvic floor symptoms and dysfunction, encompassing around 390 separate definitions/descriptors, has been developed. It is clinically-based with the most common diagnoses defined. Clarity and user-friendliness have been key aims to make it interpretable by practitioners and trainees in all the different specialty groups involved in male lower urinary tract and pelvic floor dysfunction. Male-specific imaging (ultrasound, radiology, CT, and MRI) has been a major addition whilst appropriate figures have been included to supplement and help clarify the text.

Conclusions: A consensus-based Terminology Report for male lower urinary tract and pelvic floor symptoms and dysfunction has been produced aimed at being a significant aid to clinical practice and a stimulus for research.

Carlos D'Ancona (Content) and Bernard Haylen (Production) are equal first authors.

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KEYWORDS

lower urinary tract dysfunction, lower urinary tract symptoms, male, male urinary tract imaging, male urodynamics, terminology

INTRODUCTION

There is currently no single document addressing all elements required for diagnoses applicable to adult (fully grown and physically mature¹ – *new*) male lower urinary tract and pelvic floor dysfunction. Indeed, the diagnostic entities themselves may have not been all completely defined. The term “diagnosis” is defined as “the determination of the nature of a disease; **clinical**: made from a study of the symptoms and signs of a disease¹; **laboratory**:” investigative options to be mentioned. Such a specific report would require a full outline of the terminology for all symptoms, signs, urodynamic investigations for male lower urinary tract (LUT) and pelvic floor (PF) dysfunction, the imaging associated with those investigations and the most common diagnoses.

It may have been possible in the past to combine all terminology for lower urinary tract function for men, women and children into one Report. The International Continence Society (ICS) has provided leadership in terminology for lower urinary tract dysfunction over decades employing combined or generic reports. The 1988² and 2002³ Reports by the Committee on Standardization of Terminology are such examples. With the increasing specificity and complexity of the diagnoses in both sexes, combined reports, let alone attempting to cover “all patient groups from children to the elderly,”³ may now be an anachronism. With evidence that the absence of specific female diagnoses as well as other female specific terminology, may not have been advantaged by a combined approach,⁴ there occurred the development and 2010 publication of an International Urogynecological Association (IUGA)/ICS Joint Report on the Terminology for Female Pelvic Floor Dysfunction.⁵ The 2002 Report³ still provides the traditional core male terminology and some useful modifications, many of which are repeated in this document. The current report, with the large number of *new* and *changed* definitions, acknowledges that a male-specific update of terminology for LUT and PF symptoms and dysfunction is now timely.

It is hoped that some of the advantages noted in the female-specific document⁵ might be seen here in this male document: (i) more comprehensive coverage of male-specific terminology; (ii) greater coherency and user-friendliness; (iii) greater specificity of male diagnoses; and (iv) more accurate communication for clinical and research purposes. It is also an aim in this document, to develop a general male terminology,

forming a “backbone” or “core” terminology, to facilitate an update of the other subcategories of male-specific terminologies. There have been seven other (IUGA-ICS) female PF-related terminology documents,^{6–12} all published, following the production of the initial joint IUGA/ICS document on female pelvic floor dysfunction.⁵ The authors of that document⁵ have kindly permitted the template of that Report to be used as the basis for the current Report. Four other male terminology reports have been initiated: (i) male anorectal dysfunction; (ii) surgical management of male LUT dysfunction; (iii) sexual health in men with LUT/PF dysfunction and (iv) conservative management of male LUT/PF dysfunction, to follow the publication of this “core” report.

This Terminology Report is inherently and appropriately a definitional document, collating the definitions of those terms, that is, words used to express a defined concept in a particular branch of study,¹ here core male terminology. Emphasis has been on comprehensively including those terms in current use in the relevant peer-reviewed literature. The aim is to assist clinical practice and research. Explanatory notes on definitions have been referred, where possible, to the “Footnotes section.” Table 1 lists the number of definitions: (i) new; (ii) changed; (iii) total by section, compared with the previous male-inclusive Reports.^{2,3}

As with its female terminology equivalent, qualities for a male-specific terminology report should be:

- (1) User-friendly: It should be able to be understood by all clinical and research users.
- (2) Clinically-based: Symptoms, signs, validated investigations and imaging should be presented for use in forming diagnoses. Sections 1-4 will address symptoms, signs, urodynamic investigations and current associated imaging modalities routinely used in the office, urodynamic laboratory, or imaging department to make those diagnoses. Readership is not assumed to be limited to medical specialists, accounting for a more extended “basic” physical examination (Section 2). Related radiological investigations, computerized tomography (CT) and magnetic resonance imaging (MRI) as well as a description of electromyography (EMG) has been included. This report limits terminology for neurogenic lower urinary tract dysfunction (LUTD) as this is covered by a separate ICS Report.¹³

TABLE 1 Total, new and changed definitions (compared with previous male-inclusive Reports^{2,3})

Section	New definitions/descriptors	Changed definitions/descriptors	Total
Introduction & Symptoms	60	23	118
Signs	73	14	98
Investigations	23	25	106
Imaging	42	n/a	42
Diagnoses	14	9	26
Total	211 (54%)	71 (18%)	390

- (3) Section 5 will address the most common diagnoses of male lower urinary tract and pelvic floor dysfunction. The terms³ “urodynamic observation” and “condition” (non-medical) have not been used in this report. The scope of the report will exclude (i) diagnostic pathology (blood, urine, histology); (ii) more invasive investigations requiring an anesthetic; (ii) evidence-based treatments for each diagnosis.
- (4) Origin: Where a term's existing definition (from one of multiple sources used) is deemed appropriate, that definition will be included and duly referenced. Many terms in male lower urinary tract and pelvic floor function, because of their long-term use, have now become generic, as apparent by their listing in medical dictionaries.
- (5) Able to provide explanations: Where a specific explanation is deemed appropriate to explain a change from earlier definitions or to qualify the current definition, this will be included as an addendum to this paper (*Footnote [FN] 1,2,3 ...*). Wherever possible, evidence-based medical principles will be followed.

As in earlier ICS Reports,^{2,3,5} when a reference is made to the whole anatomical organ, the *vesica urinaria*, the correct term is the bladder. When the smooth muscle structure known as the *m. detrusor vesicae* is being discussed, then the correct term is detrusor.

It is suggested that acknowledgement of these standards in written publications related to male lower urinary tract and pelvic floor symptoms and dysfunction, be indicated by a footnote to the section “Methods and Materials” or its equivalent, to read as follows: “Methods, definitions and units conform to the standards recommended by the International Continence Society, except where specifically noted.”

SECTION 1: SYMPTOMS

Symptom: Any morbid phenomenon or departure from the normal in structure, function, or sensation, possibly indicative of a disease or health problem. Symptoms are either

volunteered by, or elicited from the individual, or may be described by the individual's partner or caregiver.^{2,3,5}

Complaint: The description of the symptom.¹ (*NEW*)

Main (Chief) Complaint: The symptom that a patient states as the main reason for seeking medical advice.¹ (*NEW*) The degree of “bother (worry, concern)” for other symptoms can be variable.¹⁴ (*NEW*)

Lower urinary tract symptom (LUTS): A symptom related to the lower urinary tract; it may originate from the bladder, prostate, urethra, and/or adjacent pelvic floor or pelvic organs, or at times be referred from similarly innervated anatomy, for example, lower ureter. (*NEW*)

STORAGE SYMPTOMS

1.1 Storage Symptoms: Lower urinary tract symptoms occurring during the bladder storage phase. (*NEW*)

General Storage symptoms

1.1.1 Increased urinary frequency: Complaint that voiding occurs more frequently than deemed normal by the individual (or caregivers).^{3,5} Time of day and number of voids are not specified. (*NEW*)

1.1.2 Increased daytime urinary frequency: Complaint that voiding occurs more frequently during waking hours than previously deemed normal by the individual (or caregivers).^{3,5} FN1.1 NB pollakiuria FN1.2 (*CHANGED*)

1.1.3 Nocturia: The number of times urine is passed during the main sleep period. Having woken to pass urine for the first time, each urination must be followed by sleep or the intention to sleep. This should be quantified using a bladder diary.¹⁸

1.1.4 Polyuria (global symptom): Complaint that the urine excretion volume over 24 h is noticeably larger than the previous experience.^{FN1.4} (*NEW*)

1.1.4.1 Diurnal polyuria: Complaint that daytime urine excretion volume is noticeably larger than the previous experience. (*NEW*)

1.1.4.1 Nocturnal polyuria (symptom)¹⁸: Complaint of passing large volumes of urine at night-time. (*NEW*)

Sensory symptoms

1.1.5 Bladder filling (sensory) symptoms: Abnormal sensations experienced during bladder filling.¹ *(NEW)*

1.1.5.1 Increased bladder filling sensation: Complaint that the sensation of bladder filling occurs earlier or is more intense or persistent to that previously experienced.^{3,5} *(CHANGED)* N.B. This differs from urgency by the fact that micturition can be postponed despite the desire to void.

1.1.5.2 Urgency: Complaint of a sudden, compelling desire to pass urine which is difficult to defer.^{3,5} FN1.5, FN1.6

1.1.5.3 Reduced bladder filling sensation: Complaint that the sensation of bladder filling is less intense or occurs later in filling than previously experienced. *(CHANGED)*

1.1.5.4 Absent bladder filling sensation: Complaint of both the absence of the sensation of bladder fullness and a definite desire to void³

1.1.5.5 Non-specific (atypical) bladder filling sensation (bladder dysesthesia): Complaint of abnormal bladder filling sensation such as the perception of vague abdominal bloating, vegetative symptoms (nausea, vomiting, faintness), or spasticity. *(CHANGED)* F1.7 It differs from normal bladder filling sensation or pain, pressure or discomfort of the bladder.

Incontinence symptoms

1.1.6 Urinary incontinence symptoms¹⁶: Involuntary loss of urine experienced during the bladder storage phase FN1.8, FN1.9 *(NEW)*

1.1.6.1 Urinary incontinence (symptom): Complaint of involuntary loss of urine.^{3,5} FN 1.9

1.1.6.2 Urgency urinary incontinence (UUI)^{3,5}: Complaint of involuntary loss of urine associated with urgency.

1.1.6.3 Stress urinary incontinence (SUI): Complaint of involuntary loss of urine on effort or physical exertion including sporting activities, or on sneezing or coughing.^{3,5} N.B. “*activity (effort)-related incontinence*” might be preferred in some languages to avoid confusion with psychological stress. FN1.10

1.1.6.4 Mixed urinary incontinence (MUI): Complaints of both stress and urgency urinary incontinence, that is, involuntary

loss of urine associated with urgency as well as with effort or physical exertion including sporting activities or on sneezing or coughing (stress).^{3,5}

1.1.6.5 Enuresis: Complaint of intermittent (non-continuous) incontinence that occurs during periods of sleep.¹⁸ *(CHANGED)*

1.1.6.6 Continuous urinary incontinence: Complaint of continuous involuntary loss of urine.^{3,5} *(CHANGED)*

1.1.6.7 Insensible urinary incontinence: Complaint of urinary incontinence where the individual is aware of urine leakage but unaware of how or when it occurred.⁵ *(CHANGED)*

1.1.6.8 Postural urinary incontinence: Complaint of urinary incontinence during change of posture or position, for example, from supine or seated to standing.FN1.12 *(NEW)*

1.1.6.9 Disability associated incontinence: Complaint of urinary incontinence in the presence of a functional inability to reach a toilet/urinal in time because of a physical (eg, orthopedic, neurological) and/or mental impairment. *(NEW)*

1.1.6.10 Overflow incontinence: Complaint of urinary incontinence in the symptomatic presence of an excessively (over-) full bladder (no cause identified). *(NEW)*

1.1.6.11 Sexual arousal incontinence¹⁹: Complaint of involuntary loss of urine during sexual arousal, foreplay and/or masturbation. *(NEW)*

1.1.6.12 Climacturia¹⁹: Complaint of involuntary loss of urine at the time of orgasm. *(NEW)*

Storage symptom syndrome

1.1.7 Overactive bladder (OAB, urgency) syndrome: Urinary urgency, usually accompanied by increased daytime frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry), in the absence of urinary tract infection or other detectable disease.^{3,5} *(CHANGED)*

VOIDING SYMPTOMS

1.2 Voiding symptoms: Lower urinary tract symptoms during the voiding phase (experienced during micturition). *(NEW)*

1.2.1 Hesitancy: Complaint of a delay in initiating voiding (when the individual is ready to pass urine). *(CHANGED)*

- 1.2.2. Paruresis (“bashful” or “shy bladder”):** Complaint of the inability to initiate voiding in public (i.e. voiding in the presence of other persons) despite there being no difficulty in private.²⁰
FN1.13 (NEW)
- 1.2.3 Episodic inability to void:** Complaint of occasional inability to initiate voiding despite relaxation and/or an intensive effort (by abdominal straining, Valsalva maneuver or suprapubic pressure). (NEW)
- 1.2.4 Straining to void:** Complaint of the need to make an intensive effort to either initiate, maintain or improve voiding or the urinary stream.^{3,5} (CHANGED)
- 1.2.5 Slow (urinary) stream:** Complaint of a urinary stream perceived as overall slower than previous performance or in comparison with others.^{3,5}
- 1.2.6 Intermittency:** Complaint of urine flow that stops and starts on one or more occasions during one voiding episode.^{3,5}
- 1.2.7 Terminal dribbling:** Complaint that during the final part of voiding there is noticeable slowing of the flow to drops or a trickling stream. (CHANGED)
- 1.2.8 Spraying (splitting) of urinary stream:** Complaint that the urine passage is a spray or split rather than a single directional stream.^{3,5} (CHANGED)
- 1.2.9 Position-dependent voiding:** Complaint of having to adopt specific positions to be able to void spontaneously or to improve bladder emptying, for example, needing to void in a seated position. (NEW)
- 1.2.10 Dysuria:** Complaint of pain, burning, other discomfort, or difficulty during voiding. Discomfort may be intrinsic to the lower urinary tract (eg, bladder or urethra), external, or referred from other adjacent similarly innervated structures, for example, lower ureter. FN1.14 (CHANGED)
- 1.2.11 Stranguria:** Complaint of voiding which is slow, difficult and spasmodic (at times “drop by drop”), usually associated with pain. (NEW)^{FN1.15}
- 1.2.12 Hematuria:** Complaint of passage of visible blood mixed with urine. This may be initial (at the beginning), terminal (at the end) or total (throughout bladder emptying). (NEW)
- 1.2.13 Pneumaturia¹:** Complaint of the passage of gas (or air) from the urethra during or after voiding. (NEW)
- 1.2.14 Fecaluria¹:** Complaint of passage of feces (per urethram) in the urine. (NEW)
- 1.2.15 Chyluria (albiduria)¹:** Complaint of passage of chyle (pale or white, milky cloudy) in the urine.¹ (NEW)

1.2.16 Urinary retention: Complaint of the inability to empty the bladder completely.¹ (NEW)

1.2.16.1 Acute urinary retention (AUR): Complaint of a rapid onset, usually painful suprapubic sensation (from a full bladder) due to inability to void (non-episodic), despite persistent intensive effort.^{FN1.16} (NEW)

1.2.16.2 Chronic urinary retention (CUR): Complaint of chronic or repeated inability to empty the bladder, despite the ability to pass some urine. This may result in the frequent passage of small amounts of urine or urinary incontinence and a distended bladder FN1.17 (NEW)

POST-VOIDING SYMPTOMS

1.3 Postvoiding Symptom: Lower urinary tract symptom experienced after voiding has ceased. (NEW)

1.3.1 Feeling of incomplete (bladder) emptying: Complaint that the bladder does not feel empty after voiding has ceased.^{3,5} (CHANGED)

1.3.2 Need to immediately re-void (“Encore” or “Double” voiding): Complaint that further voiding is necessary soon after passing urine (cessation of flow).^{3,5} (CHANGED)

1.3.3 Post-voiding incontinence: Complaint of a further involuntary passage (incontinence) of urine or dribbling following the completion of voiding^{3,5} FN1.18. (NEW)

1.3.4 Post-micturition urgency: Complaint of persistent urgency post-voiding. (NEW)

Voiding symptom syndrome (proposal for further research) – Underactive bladder syndrome: FN1.19

1.4 Lower Urinary Tract Pain and/or Other Pelvic Pain

1.4.1 Pain: A variably unpleasant sensation.¹ It may be described as pressure or discomfort by the patient. Pain should be characterized by site, type, frequency, duration, precipitating, and relieving factors.^{FN1.20; FN 1.21} (CHANGED)

1.4.2 Bladder pain: Complaint of suprapubic or retropubic pain, pressure or discomfort related to the bladder, and usually associated with bladder filling. It may persist or be relieved after voiding.^{3,5} (CHANGED)

1.4.3 Urethral pain: Complaint of pain, pressure or discomfort felt in the urethra^{3,5} before, during and/or after voiding and the man indicates the urethra as the site. (CHANGED)

- 1.4.4 Scrotal pain:** Complaint of pain, pressure or discomfort felt in and around the scrotum.³ It may be localized to the testis, epididymis, cord structures, or scrotal skin.
- 1.4.5 Perineal pain:** Complaint of pain, pressure, or discomfort felt on the surface or in the depth of the tissue between the scrotum and the anus.³
- 1.4.6 Pelvic pain:** Complaint of pain, pressure, or discomfort related to the pelvis but not clearly related to the bladder, urethra, scrotum, or perineum.³
- 1.4.7 Ejaculatory pain:** Complaint of pain, pressure, or discomfort felt in the perineum, suprapubic region and/or penis during ejaculation, but may continue for a time afterwards. *(NEW)*_{FN 1.22}
- 1.4.8 Anorectal pain symptoms:** Complaint of pain, pressure or discomfort particularly during defecation or straining to defecate but can occur at any time. *(NEW)*
- 1.4.8.1 Pain during straining /defecation:** Pain during defecation or straining to defecate.
- 1.4.8.2 Inflammatory anorectal pain:** Pain characterized by burning or stinging (inflammation, radiation, sepsis). *(NEW)*
- 1.4.8.3 Non-inflammatory anorectal pain:** Blunted anorectal pain (proctalgia fugax, Levator ani syndrome, pudendal neuralgia). *(NEW)*
- 1.4.9 Coccygeal pain (coccydynia):** Complaint of pain, pressure, or discomfort in the coccygeal region. *(NEW)*
- 1.4.10 Pudendal pain (neuralgia):** Complaint of pain, pressure, or discomfort in one or more of the areas innervated by the pudendal nerve (may be caused by inflammation or entrapment of the pudendal nerve and involving its dermatome). *(CHANGED)*
- 1.4.11 Chronic pelvic pain syndromes:** See ICS standard for terminology in chronic pelvic pain syndromes.²³ _{FN1.21}
- 1.5 Urinary tract infection (UTI)**
- 1.5.1 Symptoms of acute urinary tract infection:** Symptoms such as increased bladder sensation, urgency, frequency, dysuria/stranguria, pain in the lower urinary tract with or without urgency urinary incontinence might suggest lower urinary tract infection. Confirmation of a UTI requires evidence of significant microorganisms and pyuria. _(FN1.23, FN 1.24) *(CHANGED)*
- 1.5.2 Recurrent urinary tract infections (UTIs):** A history of at least two symptomatic and medically diagnosed UTI in the previous 12 months._{FN1.25} The previous UTI(s) should have resolved prior to a further UTI being diagnosed. *(CHANGED)*.
- 1.5.3 Urethral discharge:** Of mucus, pus, or blood, from the urethral meatus. *(NEW)*
- 1.6 Symptoms of sexual dysfunction:** Abnormal sensation and/or function experienced by a man during sexual activity. *(NEW)*
- 1.6.1 Altered Libido:** Change in interest in sexual activity. *(NEW)*
- 1.6.1.1 Decreased libido:** Complaint of decreased interest in sexual activity in comparison to previous experience. *(NEW)*
- 1.6.1.2 Increased libido:** Complaint of increased interest in sexual activity in comparison to previous experience. *(NEW)*
- 1.6.2 Erectile dysfunction²⁵:** Complaint of inability to achieve and sustain an erection firm enough for satisfactory sexual performance. *(NEW)*
- 1.6.3 Ejaculatory dysfunction:** Complaint of alteration of the emission of seminal fluids during ejaculation. *(NEW)*
- 1.6.3.1 Anejaculation:** Complaint of absence of seminal fluid emission. May be associated with the absence of the sensation of orgasm or anorgasmia. *(NEW)*
- 1.6.3.2 Delayed ejaculation:** Complaint of an increase in the time taken for ejaculation to occur. *(NEW)*
- 1.6.3.3 Premature ejaculation:** Complaint of a persistent or recurrent pattern of too rapid achievement of ejaculation during partnered sexual activity,¹ that is, before the individual wishes it. _{FN 1.26} *(NEW)*
- 1.6.3.4 Decreased (low) semen volume^{**}:** Complaint of smaller amount of seminal fluid than normal or previously experienced _{FN1.27.} *(NEW)*
- 1.6.3.5 Increased (high) semen volume:** Complaint of higher amount of seminal fluid than normal or previously experienced. *(NEW)*_{FN1.27}
- 1.6.4 Hematospermia:** Complaint of the appearance of visible blood in the seminal fluid. Color of the seminal fluid may be red or brown. *(NEW)*
- 1.6.5 Penile pain with intercourse (male dyspareunia):** Complaint of any penile discomfort occurring during intercourse. May be caused by penile disease, vaginal anatomy (eg, vaginal tightening, scarring, or exposed mesh) and/or may relate to various positions with intercourse. _{FN1.28} *(NEW)*

1.6.6 Obstructed intercourse: Complaint that vaginal intercourse is not possible due to perceived obstruction. Whilst this may be a partner issue, it can occur in cases of penile curvature (Peyronie's disease) or penile carcinoma. (*NEW*)

1.7 Symptoms of anorectal dysfunction^{5,10,27}; FN1.29

1.7.1 Anorectal incontinence (symptoms): Complaint of involuntary loss of flatus or feces.^{5,10} Can be further subdivided into:

1.7.1.1 Flatal incontinence: Complaint of involuntary loss of flatus (gas).^{5,10}

1.7.1.2 Fecal incontinence: Complaint of involuntary loss of feces.^{5,10}

- when feces is solid and/or
- when feces is liquid

1.7.1.3 Fecal (rectal) urgency: Complaint of a sudden, compelling desire to defecate that is difficult to defer.^{5,10}

1.7.1.4 Fecal (flatal) urgency incontinence: Complaint of involuntary loss of feces (flatus) associated with fecal urgency.^{5,10,27}

1.7.1.5 Passive (insensible) fecal incontinence: Complaint of involuntary soiling of liquid or solid stool without sensation or warning. (*NEW*)

1.7.1.6 Overflow fecal incontinence: Complaint of involuntary loss of stool due to an overfull rectum or fecal impaction. (*NEW*)

1.7.1.7 Coital fecal incontinence: Complaint of involuntary loss of stool occurring with intercourse.^{5,10}

1.7.1.8 Stress fecal incontinence (SUD): Complaint of involuntary loss of feces on effort or physical exertion including sporting activities, or on sneezing or coughing. (*NEW*)

1.7.2 Anorectal sensory symptoms

1.7.2.1 Diminished rectal sensation (rectal hyposensitivity): Complaint of diminished or absent sensation of filling in the rectum. (*CHANGED*)

1.7.2.2 Increased rectal sensation (rectal hypersensitivity): Complaint of a desire to defecate (during rectal filling) that occurs earlier or more persistent to that previously experienced. (*NEW*)

NB: for 1.7.2.1 and 1.7.2.2, can be to (i) first sensation; (ii) urge sensation; (iii) maximum tolerated volume.

1.7.2.3 Tenesmus: Complaint of an urgent desire to evacuate the bowel, accompanied by

involuntary straining and the passage of little fecal matter.¹

1.7.3 Defecatory or post-defecatory symptoms: Symptoms experienced during or following the act of defecation. (*NEW*)

1.7.3.1 Constipation: Complaint that bowel movements are infrequent and/or incomplete and/or there is a need for frequent straining or manual assistance to defecate. (Rome IV criteria²⁸) FN1.30.

1.7.3.1.1 Slow transit: infrequent bowel motions due to delay in transit of bowel contents to reach rectum.

1.7.3.1.2 Obstructed defecation: Complaint of difficulty in evacuation due to a mechanical obstruction.

1.7.3.2 Feeling of incomplete bowel evacuation: Complaint that the rectum does not feel empty after defecation. May be accompanied by a desire to defecate again.^{5,10}

1.7.3.3 Straining to defecate: Complaint of the need to make an intensive effort (by abdominal straining or Valsalva) or to use abdominal massage to either initiate, maintain, or improve defecation.^{5,10}

1.7.3.4 Manual defecatory assistance

1.7.3.4.1 Internal: Anorectal Digitation: Complaint of the need to use of fingers in the rectum to manually assist in evacuation of stool contents by scooping, stretching and/or stimulation.⁵ (*NEW*)

1.7.3.4.2 External: Perineal pressure or buttock separation: Complaint of the need to press on the perineum or separate the buttocks to assist defecation. (*NEW*)

1.7.3.5 Post defecatory soiling: Complaint of soiling occurring after defecation. (*NEW*)

1.7.3.6 Rectal bleeding/mucus: Complaint of the loss of blood or mucus per rectum.

1.7.4 Anorectal prolapse: Complaint of external protrusion (bulge) of the anus or rectum (differentiation on subsequent examination between rectal mucosal prolapse and full thickness rectal wall prolapse which includes muscle and serosal layers). (*CHANGED*)

1.8 Other Relevant History

Current medications, previous urological operations, radiotherapy, and catheterization should be noted.

Footnotes for Section 1

1.1: Milsom et al.¹⁵ first reported that frequency caused by an overactive bladder was arbitrarily defined as more than eight micturitions per 24 h, given that the normal voiding frequency in healthy individuals is typically under six micturitions per 24 h. It was higher than previously reported for healthy women using a frequency/volume chart (median 5.5 micturitions per 24 h).^{15–17}

1.2: Pollakiuria: Complaint of abnormally (extraordinary¹) frequent micturition (rarely used definition).

1.3: It is common to void during the night when sleep is disturbed for other reasons—eg, insomnia—this does not constitute nocturia.

1.4: Polyuria is more fully defined in the “Signs” section.

1.5: “Urgency” replaces “urge” as the “accepted” terminology for the abnormal rather than the normal phenomenon.

1.6: The use of the word “sudden,” defined as “without warning or abrupt,” used in earlier definitions^{2,3,5} has been subject to much debate. Its inclusion has been continued.

1.7: This symptom generally occurs where there is some form of neurological disease.

1.8: “Continence” is defined as absence of involuntary leakage of bowel and bladder contents (i.e. normal voluntary control of bowel and bladder function).

1.9: In each specific circumstance, urinary incontinence should be further described by specifying relevant factors such as type, severity, precipitating factors, social impact, effect on hygiene, and quality of life, the measures used to contain the leakage, and whether or not the individual seeks or desires help because of urinary incontinence.

1.10: This change is to accommodate for ambiguity in some languages between stress and anxiety. This symptom would most commonly occur in men who have undergone (radical) prostatectomy. Men who had radical prostatectomy may experience activity-related incontinence and/or during sex.¹⁹

1.11: Small amounts of urine may be leaked without warning.

1.12: Men with post-prostatectomy incontinence do report this. It also happens in men after artificial sphincter placement. When they get up, they leak. Can be due to stress and without urge or other associated symptoms in the standing or upright position.

1.13: The term “pareuresis” is not in common usage, although the symptom is well-recognised.²⁰ Pareuresis is defined as the fear of being able to urinate in situations where other persons are present. Diagnostic and statistical manual of mental disorders. Arlington, VA: American Psychiatric Association; 2013.

1.14: Dysuria is a type of urethral pain but could be urethral in origin or referred there from a pathological process in bladder, lower ureter or prostate.

1.15: The symptom of “stranguria” is poorly understood, overlapping at times with urethral pain, dysuria, and pelvic pain.

1.16: The bladder is distended, palpable, and possibly tender. A significantly increased residual is present.

1.17: Non-neurogenic chronic urinary retention (CUR) in men (AUA consensus²¹ supported by the current authors) can be defined as an elevated post-void residual of greater than 300 mL that has persisted for at least 6 months and is documented on two or more separate occasions. Evidence is not strong. CUR can be caused by different pathologies that create detrusor underactivity and/or result in chronic bladder outlet obstruction.²¹

1.18: May occur after clothing has been adjusted, due to some “pooling” of urine in the urethra if underwear, or clothing has caused some restriction during voiding or a urethral stricture or diverticulum.

1.19: Complaints of a slow urinary stream, hesitancy and straining to void, with or without sense of incomplete bladder emptying and dribbling, sometimes with storage symptoms: symptom grouping proposed to be suggestive of detrusor underactivity²² (DU). Diagnosis of actual detrusor underactivity depends on urodynamic findings as discussed in Section 5 on Diagnoses.

1.20: It is often difficult to localize pain precisely, so descriptions as to location of the pain may be imprecise. For example, the term “bladder pain” does not necessarily indicate that the bladder is the cause. Pain thought to be arising from the bladder, or felt in the urethra, scrotum or perineum might be referred from the lower ureter, or bladder base or other pelvic organs.

1.21: The definitions of pelvic pain and especially chronic pelvic pain had been debated in several societies with a view to simplification and restructuring of the classification. The ICS has now published a report from chronic pelvic pain syndromes.²³

1.22: Painful ejaculation (previously termed “odynorgasmia”), is a poorly characterized syndrome. It may be associated with urethritis, BPH, acute or chronic prostatitis, CPPS, seminal vesiculitis, seminal vesicular calculi or ejaculatory duct obstruction. Often, no obvious etiologic factor can be found.

1.23: Commonly suggested criteria for: (i) Bacteriuria are >100 000 CFU/mL on voided specimen or >1000 CFU/mL on catheterized specimen; (ii) Pyuria are >10 WBC/mm³ in uncentrifuged urine. The presence of nitrites in the urine is supportive of a UTI involving a common organism (*E. Coli*, *Klebsiella*).

1.24: Those symptomatic patients with fewer colony counts may still harbor organisms detectable by mRNA analyses not widely available at present.²⁴ Testing for urinary microbiome is being explored but it is not widely available.

1.25: Recurrent urinary tract infections (UTIs) has not been consistently defined. They are far less common in men

than women but perhaps more significant. There is the difficulty of balancing the practical clinical definition and the scientific one. Records of diagnostic tests are often inaccessible over the medium to longer term. With a bias towards the former category, a definition might be the presence at least two symptomatic and medically diagnosed UTIs in 12 months. "Recur" strictly means to "occur again" or "be repeated."

1.26: This symptom must have been present for at least 6 months and must be experienced on almost all or all (approximately 75-100%) occasions of sexual activity. It causes clinically significant distress in the individual. It has been called early ejaculation, rapid ejaculation, rapid climax or premature climax. There is no uniform cut-off defining "premature," but a consensus of experts at the International Society for Sexual Medicine endorsed a definition of around 1 min after penetration. The International Classification of Diseases (ICD-10) applies a cut-off of 15 s from the beginning of sexual intercourse.

1.27: Mean semen volume is 3.9 mL (5th centile 1.5 mL; 95th centile 6.8 mL). Low semen volume is under 1.5 mL; high semen volume is over 6.8 mL.^{25,26}

1.28: Dyspareunia ("hispareunia"), the symptom most applicable to male discomfort on sexual intercourse, will depend on many factors including a woman's introital relaxation and/or anatomical factors.

1.29. Symptoms of defecatory dysfunction are not uncommon in men, particularly those who have undergone anal sphincterotomies for fissure-in-ano.

1.30. Rome IV Criteria for 1.8.3.1 *Constipation*²⁸: Complaint that bowel movements are (i) infrequent (<3/wk); (ii) need to strain; (iii) lumpy or hard stool bloating; (iv) sensation of incomplete evacuation; (v) sensation of anorectal obstruction or blockage abdominal pain, (vi) need for manual assistance, in more than one quarter of all defecation.

SECTION 2: SIGNS

Sign: Any abnormality indicative of disease or a health problem, discoverable on examination of the patient; an objective indication of disease or a health problem.¹ (*CHANGED*)

General principles of examination for male with symptoms of LUT/PF dysfunction²⁹: A comprehensive physical examination is done to seek potential influences on symptoms.^{FN2.1} It should include abdominal examination, focussing on the suprapubic area to detect an enlarged bladder, or other abdominal mass, and digital examination of the rectum (prostate) as well as examination of the external genitalia, the perineum and lower limbs. The hernia orifices should also be evaluated. Penile lesions including meatal stenosis, phimosis, and penile cancer must be excluded.²⁹⁻³¹

If a neurological diagnosis is suspected, then a focused neurological examination with evaluation of perianal crude and pinprick sensations need to be tested. Also, the anal muscle tone can be assessed with finger in the rectum and asking the patient to squeeze. (*NEW*)

2.1 General (visual) observations

2.1.1 Mobility: generalized muscle strength and ability to ambulate independently or with assistance. (*NEW*)

2.1.2 Skin: jaundice or pallor or skin irritation due to urinary loss. (*NEW*)

2.1.3 Nutritional Status: cachexia (possible underlying malignancy); obesity (possible endocrine abnormality²⁹ including metabolic syndrome). (*NEW*)

2.1.4 Edema of genitalia and lower extremities: Possible cardiac decompensation, renal failure, nephrotic syndrome, or pelvic and/or retroperitoneal lymphatic obstruction.²⁹⁻³¹ (*NEW*)

2.2 Abdominal examination^{3,5}: Among numerous possible abdominal signs are:

2.2.1 Bladder fullness/retention: The bladder may be felt by abdominal palpation or detected by supra-pubic percussion. ^{FN2.2} (*CHANGED*)

2.2.2 Other abdominal masses: or distension (eg, ascites). (*NEW*)

2.2.3 Scars: Indicating previous relevant surgery, trauma, or evidence of previous radiotherapy. (*NEW*)

2.2.4 Renal Area: Examination for tenderness, masses. (*NEW*)

2.3 Lower Urinary Tract/Genital Examinations/Signs

2.3.1 Genital skin:

2.3.1.1 Excoriation, redness, irritation secondary to urinary incontinence and the effect of pads or diapers. (*NEW*)

2.3.1.2 Mycotic infections (balanoposthitis, intertrigo, or scrotal): Moist, red pruritic skin usually in men with urinary or fecal incontinence, immune suppression or poorly controlled diabetes mellitus.³² (*NEW*)

2.3.1.3 Skin pigmentation: balanitis xerotica obliterans (BXO – syn. *lichen sclerosus*) and vitiligo may cause depigmentation (penile skin, scrotum, glans). (*NEW*)

2.3.1.4 Cutaneous manifestations of sexually transmitted diseases: vesicles, ulcers. (*NEW*)

2.3.2 Penile examination:

- 2.3.2.1 Foreskin abnormalities:**
- 2.3.2.1.1 Tumor or infection** (balanoposthitis, ie, inflammation of the glans penis and overlying foreskin¹). (NEW)
- 2.3.2.1.2 Phimosi**³³: Partial or complete inability to retract the prepuce due to adhesion between the glans and the prepuce or a preputial ring. FN2.3 (NEW)
- 2.3.2.1.3 Paraphimosi**³³: Entrapment of the prepuce behind the glans. FN2.3 (NEW)
- 2.3.2.2 Position of the urethral meatus**³¹:
- 2.3.2.2.1 Hypospadias:** Refers to the urethral meatus sited on *ventral surface* of the penis, either congenital or acquired, proximal to its normal position on the tip of the glans. External urethral meatus may be on the glans penis (*glandular hypospadias*), sulcus (*coronal hypospadias*), shaft (*penile hypospadias*), scrotum (*scrotal hypospadias*), or perineum (*perineal hypospadias*). (NEW)
- 2.3.2.2.2 Epispadias:** Refers to the urethral meatus sited on *dorsal surface* of the penis, either congenital or acquired, proximal to its normal position on the tip of the glans. (NEW)
- 2.3.2.2.3 Neoplastic or inflammatory lesions** within the fossa navicularis.³⁴ (NEW)
- 2.3.2.2.4 Post-hypospadias/epispadias repair:** including post-urethroplasty urethral fibrosis: palpated near the meatus or in the penile shaft. (NEW)
- 2.3.2.2.5 Postoperative fistula:** Urine is visible at or near the incision lines. (NEW)
- 2.3.2.3 Urethral examination:**
- 2.3.2.3.1 Palpation:** along the ventral aspect of the penis and inferiorly into the perineum to detect fibrosis, lumps or tenderness along the shaft. (NEW)
- 2.3.2.3.2 Tenderness:** suggestive of urethral or periurethral inflammation, often secondary to a urethral stricture³⁴ or sexually transmitted disease. (NEW)
- 2.3.2.3.3 Meatal stenosis:** narrowing changes of the distal urethra; post-infection, post-surgery. (NEW)
- 2.3.2.4 Examination of the glans and shaft**
- 2.3.2.4.1 Penile plaque:** palpation of node or plaque in the tunica usually on the dorsal aspect (perhaps related to Peyronie's disease). (NEW)
- 2.3.2.4.2 Lichen sclerosus:** tight foreskin, cracking, and bleeding.
- 2.3.2.5 General examination:** redness, ulcers, warts, (NEW)
- 2.3.3 Scrotal examination:** (NEW)
- 2.3.3.1 Normal:** The scrotum is a loose sac containing the testes and spermatic cord structures. The epididymis is palpable applied to the posterior surface of the testis as a ridge although occasionally it is sited on the anterior surface. FN 2.4 (NEW)
- 2.3.3.2 Inflammation:** The epididymis may be swollen and tender, and if severe, the inflammatory process may involve the whole scrotal content (i.e. testis and epididymis [epididymo-orchitis]) and the scrotal skin as well. FN2.5 (NEW)
- 2.3.3.3 Cystic dilatations of the epididymis:** (epididymal cysts or spermatocele) and hydroceles (fluid collections between the visceral tunica albuginea and parietal layer of the testicular peritoneum)—usually benign. The examination of these structures would be generally non-tender and without pain (as opposed to 2.3.3.2). FN2.6 (NEW)
- 2.3.3.4 Inguinal bulge:** Examination and differentiation of hernia from hydrocele or cyst of spermatic cord or groin lymph nodes. (NEW) (use of transillumination may assist though ultrasound is generally diagnostic) FN2.7
- 2.3.4 Perineal examination:** this is generally performed with the patient in the lateral supine or in the lithotomy position. (NEW)
- 2.3.4.1 Perianal dermatitis:** Skin infection at the perineum around the anus, usually associated with fecal incontinence or diarrhoea. (NEW)
- 2.3.4.2 Fissures:** A break or tear in the skin of the perineum, anal sphincter or distal rectum usually associated with anal pain. (NEW)

- 2.3.5 Rectal and prostate examination:** Digital rectal examination (DRE) is recommended^{35–37} as part of the physical examination. Generally done with the patient standing and bent over the examining table, or with the patient in the left lateral knees bent position, or in the lithotomy position. DRE is usually pain-free. *(NEW)*
- 2.3.5.1 Anal examination:** This can detect the following findings in the anal sphincter or distal rectum: *(NEW)*
- 2.3.5.1.1 Benign diseases:** hemorrhoids, fissure, anal sphincter injury, levator discomfort, or pain. *(NEW)*
- 2.3.5.1.2 Possible malignant diseases:** anal, distal rectal, and prostate carcinoma. *(NEW)*
- 2.3.5.1.3 Anal tone:** increased or decreased anal sphincter tone might suggest similar changes in the urinary sphincter and may indicate neurologic disease. *(NEW)*
- 2.3.5.1.4 Anal stricture:** a circumscribed narrowing or stenosis of the anal canal. *(NEW)*
- 2.3.5.2 Prostate gland characteristics:** size, symmetry, firmness, nodules, and its relation to the pelvic sidewall and rectum can be assessed.^{35–37} The gland is about the size of a walnut and has a consistency similar to that of the contracted thenar eminence of the thumb _{FN2.8.} *(NEW)*
- 2.3.5.3 Nodularity and/or firmness** – May indicate possible abnormality requiring further investigation.³⁷ *(NEW)*
- 2.3.5.4 Prostate tenderness:** prostate palpation, as part of a DRE, is usually pain-free. Pain with prostatic palpation is variable though if present, it may be helpful in differentiating prostate/pelvic pain syndromes.³⁴ *(NEW)*
- 2.3.5.5 Rectal examination (circumferential):** this might lead to the detection of non-urological diseases such as rectal carcinoma, fistula and fecal impaction._{FN2.9} *(NEW)*
- 2.4 Focused neurological exam**^{3,5}
- 2.4.1 Overall neurological status:** abnormalities of speech, gait as well as upper and lower extremity dexterity should be noted as they may indicate a neurological cause for the urological symptoms. Neuropathy may impact also on management options.³⁸ _{FN2.10} *(CHANGED)*
- 2.4.2 Level of neurologic abnormality:** can occasionally be localized by the pattern of sensory or motor deficit noted during physical examination using a dermatome map.³⁰ *(NEW)*
- 2.4.3 Penile, scrotal, or perianal sensory deficits:** may indicate damage or injury to sacral roots or nerves. Reflex testing in the genital area may also be performed. The most important of these is the BSR.³⁹ *(NEW)*
- 2.4.4 Bulbospongiosus reflex (BSR)**³⁹ a reflex contraction of the striated muscle of the pelvic floor (anal sphincter) and the bulbo-spongiosus muscle that occurs in response to various stimuli in the perineum or genitalia. _{FN2.11} *(NEW)*
- 2.4.5. Cremasteric reflex:** contraction of the ipsilateral cremaster muscle, drawing the testis upwards, when the upper inner aspect of the thigh is stroked longitudinally. *(NEW)*
- 2.5 Urinary Incontinence Signs**^{3,5,40,41}: All examinations for the evaluation of urinary incontinence are best performed with the individual's bladder comfortably full.
- 2.5.1 Urinary incontinence**^{3,5}: observation of involuntary loss of urine on examination.
- 2.5.2 Stress urinary incontinence (clinical stress leakage)**^{3,5}: observation of involuntary leakage from the urethral orifice synchronous with effort or physical exertion, or on sneezing or coughing.
- 2.5.3 Urgency urinary incontinence**^{3,5}: observation of involuntary leakage from the urethral orifice associated with the individual reporting a sudden, compelling desire to void. *(CHANGED)*
- 2.5.4 Extra-urethral incontinence**^{3,5}: observation of urine leakage through channels other than the urethral meatus, for example, fistula. _{FN2.12}
- 2.6 Pelvic floor muscle (PFM) function.**^{3,5,42,43} The following signs of PFM function may be assessed via the perineum (visual or tactile examination) or per rectum (digital palpation) examination. Digital rectal examination (DRE) may be less useful in male urinary dysfunctions where the urethral sphincter, inaccessible to DRE, has a more important role.⁴⁴ *(NEW)*
- 2.6.1 Perineal examination**^{3,5,42,43}—when the patient is asked to cough or bear down, the perineum should only show limited downward movement; ventral movement may occur because of the guarding actions of the pelvic floor muscles. *(CHANGED)*

2.6.1.1 Perineal elevation^{43,44}: This is the inward (ventro-cephalad) movement of the perineum and anus. FN2.13 Look for testicular lift and penile retraction. These need to be checked against movement of the scrotum and the whole penis. Correct movement occurs with the PFM only: the shaft of the penis draws in and the testes lift in a cephalad direction. These movements may be better visualized in standing than supine position.⁴⁵⁻⁴⁷ (NEW)

2.6.1.2 Perineal descent⁴³: This is the outward (dorso-caudal) movement of the perineum and anus.

2.6.2 Examinations⁴³

2.6.2.1 PFM state at rest; aspects to assess.

FN2.13

2.6.2.1.1 Myalgia: provoked by palpation. Levator muscle pain/tenderness may be elicited by palpation of these muscles via rectal examination.⁴³ FN 2.14 (NEW)

- **Tender point**: Tenderness to palpation at a specific soft tissue body site. (NEW)

2.6.2.1.2 Tone: state of the muscle, usually defined by its resting tension, clinically determined by resistance to passive movement. Muscle tone has two components, the contractile component and the viscoelastic component. Muscle tone may be altered in the presence or absence of pain. (CHANGED)

2.6.2.1.3 Increased PFM tone (non-neurogenic hypertonicity): increased tone in a patient without an intercurrent neurological diagnosis. (CHANGED)

2.6.2.1.4 Decreased PFM tone (non-neurogenic hypotonicity): decreased tone in a patient without an intercurrent neurological diagnosis. (CHANGED)

2.6.2.1.5 Symmetry: if examining in the left lateral, there will be a gravity effect and the dependent side will have a different feel to

the upper side and appear as asymmetrical. This may affect PFM tone. Not so common in men. (NEW)

2.6.2.1.6 PFM injury: for example, palpable anal sphincter gap though overall not common unlike women. (NEW)

2.6.2.2 PFM contractile function: Aspects to assess

2.6.2.2.1 Voluntary contractility⁴³: the individual is able to contract the PFM on demand. A contraction is felt as a tightening, lifting, and squeezing action under/around the finger. (NEW)

2.6.2.2.2 Strength⁴³: Force-generating capacity of a muscle. It is generally expressed as maximum voluntary contraction. (NEW)

2.6.2.2.3 Endurance⁴³: the ability to sustain near maximal or maximal force, assessed by the time a patient is able to sustain a maximal static or isometric contraction. (NEW)

2.6.2.2.4 Repeatability⁴³: the ability to repeatedly develop near maximal or maximal force, determined by assessing the maximum number of repetitions the patient can perform before detectable decline in force. Record number of contractions in a row. (NEW)

2.6.2.2.5 Co-contraction: contraction or activation of two or more muscles at the same time. Identify which muscles are co-contracting and whether the co-contraction is synergistic. (NEW)

2.6.2.2.6 Relaxation ability: return of the PFM to its original resting tone following the voluntary contraction. Also includes the ability to maintain PFM relaxation in anticipation of or during any type of touch. (NEW)

2.6.2.3 PFM response to increased intra-abdominal pressure: for example, strain/Valsalva/cough aspects to assess

2.6.2.3.1 Direction of contraction (elevation, descent)

2.6.3 Diagnoses related to PFM examinations

2.6.3.1 Overactive pelvic floor muscles: Pelvic floor muscles which do not relax, or may even contract when relaxation is functionally needed, for example, during voiding or defecation. (*CHANGED*)

2.6.3.2 Underactive pelvic floor muscles: Pelvic floor muscles which cannot voluntarily contract when instructed to do so or when required. (*CHANGED*)

2.7 Frequency-Volume Chart/Bladder Diary

2.7.1 Frequency-volume chart (FVC).^{3,5,18,48}

The recording of the time of each micturition together with the volume voided for at least 24 h. Ideally a minimum of three days of recording (not necessarily consecutive) will generally provide more useful clinical data. It is relevant to discriminate daytime and nighttime micturition.

2.7.2 Bladder diary: Adds to the FVC above, the fluid intake, pad usage, incontinence episodes, the degree of incontinence and the circumstances at the time of the leakage. ** Signs where FVC or Bladder diary are important. Episodes of urgency and sensation might also be recorded, as might be the activities performed during or immediately preceding the involuntary loss of urine. Additional information obtained from the bladder diary involves: Severity of incontinence in terms of leakage episodes and pad usage.

2.7.2.1 Daytime:¹⁸ the period between waking up with the intention of arising until going to bed with the intention of sleeping (awake hours). (*NEW*)

2.7.2.2 Night-time:¹⁸ The individual's main daily period of sleep. It commences at the time of going to bed with the intention of sleeping and concludes when the individual decides to no longer attempt to sleep and rise for the next day. (*CHANGED*)^{FN2.15, FN2.16}

2.7.2.3 Main sleep period:¹⁸ The period from the time of falling asleep to the time of rising for the next day.

2.7.2.4 Nocturnal: Occurring or active at night.¹ For example, symptoms

and signs that occur at night.¹⁸ (*CHANGED*)

2.7.2.5 Daytime (urinary) frequency.^{3,5}

Number of voids during daytime (awake hours including first void after waking up from sleep and last void before sleep)**.

2.7.2.6 Night-time (urinary) frequency:¹⁸ Total number of night-time voids irrespective of sleep.**

2.7.2.7 Nocturia: The number of times an individual passes urine during their main sleep period, from the time they have fallen asleep up to the intention to rise from that period. This is derived from the bladder diary.¹⁸

2.7.2.8 24-hour (urinary) frequency:^{3,5,18,48} Total number of daytime and night-time voids during a specified 24-hour period.** (*CHANGED*)

2.7.2.9 24-hour urine volume:¹⁸ Summation of all urine volumes during a specified 24 h period. The first void after rising is discarded and the 24-hour period begins at the time of the next void and is completed by including the first void, after rising, the following day.** (*CHANGED*)

2.7.2.10 Maximum voided volume: Highest voided volume recorded during the assessment period. (*CHANGED*) This usually equals bladder capacity.**

2.7.2.11 Average voided volume: Summation of volumes voided divided by the number of voids during the assessment period.** (*CHANGED*)

2.7.2.12 Mean maximum voided volume (functional capacity): Mean maximum voided volume in everyday activities.**

2.7.2.13 Polyuria: Excessive production of urine.^{1,3,5} It has been defined as more than 40 mL urine/kg body weight during 24 h or 2.8 L urine for a man weighing 70 kg.⁴⁸

2.7.2.14 Nocturnal urine volume:¹⁸ Total volume of urine produced during the night. Volume measurement

begins after last void preceding sleep and concludes after the first day-time void (when the individual decides to no longer attempt to sleep).^{FN2.16} **

2.7.2.15 Nocturnal (night-time) polyuria:^{18,48} ** Increased proportional production of urine during the night-time compared with the 24 h urine volume. ^{FN2.17} (**CHANGED**). Nocturnal polyuria index (NPI) is most commonly used definition (Night-time urine volume/24 h urine volume) × 100%.
- 33% in elderly, eg. >65 years;

- >20% in younger individuals
- 20-33% in “middle age”

Figure 1 (below): provides an example of a bladder diary.

2.7.2.16 Pad Testing: For individuals with urinary (fecal) incontinence symptoms, the quantification of the amount of urine (feces) lost over the duration of testing, by measuring the increase in the weight of the pads (weighed pre- and post-testing) used. This may give a guide to the severity of incontinence. Different durations from a short (1 h) test to a 24 and 48-hour tests have been used with provocation varying from normal everyday activities to defined regimens. ^{FN2.18}

DATE/TIME DD.MM.YY	LIQUID INTAKE (mL)	VOLUME OF URINE (mL)	LEAKS	PAD CHANGE
21.02.18			☆	
02:15		150		
07:15		250		
08:00	Mug 250 mL			
08:20		60	☆	PC
09:30	Cup 200mL*		☆	
10:00		100		
12:00	2 mugs 500mL*			
14:00		300		
14:30		20		
15:30	Cup 200 mL		☆	PC
16:00		100	☆	
18:00	Cup 200 mL			
19:00		100		
20:00	Glasss 200 mL	20		
20:30	Glass (wine) 50 mL		☆	
22:00				PC
23:00		150		

FIGURE 1 Bladder diary: This simple chart allows you to record the fluid you drink and the urine you pass over 3 days (not necessarily consecutive) in the week prior to your clinic appointment. This can provide valuable information. (i) Please fill in approximately when and how much fluid you drink, and the type of liquid. (ii) Please fill in the time and the amount (in mLs) of urine passed, and mark with a star if you have leaked or mark with a “PC” if you have needed to change your pad (Please find below an example of how to complete this form).
Frequency = 9; Nocturia = 1; Urine production/24hr = 1250 mL; maximum voided volume = 300 mL; average voided volume = 125 mL

Footnotes for Section 2

2.1: There is little evidence from clinical trials that carrying out a clinical examination improves care, but general consensus suggests that it remains an essential part of assessment of men with urinary incontinence² or other LUTS.

2.2: A normal bladder in the adult cannot be palpated or percussed until there is at least a volume of 150 mL of urine. At larger volumes of about ≥ 500 mL, a distended bladder may be visible in thin patients as a lower midline abdominal mass. Percussion is better than palpation for diagnosing a distended bladder. The examiner begins by percussing just above the symphysis pubis and continues cephalad until there is a change in tone from dull to resonant.³⁰

2.3: If phimosis is severe, this can cause voiding symptoms. Most penile cancers occur in uncircumcised men and arise on the prepuce or glans and may be associated with voiding symptoms.³³

2.4: Scrotal abnormalities can help in elucidating lower urinary tract symptoms in men. For example, men with epididymitis may have associated urinary infection symptoms secondary to coliform bacteriuria.³⁴

2.5: Isolated orchitis secondary to UTI is rare, however, mycobacterial infection, mumps, and BCG treatment may cause orchitis.³⁴

2.6: If very large they may distort the scrotum and urethra and interfere with normal voiding. A hydrocele is sometimes secondary to testis tumor or inflammatory processes in the epididymis or orchitis.

2.7: The presence of hernias, cystic swellings in the scrotum, and testicular tumors should be excluded by careful clinical examination.

2.8: During the DRE, prostate size and consistency can be estimated, although DRE tends to underestimate true prostate size.^{35,36}

2.9: In patients with recto-urethral fistulas, the fistula can occasionally be palpated in the anterior rectal wall. The site of the fistula at or above the anal sphincter can occasionally be noted along with the degree of induration of the anterior rectal wall. With large fistulas the urethra can be palpated, especially if there is a Foley catheter in place.

2.10: For example, a person with Parkinson's may be unable to perform intermittent catheterization because of tremor. A focused neurological exam is also recommended, especially in patients suspected of having neurogenic bladder dysfunction.³⁸ Decreased perineal sensation and anal sphincter tone may be signs of neuropathy.⁴¹

2.11: This reflex is most commonly tested by placing a finger in the rectum and then squeezing the glans penis. If a Foley catheter is in place, the BSR can also be elicited by gently pulling on the catheter. If the BSR is intact, tightening

of the anal sphincter should be felt and/or observed.³⁹ The BSR tests the integrity of the spinal cord-mediated reflex arc involving S2-S4 and may be absent in the presence of sacral cord or peripheral nerve abnormalities.³⁹

2.12: If the patient has had previous urethral or bladder surgery or trauma, the examiner should ascertain whether urinary leakage occurs through a fistula in a scar, or at any other site in the penis, perineum, groins, or lower abdomen.

2.13: Normally there is inward (cephalad) movement of the perineum and anus.

2.14: This is all part of doing a DRE, assessing anal sphincters and puborectalis.

2.15: For the purposes of the nocturia terminology, night-time is therefore defined by the individual's sleep cycle, rather than the solar cycle (from sunset to sunrise). Thus, some shift workers may have their "night" period during the daylight hours, as it is the time of their main sleep period.¹⁸

2.16: Volume measurement begins after the last void preceding sleep and concludes after the first daytime void. The first daytime void follows the individual's decision they will no longer attempt to sleep.¹⁸

2.17: There are several definitions in the literature that could be used to indicate nocturnal polyuria including:¹⁸

Nocturnal urine production based on body weight of greater than 10 mL/kg.⁴⁹

1. Rate of nocturnal urine production >90 mL/hr.⁵⁰ This is suggestive of nocturnal polyuria in men (about 450 mL per 8 h' sleep).⁵¹ There are no studies looking at the rate of nocturnal urine production in women and this may well be different from that in men.
2. Nocturnal polyuria index is the most commonly used definition for nocturnal polyuria⁵² (nocturnal urine volume/24-hour voided volume) based on nocturnal urine volume as part of total 24-hour urine volume (age dependent).
3. Nocturia index (nocturnal urine volume/maximum voided volume)⁵³ >1 : nocturia occurs because maximum voided volume is smaller than nocturnal urine volume. >1.5 : nocturia secondary to nocturnal urine over-production in excess of maximum bladder capacity, that is, nocturnal polyuria.

2.18: A pad test quantifies the severity of incontinence and may be the most objective measure of the incontinence. Severity of incontinence (quantified by pad weight) affects surgery outcomes. The 24-hour pad test and micturition diary are reliable instruments for assessing the degree of urinary loss and number of incontinent episodes, respectively. Increasing test duration to 48 and 72 h

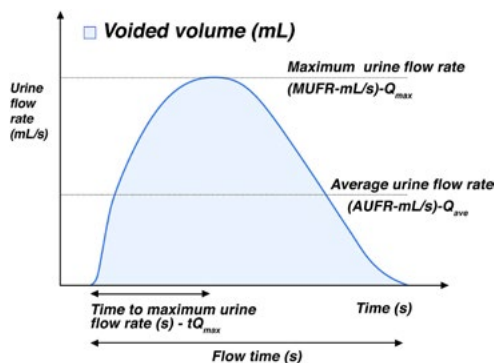


FIGURE 2 A schematic representation of urine flow over time and parameters of uroflowmetry

increases reliability but is associated with decreased patient compliance.⁵⁴ Overall, the 24-hour home test is the most accurate pad test for quantification and diagnosis of urinary incontinence because it is the most reproducible.⁵⁵ The 1-hour pad test may be used because it is easily done and standardized, however, there is no strict parallel with the 24-hour pad test and it may underestimate the weakness of the sphincter in the later part of the day.

SECTION 3: URODYNAMIC INVESTIGATIONS

Urodynamics: Measurement of all the physiological parameters relevant to the function and any dysfunction of the lower urinary tract.^{56,57} FN3.1, FN3.2. (NEW)

Clinical sequence of testing:^{3,5} Urodynamic investigations generally involve an individual attending with a comfortably full bladder for free (no catheter) uroflowmetry and post-void residual (PVR) measurement prior to filling cystometry and pressure-flow study. (NEW)

3.1 Uroflowmetry

3.1.1 Ideal conditions for free (no catheter) uroflowmetry: All free uroflowmetry studies should be performed in a completely private uroflowmetry room. Most modern uroflowmeters have a high degree of accuracy ($\pm 5\%$) though regular calibration is important (Figure 2).⁵⁸

3.1.2 Urine flow: Urethral passage of urine where the pattern of urine flow may be:^{2,3,5}

3.1.2.1 Continuous: no interruption to urine flow.

3.1.2.2 Intermittent: urine flow is interrupted.

3.1.3 Urine flow rate (UFR – unit: mL/s): Volume of urine expelled via the urethra per unit time.^{2,3,5}

3.1.4 Voided volume (VV – unit: mL): Total volume of urine expelled via the urethra during a single void.^{2,3,5} (CHANGED)

3.1.5 Maximum (urine) flow rate (MUFR – unit: mL/s) – Q_{max} : Maximum measured value of the urine flow rate^{2,3,5} corrected for artefacts.^{3,5}

3.1.6 Flow time (FT – unit: s): Time over which measurable flow actually occurs.^{2,3,5}

3.1.7 Average (urine) flow rate (AUFR – unit: mL/s) – Q_{ave} : Voided volume divided by the flow time.^{2,3,5}

3.1.8 Voiding time (VT – unit: s): Total duration of micturition, including interruptions. When voiding is completed without interruption, voiding time is equal to flow time.^{2,3,5}

3.1.9 Time to maximum urine flow rate (tQmax – unit: s): Elapsed time from the onset of urine flow to maximum urine flow.^{2,3,5}

3.1.10 Interpretation of the normality of free uroflowmetry: Because of the strong dependency of urine flow rates in men on voided volume^{59,60} and age,⁶⁰ they are best referenced to nomograms^{60–63} where the cutoff for normality has been determined and validated. The individual should comment whether voiding was representative of his usual urine flow and whether he has diurnal variation in urine flow (Figure 3A, B). (NEW)

Figure 3A: the Liverpool nomograms⁶⁰ for the maximum urine flow (Q_{max}) in men aged up to 50 years (mean 35 years). (NEW)

Figure 3B: the Liverpool nomograms⁶⁰ for the maximum urine flow rate (Q_{max}) in men aged over 50 years (mean 60 years). (NEW)

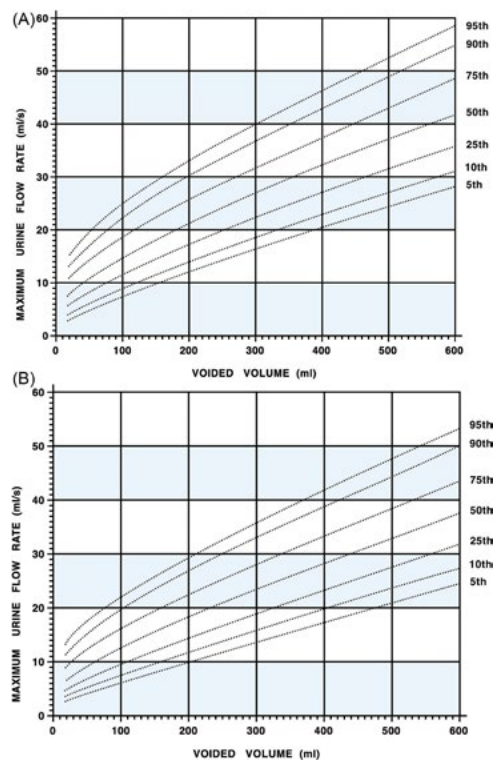


FIGURE 3 A and B, show the Liverpool nomograms⁶⁰ for the maximum urine flow rate in men (i) up to 50 years (mean 35 years) and (ii) over 50 years (mean 60 years). Equation for the maximum urine flow rate nomogram (divided by age as above) is: $\text{Sq Root (MUFRR)} = 2.37 + 0.18 \times \text{Sq Root (Void volume)} - 0.014 \times \text{age}$. (Root mean square error: 0.727) (*NEW*). References to a specific urine flow rate as the lower limit of normal provided a specific volume has been voided require validation studies

The 25th percentile appeared to be most appropriate lower limits of normality for both urine flow rates to identify those men more likely to have voiding dysfunction (more commonly bladder outlet obstruction [BOO]).⁶⁴ Higher urine flow rate percentiles occurred in men with detrusor overactivity.⁶⁴ ^{FN3.3} Some racial differences in urine flow rates have been reported. ^{FN3.4} Ideally, abnormal uroflowmetry studies should be repeated. (*NEW*)

3.2 Post-void residual (urine volume, PVR – unit: mL): Volume of urine left in the bladder at the completion of voiding.^{2,3,5}

3.2.1 Conditions for PVR measurement: PVR reading is erroneously elevated by delayed measurement due to additional renal input (1–14 mL/min) into the bladder. ^{FN3.5} Ultrasonic techniques allow immediate (within 60 s of micturition) measurement to minimize the error. Immediate insertion of a transurethral

catheter for bladder drainage can still provide an effective and accurate PVR measurement. All urethral catheters, however, may not be of equal drainage efficacy ^{FN3.6}. Ultrasound PVR measurement should ideally be repeated at least once if PVR is present. (*NEW*) An overdistended rather than “comfortably full” bladder might lead to a falsely elevated initial PVR, assessed further by repeat voiding/repeat PVR.

3.2.2 Assessment of normality of PVR: Upper limits in normal community dwelling men without LUTS are age dependent with studies reporting a cut-off value of 10–30 mL^{67–70}. *There are no adequate currently available data from which to quote expected/typical ranges of PVR in men with symptoms of lower urinary tract dysfunction.* Such studies would need to reflect the accuracy of measurement, including whether the PVR measurement is “immediate”

(eg, by ultrasound) or by urethral catheterization (unless also “immediate”). In the absence of such studies, our consensus view is that a PVR (ultrasound) over 50 mL, following double voiding, might prompt the suspicion of voiding dysfunction. (*NEW*)

3.3 Cystometry – General^{2,3,5,56,57}

3.3.1 Urodynamic studies: These usually take place in a special clinical room (urodynamic laboratory) and involve (artificial) bladder filling with a specified liquid (ICS recommends physiological saline solution or X-ray contrast if video studies) at a specified rate^{2,3,56,57}. FN3.7

3.3.2 Cystometry: Measurement of the pressure-volume relationship of the bladder during filling.^{2,3,56,57} FN3.7

3.3.3 Cystometrogram (CMG): Graphical recording of the bladder pressure(s) and volume(s) over time.^{2,3,56,57}

3.3.4 Conditions for cystometry including

3.3.4.1 Pressures (zeroing);*

3.3.4.2 Pressure transducers;*

3.3.4.3 Catheter mounted transducers; *

3.3.4.4 Initial bladder volume;*

3.3.4.5 Fluid medium* FN3.7 * Covered in references^{56,57}

3.3.4.6 Temperature of fluid: Fluid at room temperature is mostly used. It can be warmed to body temperature but without evidence that this influences results.^{71,72} FN3.8 (*CHANGED*)

3.3.4.7 Position of patient: Sitting (standing) position is more provocative for abnormal detrusor activity (ie, overactivity) than the supine position. At some point in the test, filling might desirably take place with the patient standing (in those patients able to do so).^{71,73} FN3.9 (*CHANGED*) Many men will void standing.

3.3.4.8 Filling rate: The filling rate, including any changes during testing, should be noted on the urodynamic report^{3,56,57,71,73–76}. FN3.10. A medium fill rate (25-50 mL/min) should be applicable in most routine studies. Much slower filling rates (under 25 mL/min) are appropriate in men where there are concerns for poor compliance or with a bladder diary showing low bladder capacity or those

with neuropathic bladder. A higher filling rate is greater than 50 mL/min.

(*CHANGED*)

3.3.5 Intravesical pressure (P_{ves} - unit: cm H₂O):

The pressure within the bladder (as directly measured by the intravesical catheter).^{2,3,56,57}

3.3.6 Abdominal pressure (P_{abd} - unit: cm H₂O):

The pressure in the abdominal cavity surrounding the bladder. It is usually estimated from measuring the rectal pressure, though the pressure through a bowel stoma can be measured as an alternative. FN3.11 The simultaneous measurement of abdominal pressure is essential for interpretation of the intravesical pressure trace.^{2,3,5} Artifacts on the detrusor pressure trace may be produced by a rectal contraction.^{2,3,56,57} (*CHANGED*)

3.3.7 Detrusor pressure (P_{det} - unit: cm H₂O):

The component of intravesical pressure that is created by forces in the bladder wall (passive and active). It is calculated by subtracting abdominal pressure from intravesical pressure ($P_{det} = P_{ves} - P_{abd}$).^{2,3,56,57} FN3.12

3.4 Filling Cystometry^{2,3,56,57}

3.4.1 Filling cystometry: Pressure-volume relationship of the bladder during bladder filling. It begins with the commencement of filling and ends when a “permission to void” is given by the urodynamicist^{2,3,5,56,57} or with incontinence (involuntary loss) of the bladder content (Figure 4).⁷¹ (*CHANGED*)

3.4.2 Aims of filling cystometry: To assess bladder sensation, bladder capacity, detrusor activity and compliance as well as to document (the situation of and detrusor pressures during) urine leakage. (*CHANGED*)

3.4.3 Bladder sensation during filling cystometry: Usually assessed by questioning the individual in relation to the fullness of the bladder during cystometry.

3.4.3.1 First sensation of bladder filling: The feeling when the individual first feels bladder filling.^{3,5,71,75} FN3.13

3.4.3.2 First desire to void: The first feeling that the individual may wish to pass urine.^{3,5} FN3.13

3.4.3.3 Normal desire to void: The feeling that leads the individual to pass urine at the next convenient moment, but voiding can be delayed if necessary.^{3,5}

3.4.3.4 Strong desire to void: The persistent desire to pass urine without the fear of leakage.^{3,5,71} FN 3.13

3.4.3.5 Urgency: Sudden, compelling desire to void which is difficult to defer.^{3,5}

FN1.4, FN1.5

3.4.3.6 Bladder oversensitivity⁵—Increased bladder sensation during bladder filling with: (*NEW – male*)

- earlier first desire to void;
- earlier strong desire to void, which occurs at low bladder volume;
- lower maximum cystometric bladder capacity (**3.4.4.2**);
- no abnormal increases in detrusor pressure.

3.4.3.7 Reduced bladder sensation: Bladder sensation perceived to be diminished during filling cystometry.

3.4.3.8 Absent bladder sensation: No bladder sensation during filling cystometry, at least to expected capacity of 500 mL.

3.4.3.9 Pain: the complaint of pain during filling cystometry is abnormal. Its site, character and duration should be noted.

3.4.4 Bladder capacity during filling cystometry^{3,5,56,57}

3.4.4.1 Cystometric capacity (units: mL):

Bladder volume at the end of filling cystometry, when a “permission to void” is usually given by the urodynamicist. This endpoint and the level of the individual's bladder sensation at that time, for example, “normal desire to void,” should be noted. This endpoint might be higher than normal in men with reduced bladder sensation.

3.4.4.2 Maximum cystometric capacity (units: mL): In individuals with normal sensation, this is the volume when one can no longer delay micturition during filling cystometry. FN3.14,

FN3.15, FN3.16

3.4.5 Detrusor function during filling cystometry

3.4.5.1 Normal detrusor activity/function:^{3,5}

There is little or no change in pressure with filling. There are no detrusor contractions, spontaneous or provoked with activities such as postural changes, coughing or hearing the sound of running water. FN3.17 (*CHANGED*)

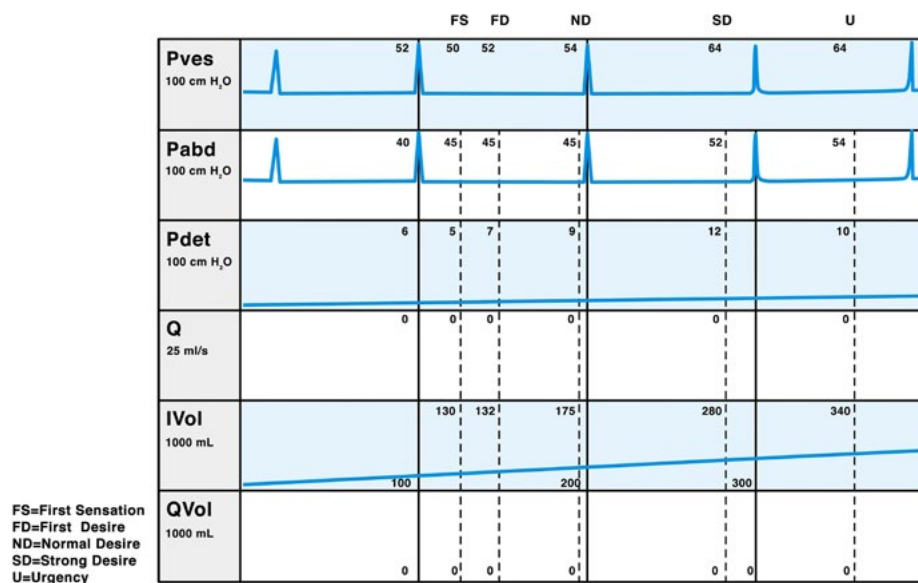


FIGURE 4 Normal filling cystometry on multichannel urodynamics. (first desire 132 mL, normal desire to void 175 mL, strong desire to void 280 mL, urgency 340 mL. Detrusor contraction is absent during filling cystometry). Cough artefacts and good subtraction of P_{abd} from P_{ves} to get P_{det} are demonstrated

3.4.5.2 Detrusor overactivity (DO):^{3,5} The occurrence of detrusor contraction(s) during filling cystometry. These contractions, which may be spontaneous or provoked, produce a wave form on the cystometrogram, of variable duration and amplitude. The contractions may be phasic or terminal. They may be suppressed by the patient or uncontrollable (**CHANGED**). Symptoms, for example, urgency and/or urgency incontinence or perception of the contraction may (note if present) or may not occur.

3.4.5.2.1 Idiopathic (primary) detrusor overactivity: No identifiable cause for involuntary detrusor contraction (s). (**CHANGED**) (Figure 5)

3.4.5.2.2 Neurogenic (secondary) detrusor overactivity:^{3,5,13,} Detrusor overactivity and evidence (history; visible or measurable deficit) of a relevant neurological disorder. (**CHANGED**)

3.4.5.2.3 Non-neurogenic (secondary) detrusor overactivity:

An identifiable possible non-neurological cause exists for involuntary detrusor contraction(s) during bladder filling. For example, functional (obstruction); stone, tumor (eg, carcinoma in situ), UTI.

FN3.18 (**CHANGED**)

3.4.6 Bladder (detrusor) compliance (unit: mL/cm H₂O)^{3,5,56,57,77-79}

3.4.6.1 Description: Relationship between the change in bladder volume and simultaneous change in detrusor pressure as a measure for the distensibility of the bladder.^{3,5}

3.4.6.2 Calculation: Divide the change of volume (ΔV) by the simultaneous change in detrusor pressure (ΔP_{det}) during filling cystometry – ($C = \Delta V / \Delta P_{det}$). The compliance reflects the amount of fluid in the bladder to increase bladder pressure by 1 cm H₂O and is expressed as mL per cm H₂O.

3.4.6.3. Factors affecting the measurement of bladder compliance:

3.4.6.3.1 Bladder filling speed: The bladder should be filled at up to 50 mL/min if there is no

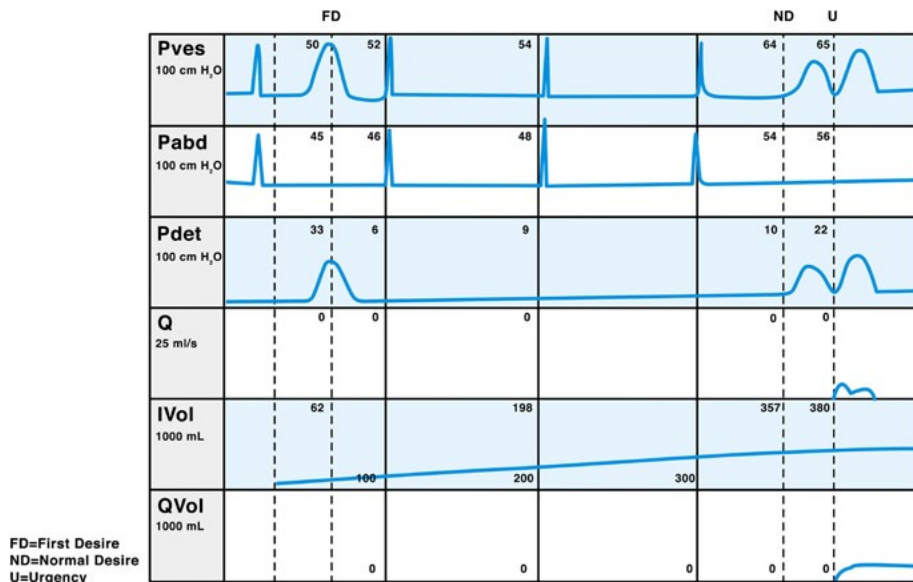


FIGURE 5 Filling cystometry demonstrating detrusor overactivity: First desire to void occurred at 62 mL together a contraction; normal desire to void at 357 mL; urgency at 380 mL followed by a detrusor contraction There is also high pressure – slow flow during voiding

reason to suspect poor bladder compliance. Faster filling is more provocative and may artificially reduce bladder compliance. This artifact may settle when filling is interrupted or repeated with slower speed. *(CHANGED)*

3.4.6.3.2 Contractile/relaxant properties of the detrusor (decreased compliance):

Properties of the bladder wall may reduce compliance, for example, pelvic radiation or chemotherapy or bladder overstretch. *(CHANGED)* Bladder outlet obstruction can result in detrusor muscle hypertrophy, intramural collagen and elastin deposition and contribute to reduced compliance. *(NEW)*

3.4.6.3.3 Other factors affecting bladder compliance⁷⁸ (increased compliance):

Bladder diverticula (also pseudodiverticula) and vesico-ureteric reflux (high grade). *(NEW)*

3.4.6.4 Starting point for compliance calculations: Usually the detrusor pressure at the start of bladder filling and the corresponding bladder volume (usually zero).³ Special attention should be made to ensure bladder is emptied at the commencement of measurement; incomplete emptying may artificially decrease bladder compliance. *(CHANGED)*

3.4.6.5 End point for compliance calculations: Detrusor pressure (and corresponding bladder volume) at cystometric capacity (allow time for pressure to settle after cessation of filling). Both points are measured excluding detrusor contraction. In the case of detrusor overactivity with leakage, both points should be measured or immediately before the start of any detrusor contraction (and therefore causes the bladder volume to decrease, affecting compliance calculations). Low compliance has been defined (in

women) as bladder compliance <10 mL/cm H₂O (neurogenic) or <30 mL/cm H₂O (non-neurogenic). Normal compliance is >30 mL/cm H₂O (neurogenic) and 40 mL/cm H₂O (non-neurogenic).⁷⁹ Recommended values in men have not been well-defined. FN3.19 *(CHANGED)*

3.4.7 Repeat Cystometry: FN3.20 The repetition of the urodynamic testing when abnormal bladder function, discrepancies between history and suspected urodynamic findings, technical errors and/or artifacts have been observed at immediate post-test analysis. *(CHANGED)*

3.4.8 ICS Standard Urodynamic Test:⁵⁷ Free uroflowmetry, postvoid residual, cystometry, and pressure-flow study are termed ICS standard urodynamic test (ICS-SUT).FN3.21 *(CHANGED)*

3.5 Urethral function during filling cystometry (filling urethro-cystometry): As filling urethro-cystometry is less well-explored in men than women, readers are referred to other reports for methodology.^{56,57,80}

3.6 Urethral closure mechanism

3.6.1 Normal urethral closure mechanism: A positive urethral closure pressure is maintained during bladder filling, even in the presence of increased abdominal pressure, although it may be overcome by detrusor overactivity.

3.6.2 Incompetent urethral closure mechanism: Leakage of urine occurs during activities which might raise intra-abdominal pressure in the absence of a detrusor contraction.

3.6.2.1 Urodynamic stress incontinence (USI): Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

3.6.2.2 Subtype: Intrinsic sphincter deficiency (ISD): Very weakened urethral closure mechanism.

3.6.3 Leak point pressures:^{2,3,5,80,81,82} There are two types of leak point pressure measurement. The pressure values at leakage should be measured at the moment of leakage.

3.6.3.1 Detrusor leak point pressure (DLPP – unit: cm H₂O): This is a static test. The pressure is the lowest value of the detrusor pressure at which leakage is

observed during cystometry in the absence of increased abdominal pressure. DLPP is a reflection of the resistance of the bladder outlet or urethral sphincter. High DLPP (eg, over 40 cm H₂O⁸⁰) may put patients at risk for upper urinary tract deterioration, or secondary damage to the bladder in the cases of known underlying neurological disorders such as spinal cord injury or MS.⁸¹ There are no data on any correlation between DLPP and upper tract damage in non-neurogenic patients. *(CHANGED)*

3.6.3.2 Abdominal leak point pressure (ALPP – unit: cm H₂O): This is a dynamic test. It is the intentionally increased abdominal pressure that provokes urinary leakage in the absence of a detrusor contraction.⁸² The patient can achieve this by coughing (CLPP) or straining (Valsalva Leak Point Pressure – VLPP). The VLPP allows measuring the lowest pressure (measured by the bladder or abdominal pressure) that causes urine leakage.

3.7 Pressure-Flow Studies^{2,3,5,56,57} FN3.24

3.7.1 Pressure-flow studies: Pressure-volume (urinary flow) relationship of the bladder during voiding.^{1–3,5,56,57} It begins when the “permission to void” is given by the urodynamicist and ends when the man considers his voiding has finished. Measurements to be recorded should be the intravesical (P_{ves}) and abdominal (P_{abd}) pressures and calculate the detrusor pressure (P_{det}) as well as the urine flow rate. FN3.22 *(CHANGED)*

3.7.2 Detrusor pressure and other measurements during pressure-flow studies (Figure 6)^{2,3,5,56,57}

3.7.2.1 Detrusor opening pressure (unit: cm H₂O): Detrusor pressure recorded immediately before the commencement of urine flow. *(CHANGED)*

3.7.2.2 Flow delay (unit: s): The time elapsed from initial rise in pressure to the onset of flow. This is the initial isovolumetric contraction period of micturition. It reflects the time necessary for the fluid to pass from the point of pressure

measurement to the uroflow transducer. FN3.23 *(CHANGED)*

3.7.2.3 Urethral opening pressure ($P_{det,uo}$ – unit: cm H₂O): Detrusor pressure recorded at the onset of measured flow (consider time delay – usually under 1 s).

3.7.2.4 Maximum detrusor pressure ($P_{det,max}$ – unit: cm H₂O): Maximum registered detrusor pressure during voiding.

3.7.2.5 Detrusor pressure at maximum flow ($P_{det,Qmax}$ – unit: cm H₂O): Detrusor pressure recorded at maximum urine flow rate.

3.7.2.6 Detrusor pressure at end of flow ($P_{det,ef}$ – unit: cm H₂O): Detrusor pressure recorded at the end of urine flow.

3.7.2.8 Postvoiding detrusor contraction: An increase in detrusor pressure (P_{det}) following the cessation of urinary flow *(NEW)*

3.7.3 Detrusor function during voiding^{2,3,5,56,57}

3.7.3.1 Normal detrusor contractile function: Normal voiding in men is achieved by an adequate continuous detrusor contraction that leads to complete bladder emptying within a normal time span. It depends on central initiation and stimulation of the reflexes involved. The amplitude of the detrusor contraction (detrusor contraction strength/power) tends to increase in response to any increased urethral resistance until the bladder is empty.⁸³ *(CHANGED)*

3.7.3.2 Detrusor underactivity (DU): Low detrusor pressure or short detrusor contraction time, usually in combination with a low urine flow rate resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span. (c.f. the term “hypocontractile detrusor” or detrusor hypocontractility describes a detrusor contraction of reduced strength). Detrusor underactivity can be of neurogenic^{13,84} or non-neurogenic origin. *(CHANGED)*

3.7.3.3 Acontractile detrusor: The detrusor cannot be observed to contract (ie, no increase in P_{det}) during urodynamic studies resulting in failure to void

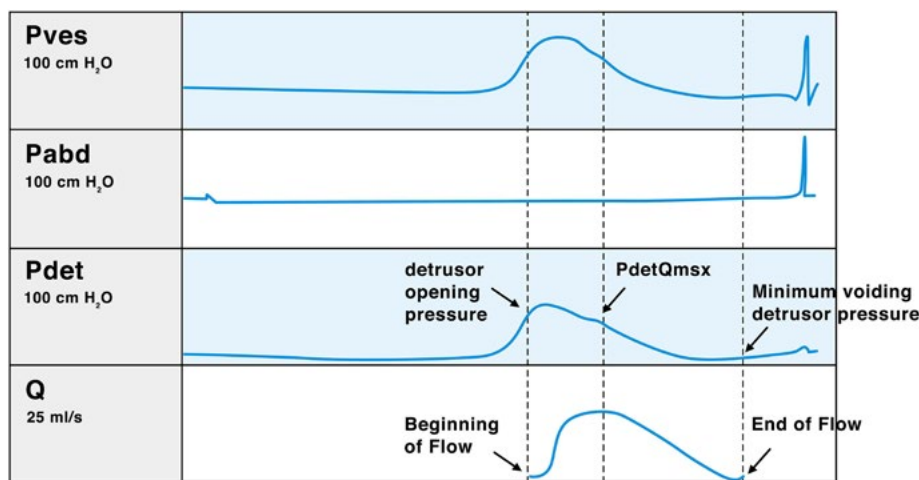


FIGURE 6 A schematic diagram of a pressure-flow study

(CHANGED). Limited voiding may occur by straining. The possibility of “inhibition” of a detrusor voiding contraction must be considered if the man subsequently voids normally post-cystometry. An acontractile detrusor can be of neurogenic or non-neurogenic origin. Neurogenic acontractile detrusor should replace the term “detrusor areflexia.”

3.8 Urethral function during voiding: This can be interpreted by the pressure-flow trace assisted at times by video cysto-urethrography (video-urodynamics – 4.3.4) and electromyography (EMG – 3.9) as available.

3.8.1 Normal urethral function during voiding:

Initiation of voiding begins with voluntary relaxation of the pelvic floor and striated sphincters (rhabdosphincter). The bladder then contracts with the bladder neck, the latter then opening due to its spiral arrangement of fibres. Voiding is prompted with the urethra being continuously relaxed to allow micturition at a normal detrusor pressure and urine flow, resulting in complete bladder emptying.^{85,86}

FN3.24, FN3.25, FN3.26

3.8.2 Abnormal urethral function during voiding:

The urethral sphincter(s) do not relax completely or they are (temporarily) contracted during voiding, resulting in increased detrusor

pressure. Bladder emptying may be complete or incomplete (PVR present).

3.8.2.1 Bladder outlet obstruction (BOO):^{87,88}

This is the generic term for obstruction during voiding. It is a reduced urine flow rate with a simultaneously increased detrusor pressure^{FN3.27}. The Bladder Outlet Obstruction Index ($BOOI = P_{det, Q_{max}} - 2Q_{max}$) will give a guide to the likelihood of obstruction being present.⁸⁷

BOOI <20 cm H₂O = non-obstruction;
BOOI 20-40 cm H₂O = equivocal;
BOOI >40 cm H₂O = obstruction)

(CHANGED)

3.8.2.2 Dysfunctional voiding: is character-

ized by an intermittent and/or fluctuating flow due to inadequate or variable relaxation generally of the sphincters during voiding in neurologically normal men (i.e. no historical, visible or measurable evidence of neurological disease). (CHANGED) Dysfunctional voiding may cause functional bladder outlet obstruction. This type of voiding may also be the result of an acontractile or underactive detrusor (voiding with abdominal straining). Video-urodynamics is required to diagnose primary bladder neck obstruction and/or rhabdosphincter discoordination.⁸⁷

3.8.2.3 Detrusor sphincter dyssynergia (DSD):⁸⁸ Dyscoordination between

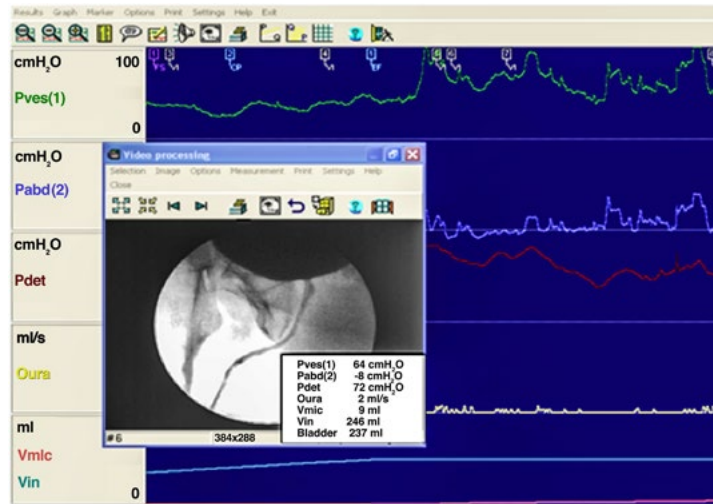


FIGURE 7 Primary bladder neck obstruction in non-neurogenic patient: Urodynamic trace plus imaging

detrusor and rhabdosphincter function during voiding due to a neurological abnormality (ie, detrusor contraction synchronous with contraction of the urethral and/or periurethral striated muscle). This is a feature of neurological voiding disorders. Neurological features should be sought.⁸⁸ Video-urodynamics (4.3.4) is generally valuable to conclude this diagnosis. DSD generally occurs due to a lesion above the sacral level 3 but below pons. Sphincter EMG might be

helpful where facilities for video-urodynamics are unavailable.

3.8.2.4 Primary Bladder Neck Obstruction (non-neurogenic): During voiding, the bladder neck smooth muscle fails to adequately open. The detrusor pressure increases to try to overcome the resistance of the bladder neck and allow urine to flow (Figure 7).

3.8.3 Pressure-Flow Analysis Graphical presentation of the results or calculations based on the pressure-flow measurement (passive urethral

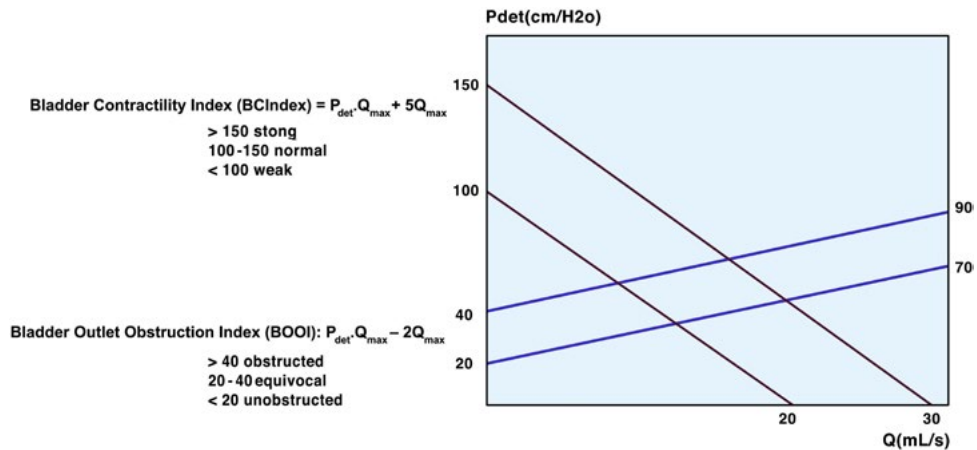


FIGURE 8 ICS Nomogram⁸⁹

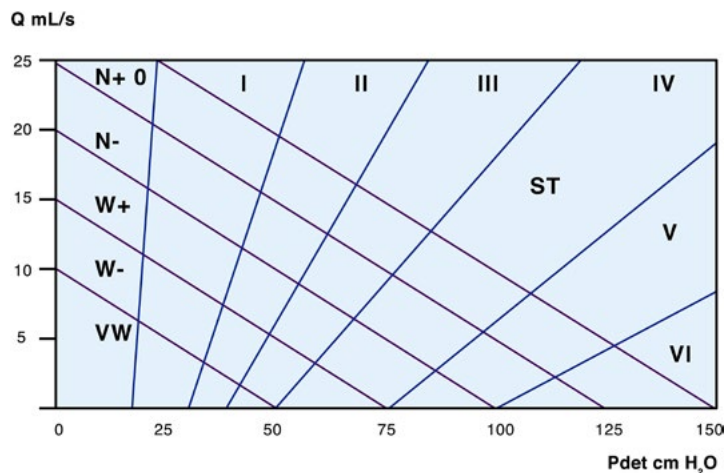


FIGURE 9 Schäfer Nomogram^{90,91}

pressure relationship, PURR) have been developed into nomograms. Different nomograms use a variable amount of information of the pressure-flow plot. Figures 8–10 are available to assess bladder outlet obstruction in men^{89–92}

3.8.3.1 ICS Nomogram⁸⁹: Only P_{det} at Q_{max} is plotted into the nomogram (one point

determination of bladder outlet resistance). Depending on the position of this point on the nomogram, the patient can be categorised as “unobstructed,” “equivocal,” or “obstructed.” The calculation of BOOI is used to express bladder outlet resistance as a continuous variable. BOOI can be extracted from

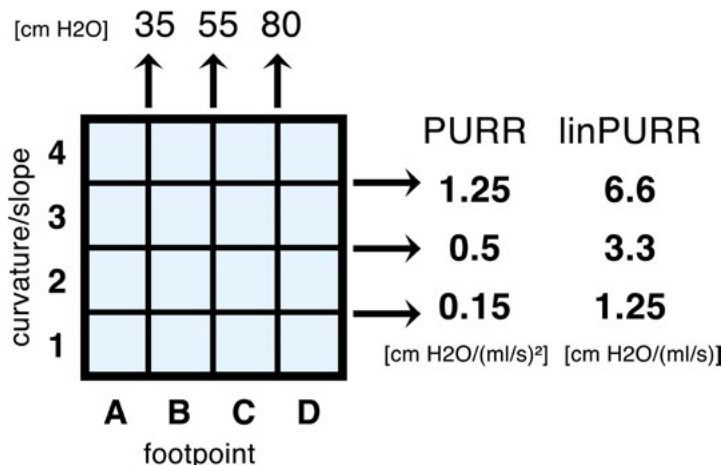


FIGURE 10 CHES Nomogram⁹² for the two-dimensional classification of bladder outlet obstruction (assessment of compressive and/or constrictive BOO). The entire information of the pressure-flow plot is used to calculate the passive urethral resistance relation (quadratic PURR, ie, the lowest detrusor pressure for each urine flow during the recorded void; multiple point determination of bladder outlet resistance). The PURR footprint (ie, crossing-point of the PURR with the pressure-axis) and PURR curvature (ie, PURR ascent) are used to determine bladder outlet resistance. In total, 16 different fields are generated by using the threshold values indicated in the figure. Only field A1 testifies “non-obstruction”; field A2 and B1 indicate “equivocal obstruction” and all other fields indicate different types of obstruction. The increase in the footprint (A to D) indicates compressive BOO whilst the increase in the curvature (1 to 4) indicates constrictive BOO. (NEW)

the nomogram by drawing a line between $P_{\text{det.Qmax}}$ and the cutting point of the Y-axis (n.b. the line must be parallel to the lines drawn into the nomogram (ie, those for “unobstructed,” “equivocal,” or “obstructed”)).^{FN3.28, FN3.29, FN3.30} (NEW)

3.8.3.2 Schäfer Nomogram^{90,91}: $P_{\text{det.mu0}}$ (minimal urethral opening detrusor pressure) and $P_{\text{det.Qmax}}$ (detrusor pressure at maximum urine flow) together with corresponding urine flow rates are plotted into the nomogram (2-point determination of the bladder outlet resistance). The line between the two points represents the linearized passive urethral resistance relationship (linPURR) and the location of the linPURR in the nomogram indicates the amount of bladder outlet resistance of the patient. The nomogram differentiates 7 grades of bladder outlet resistance (grades 0 and I=no bladder outlet resistance); grades II to VI indicate increasing grades of BOO. The length (endpoint) of linPURR indicates detrusor contraction strength that can be very weak (VW), weak (W), normal (N), or strong (ST). (NEW)

3.9 Electromyography (EMG)

3.9.1 Purpose: Reflects the activity of the striated musculature (peri-urethral, rhabdosphincter and pelvic floor). EMG is poorly standardized with variance in the type of needle, needle versus patch electrode, and electrode placement.⁹³ Perineal patch electrodes are often preferred for easier placement, patient tolerance and allow greater mobility. However, they measure all the above striated musculature. In contrast, needle electrodes can be placed in the area of interest and measure activity of defined muscles or muscle groups for example, rhabdosphincter. (NEW)

3.9.2 Interpretation: May be difficult due to artifacts introduced by other equipment. In the urodynamic setting, an EMG is useful as a gross indication of the patient's ability to control the pelvic floor. (NEW)

3.9.3 Detrusor-sphincter dyssynergia (DSD): Simultaneous contraction of the detrusor and (rhabdosphincter) urethral sphincters with the

evidence of a neurological disorder (either visible or measurable neurological deficit or a history of neurological disease). The classification of DSD can be divided into two groups continuous versus intermittent. DSD type and degree of SCI lesions seem to correlate.^{93,94} (NEW)

3.9.3.1 Type 1 DSD occurs in patients with incomplete neurological lesions. Type 1 – there is a progressive increase in external urinary sphincter (EUS) contraction activity that peaks at maximal detrusor contraction followed by sudden relaxation of the EUS as the detrusor pressure declines allowing urination (Figure 12). (NEW)

3.9.3.2 Type 2 DSD occurs more often in patients with complete lesions. Type 2 – occurs with continuous EUS contraction throughout the entire detrusor contraction resulting in urinary obstruction or inability to urinate.^{93,94} (NEW)

3.10 Ambulatory urodynamics: A functional test of the lower urinary tract for which a transurethral catheter is placed in the bladder (and, in some protocols, another one in the rectum as is typical for a urodynamic study) performed outside the clinical setting, involving natural bladder filling by drinking and continuous recording of the bladder pressure (P_{ves}) for a longer period of time (eg, 12h). Ambulatory urodynamics can reproduce bladder function and urine loss during the individual's normal everyday activities. (CHANGED)

3.11 Non-invasive urodynamics: The penile cuff⁹⁵ and condom catheter⁹⁶ and urethral device⁹⁷ have been developed as non-invasive alternatives to pressure-flow studies. The principle of these tests is to interrupt the flow and measure the bladder pressure. The detrusor contraction is maintained and the urethral sphincter remains open; the column of fluid from the urethra to the bladder is sufficient to measure the bladder pressure (isovolumetric pressure). The external pressure on the urethra, which is needed to interrupt the flow, should be identical to the pressure in the bladder (ie, isovolumetric bladder pressure – $P_{\text{ves, iso}}$). Therefore, $P_{\text{ves, iso}}$ provides information on bladder pressure during voiding and, when urinary flow is also measured, it is able to distinguish between obstruction and non-obstruction (Figure 11). (NEW)

3.12 Videourodynamics (Fluorourodynamics): Functional test of the lower urinary tract in which filling

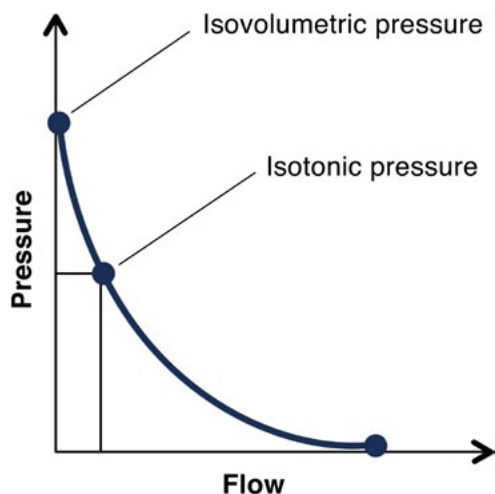


FIGURE 11 Isometric and isotonic pressure are indirectly related to the condition of the muscles fibers (detrusor). The isometric contraction of the detrusor, that is contraction without length modification or without shortening of the muscle fibers. Isovolumetric pressure is established by the isometric contraction of the detrusor (no flow). Isotonic contraction is developing force with length modification and therefore, shortening the muscle fibers. In this case, the isotonic pressure is referring to the fact that it is being developed in the voiding phase

cystometry and pressure-flow studies (and possibly EMG) are combined with real-time imaging of the lower urinary tract (Figure 12). (see 4.3.3). (CHANGED)

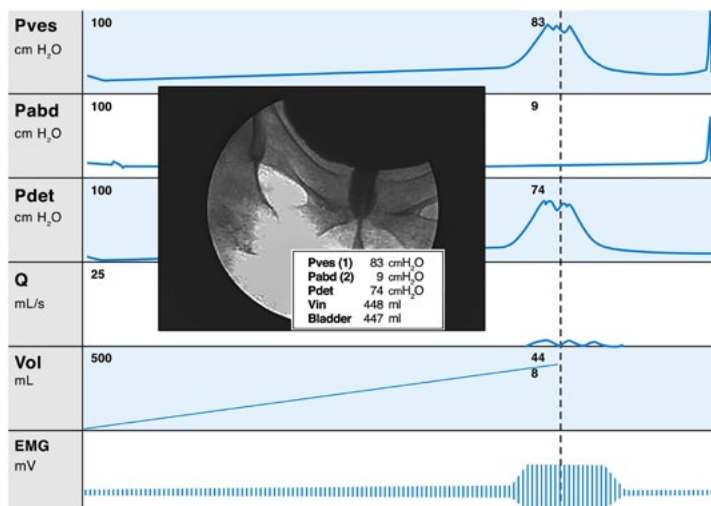


FIGURE 12 Videourodynamics with EMG: During the voiding phase, high detrusor pressure, slow urine flow, increased electrical muscle activity and the image shows dilatation of the proximal urethra and narrowing of the membranous urethra (rhabdosphincter)

3.12.1 Bladder neck at rest: Shut and competent on coughing and straining, possible exception post-prostatectomy.

3.12.2 Bladder neck during voiding: Bladder neck opens like a funnel.

3.12.3 Bladder neck obstruction during voiding: Bladder neck remains closed.

Footnotes for Section 3

3.1: Urodynamics is the general term to describe all the measurements that assess the function or dysfunction of the LUT by the measurement of relevant physiological parameters.^{56,57}

3.2: Urodynamic tests: Over the years, a variety of terms have been developed for the group of diagnostic tests that evaluate LUT function: uroflowmetry, post void residual (PVR), cystometry, pressure-flow studies, electromyography (EMG), urethral pressure profile (UPP), and videourodynamics (videocystourethrography – VCU) are the terms most frequently used in the scientific literature.^{56,57}

3.3: Men with detrusor overactivity had the highest urine flow rates. Detrusor overactivity (previously “instability”) was present in 71% of men with centile rankings for the maximum urine flow rate over 50 mL/s.⁶⁴

3.4: There is a notable difference between the available nomograms (Liverpool, Siroky, and Bristol), particularly between race and in older patients.⁶⁰⁻⁶³

3.5: These are figures for maximal diuresis in women in response to fluid loads of 500 mL and 1000 mL.

Equivalent male diuresis data is unavailable.⁶⁵ However, maximum diluting capacity of urine is generally regarded as 20 L/day which converts to 13.9 mL/min (exactly the same as female data⁶⁵).

3.6: Not all catheters empty with similar efficacy. There is evidence in women that a less-compressible (silicone or plastic) catheter is much more effective than a more compressible (latex) catheter in draining the bladder.⁶⁶ Such evidence in men is unavailable.

3.7 Continuous fluid filling of the bladder via a transurethral (or other route, eg, cystostomy or Mitrofanoff) catheter, at least with intravesical and abdominal pressure measurement and display of detrusor pressure, including cough (stress) testing. Cystometry ends with "permission to void" or with incontinence of the total bladder content. The fluid type and temperature, filling method and rate, catheter sizes, pressure recording technique, and patient position should all be specified in the urodynamic protocol.

3.8: Body temperature fluid and room temperature fluid do not differently affect bladder sensory thresholds and do not unequally provoke detrusor overactivity or lower urinary tract irritation.^{71,72}

3.9: Detrusor overactivity would have been missed in 76% of cases of cystometry was done in the supine position and 60% would have been missed if the study was done supine compared to seated^{71,73}. The sitting or standing position is the most representative for daily life situations and is probably the least uncomfortable and/or embarrassing for the patient.⁷³

3.10: Filling rate, especially when very fast and the volume infused is much larger than the functional bladder capacity, may influence the results or the representativeness of the cystometry. Evidence that filling rate should be changed during the cystometry is lacking. Diuresis, during cystometry, adds volume that is not recorded by the urodynamic system with automated filling volume recording, but that is relevant for interpretation of the results.

3.11: There is no specific evidence, but the position of the catheter-tip is usually above the bladder in a stoma, and bowel activity may much more likely cause artifacts in those cases, hampering measurement of absolute abdominal pressures, detrusor subtraction pressure, and therefore, the interpretation.

3.12: The urodynamic pressure is the excess pressure above atmosphere at the hydrostatic level of the upper edge of the symphysis pubis. This is valid for all pressures recorded with fluid-filled lines.

3.13: Values evaluated in healthy men^{75,76} (mean \pm SD) are (i) First sensation of bladder filling: 222 mL \pm 150 mL; (ii) First desire to void: 325 \pm 140 mL; (iii) Strong desire to void: 453 \pm 94 mL.

3.14: Maximum cystometric capacity that should be in healthy adult men, mean 552 mL (range 317-927 mL).⁷⁶

3.15: Filling of more than 800 mL is seldom useful⁷¹.

3.16: Maximum bladder capacity under anaesthetic ("anatomical bladder capacity") – the volume to which the bladder can be filled under deep general or spinal anaesthetic, without urinary leakage, is rarely reported in scientific literature but may be of relevance in interstitial cystitis.⁷¹

3.17: "Normo-active detrusor" as several studies have demonstrated detrusor overactivity during filling in healthy individuals.

3.18: UTI is a very uncommon cause of DO. Most centres do not do urodynamic studies in the presence of an active infection because of the risk of septicaemia.

3.19: Normal values of bladder compliance in men have not been well-defined. Bladder compliance in the volunteers was higher than usually considered normal in adults during cystometric bladder filling.⁷⁶ In 28 healthy volunteers, men with mean age of 24 years (range 19-28), the mean compliance was 56.1 mL/cm H₂O (SD 37.3). Since no precise figures exist for normal compliance in men, a prospective study of a large normal population is needed.

3.20: There is no convincing evidence that the clinical diagnosis on the basis of the first cystometry is often changed on repetition of the test. There is no definite evidence that immediate repetition of an adequately performed urodynamic test "for confirmation" is required. The recommendation of immediate repetition of the test: (i) when doubt exists as to whether the test has answered the clinical question; (ii) when technical errors and artifacts have been observed at immediate post-test analysis.

3.21: Cystometry and pressure-flow study, free uroflowmetry and PVR are termed ICS standard urodynamic test (ICS-SUT). This may be supplemented with other tests such as EMG, imaging, continuous urethral pressure(s), and/or urethral pressure profile measurements. All tests are performed in the patient's preferred or most usual position: comfortably seated and/or standing if possible.^{56,57}

3.22: Voiding physiology depends on central neural activation, bladder contractility and coordinated urethral relaxation throughout the process. There remains much to learn about these components including central activation and its potential grading, and its role and interactions in detrusor underactivity and dysfunctional voiding.

3.23: It is usually between 0.5 to 0.8 s depending on the individual's position and the distance to the uroflowmeter.

3.24: The first "event" in voiding is relaxation of the pelvic floor. This may mean a drop in intra-abdominal

pressure in the rectal line, and an associated increase in the detrusor pressure which does not imply a detrusor contraction.

3.25: As any other muscular contraction, detrusor contraction has an isometric and an isotonic component. The isometric component means that detrusor fibers do not shorten and intravesical pressure rises. The isotonic component produces changes in fiber length; there is shortening and a flow ensues. The first is represented externally as P_{ves} or P_{det} and the second by flow. In voiding cystometry, in the presence of flow, detrusor pressure is a function of these two variables, governed by urethral resistance to flow.

3.26: Voluntary interruption of voiding: If the need to interrupt the flow were to arise, contraction of the pelvic floor and urethral sphincters can do this, resulting in an isometric detrusor pressure rise. Urine in the proximal urethra is milked back into the bladder.

3.27: In men with symptoms of lower urinary tract dysfunction, urine flow (rate) and PVR are important markers of bladder outlet obstruction, but are also dependent on the central initiation and continuation of the detrusor contraction and pressure. In the original definition, only pressure and urine flow were included.

3.28: Voiding cystometry graphic presentation: It has been recommended to present pressure-flow studies with a plot of the flow rate (mL/s) on the X-axis and the synchronous detrusor pressure (cm H₂O) on the Y-axis in addition to the time-based graphs but the axis can be reversed. These plots can be added a cut-off value or a range of normality and equivocal zones. These cut-off values are population specific, varying widely among male patients.

The relation between detrusor pressure and generated synchronous flow indicate “*urethral resistance*.” With computing, these plots can be drawn since the beginning to the end of flow. *Urethral resistance* is then appreciated graphically throughout the whole emptying phase. Most of these resistance points are considered to be driven by urethral muscular activity. The point of less calculated resistance should be taken as an approximation to the urethral resistance free of active muscular urethral and peri-urethral contractions. This concept of “*passive urethral resistance relation*” is then taken as an “anatomical obstruction” caused by fixed structures as the prostate or strictures.

Pressure-flow plots as a measure of detrusor voiding contraction. “*Detrusor contractility*” can be used for any method that diagnoses or aims to diagnose “intrinsic” detrusor muscle properties (eg, potential [maximum] force or velocity), by any method.

In a given group of patients the *detrusor contractility* can be calculated upon series of stop-flow or interrupted-

voiding tests and mathematical or graphical analysis methods of pressure, flow and or other parameters. Cut-off values or a continuous scale of contractility can then be drawn. Independently of the magnitude of the detrusor contraction, it can be fading before the total emptying leading to incomplete voiding; “unsustained contraction” or “fading contraction” may then be used.

3.29: “ICS Nomogram”[®] formerly known as Abrams-Griffiths Nomogram and “Abrams-Griffiths number” (now BOOI) is more commonly used.

3.30: Catheter flow should be compared with free flow to ascertain whether dysfunctional voiding might only occur during urodynamics due to catheter placement.

SECTION 4: IMAGING

4.1 Overview: Imaging has become increasingly important in the assessment of male lower urinary tract and pelvic floor dysfunction. Table 2 indicates possible imaging modalities by site and the main goals from kidney to pelvic floor. (NEW)

Application of the individual imaging technique is dependent on the suspected abnormality, ability of the imaging technique to visualize this abnormality and image resolution. In case of competing imaging techniques, non-radiological techniques should be preferred to avoid radiation exposure. (NEW)

4.2 Ultrasound Imaging

4.2.1 Ultrasound in the assessment of the lower urinary tract: As noted in Table 2, ultrasound imaging has become a relevant imaging modality in all sites that might be subject to investigation of male lower urinary tract and pelvic floor dysfunction both in the office and in the urodynamic suite. (NEW)

4.2.2 Modalities in current routine clinical use:

4.2.2.1 Transrectal: Linear array or sector scanning per rectum. (NEW)

4.2.2.2 Transabdominal: Curved or linear arrays applied to the abdomen. (NEW)

4.2.2.3 Perineal: Curved or linear array probe applied to the perineum (transperineal). (NEW)

4.2.2.4 Scrotal: Linear array probe applied to scrotum looking at testes, epididymes and intrascrotal abnormalities. (NEW)

4.2.3 Current routine uses of ultrasound in male LUT/PF dysfunction

4.2.3.1 Post-void residual (PVR): Transabdominal^{98,99} or transrectal¹⁰⁰ (see section

TABLE 2 Imaging modalities by site and goal

Location	Imaging technique	Purpose
Upper Urinary Tract	<ul style="list-style-type: none"> • Renal ultrasound • IVU with X-ray or CT • IVU with MRI 	detects the presence and degree of hydronephrosis, urothelial carcinoma/tumors, stones, other renal or ureteric abnormalities/ diseases.
Bladder	<ul style="list-style-type: none"> • Ultrasound bladder scanner • Transabdominal ultrasound • Transrectal ultrasound • CT • MRI 	measurement of post-void residual (PVR), detrusor or bladder wall thickness, intravesical prostatic protrusion (IPP) or bladder weight (to help judge BOO) or calcification. Evaluate the presence of other diagnoses such as neoplasm, stones or foreign bodies.
Prostate	<ul style="list-style-type: none"> • Transrectal ultrasound (3D, contrast-enhanced, Doppler) • Transabdominal ultrasound • MRI (T2-weighted, multiparametric, prostate segmentation, functional MRI). 	evaluate prostate volume, prostate anatomy, BOO. MRI: Evaluation for prostate cancer
Scrotum	<ul style="list-style-type: none"> • Scrotal ultrasound 	Testis, epididymis, tunica vaginalis
Urethra	<ul style="list-style-type: none"> • X-Ray (retrograde or antegrade urethrography) • MRI • Ultrasound 	evaluate congenital abnormalities, fistula, diverticula, (post-surgical) stricture, neoplasm
Ano-rectum	<ul style="list-style-type: none"> • Endoanal ultrasound (10-13-16 Hz axial and sagittal array) • Defecography • MRI 	Anal sphincter integrity; peri-anal sepsis, pelvic floor coordination during defecation
Penis	<ul style="list-style-type: none"> • Ultrasound • CT • MRI 	Peyronie's disease, corpora cavernosa rupture.
Lower urinary tract	<ul style="list-style-type: none"> • Video-cystourethrography • Video-urodynamic 	Evaluate of the bladder during filling and/or voiding, vesico-ureteric reflux; bladder morphology – trabeculation, diverticulum; anatomical site; BOO; type of stress incontinence; urethral diverticulum; strictures, fistulae

3.2.2) ultrasound measurement of the bladder volume. The following formula shows the lowest transabdominal measurement error when compared with catheterization.⁹⁹ PVR calculation (by abdominal ultrasound) is done by multiplying the width (left to right borders), depth (anterior to posterior borders) and length (cranial to caudal borders) and multiplying this result with 0.52 (there are different multiplication factors available but 0.52 is the most common one) (Figure 13). *(NEW)*

$$\text{Volume} = (\text{width} \times \text{depth} \times \text{length}[\text{cm}]) \times 0.52[\text{mL}]$$

4.2.3.2 Intercurrent abnormalities: For example, prostate volume (transabdomi-

nal, intraabdominal, retroperitoneal, or intrapelvic tumor, hydronephrosis). *(NEW)*

4.2.3.3 Bladder abnormalities: For example, tumor, foreign body, overdistension, stones. *(NEW)*

4.2.3.4 Detrusor wall thickness (DWT) or bladder wall thickness (BWT): Transabdominal visualization of the anterior bladder wall with a (linear) high frequency ultrasound scanner for the detection of BOO if DWT is ≥ 2 mm in bladders filled with ≥ 250 mL (Figure 14) or BWT is ≥ 5 mm in bladders filled with 150 mL (Figure 14).¹⁰¹⁻¹⁰⁵ *(NEW)*

4.2.3.5 Ultrasound-estimated bladder weight (UEBW): can be calculated

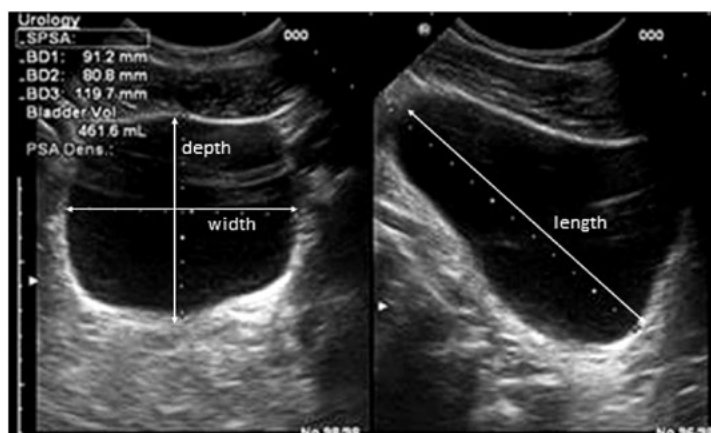


FIGURE 13 Determination of bladder (post-void residual) volume by transabdominal ultrasound imaging

by measuring the urine volume in the bladder and BWT and applying the following formula (Figure 15).^{106,107} (*NEW*)

4.2.3.6 Intravesical Prostatic Protrusion (IPP):

Transabdominal measurement of the distance of the bladder base until the tip of the prostate in the bladder lumen¹⁰⁸ (Figure 16A and B). It is recommended to fill the bladder with 100-200 mL of fluid in order to receive representative measurements; bladder

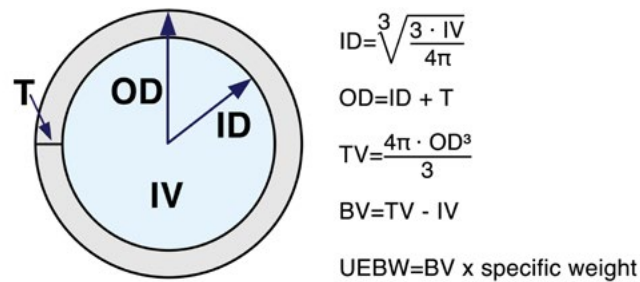
filling over 400 mL will lower IPP values.¹⁰⁸ The IPP measurement can be divided into three grades: grade I = 0-4.9 mm; grade II = 5-10 mm; grade III = >10 mm.¹⁰⁹ IPP grade III is associated with prostate-related BOO.

4.2.3.7 Urethral abnormality: For example, diverticulum, urethral stenosis, degree, and depth of spongiofibrosis. (*NEW*)

4.2.3.8 Postoperative findings: For example, post-prostatectomy (urethral shape), male sling position, artificial urinary



FIGURE 14 Ultrasound measurement of detrusor wall thickness (DWT) at the anterior bladder wall with a linear 7.5 MHz ultrasound array in a bladder filled >250 mL; the hypoechoic detrusor (black bar) is sandwiched between the hyperechoic (white) mucosa (bottom) and adventitia (top).^{101,102} DWT is measured from the inner border of the mucosa to the inner border of the adventitia as demonstrated in the figure, whereas BWT is measured from the outer border of the mucosa to the outer border of the adventitia



IV = inner volume; ID = inner radius; OD = outer radius; T=(bladder wall) thickness;
 TV = total volume. Note again, "D" refers to "radius" not "diameter". Volume of
 bladder wall itself should be $\frac{4}{3}\pi$ times (Rt3-Rid3)

FIGURE 15 UEBW^{106,107} FN 4.1. IV = inner volume; ID = inner radius; OD = outer radius; T = (bladder wall) thickness; TV = total volume. Note again, "D" refers to "radius" not "diameter". Volume of bladder wall itself should be $\frac{4}{3}\pi$ times (Rt3-Rid3)

sphincter –placement of cuff and reservoir, bulking agents. (NEW)

4.2.3.9 Prostate ultrasound: determination of prostate and transition zone volume, prostate shape and visualization of the prostate parenchyma for calcifications, cysts, abscesses, or enlargement (Figure 17). (NEW)

4.2.4 Pelvic floor: For example, anal sphincter defects (see below)

4.2.5 3D and 4D Ultrasound: research modalities at present FN 4.2

4.2.6 Other assessments: Synchronous ultrasound screening of the bladder and/or urethra and measurement of the bladder and abdominal pressure during filling cystometry and pressure flow study (Video-ultrasound-urodynamics). (NEW)

4.2.7 Anal ultrasound (Endosonography^{110,111}):

This is the gold standard investigation in the assessment of anal sphincter integrity. There is a high incidence of defecatory symptoms in men with anal sphincter defects (Figure 18). (NEW)

4.2.7.1 Endoanal ultrasonography (EAUS)

or Anal Endosonography (AES):

Ultrasound of the anal canal performed with a pole-like ultrasound probe placed in the anal canal giving a 360 degree image of the anal canal. It is usually performed with the patient placed in the lithotomy, prone position or sometime left lateral. Two dimensional AES; three dimensional AES – three-dimensional reconstruction of the anal canal is performed using either axial or sagittal images. (NEW)

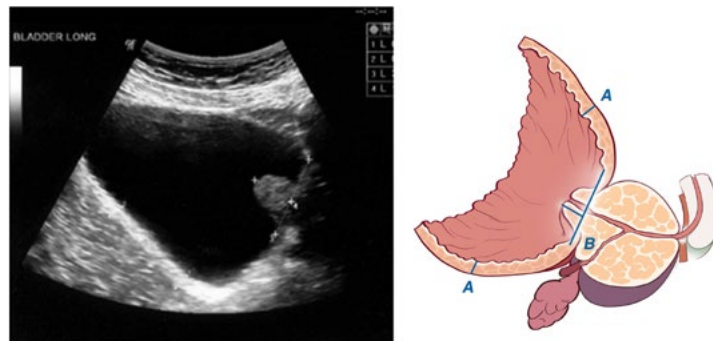


FIGURE 16 A: Transabdominal ultrasound measurement of intravesical prostatic protrusion (IPP). B: How to measure IPP – base of bladder (line A) to the most cranial part of the prostate (line B)

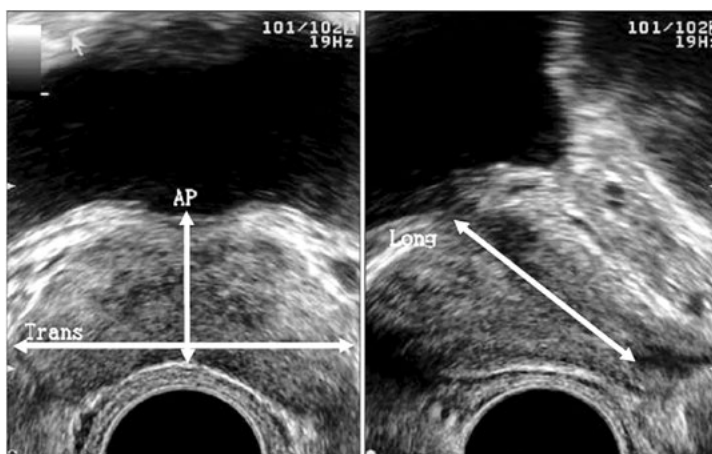


FIGURE 17 Prostatic volume by transrectal ultrasound

4.2.7.2 Anal Canal – The anal canal in adults is between 2.5 and 5 cm in length and begins as the rectum narrows, passing posteriorly between the levator ani. Three levels of assessment in the axial plane.¹¹¹ (NEW)

4.2.7.2.1 Upper level: the hyperechoic sling of the puborectalis muscle (PR) and the complete ring of the internal anal sphincter (IAS). (NEW)

4.2.7.2.2 Middle level: corresponds to the superficial part of the EAS (concentric band of mixed echogenicity), the conjoined longitudinal layer, the IAS (concentric hypoechoic ring), and the transverse superficial perineal muscles. (NEW)

4.2.7.2.3 Lower level: corresponds to the subcutaneous part of the EAS where the IAS is absent. (NEW)

4.2.7.3 Internal anal sphincter – The caudal continuation of the circular smooth muscle of the rectum forms the internal anal sphincter, which terminates caudally in a clearly defined edge, at a variable distance from the anal verge. (NEW)

4.2.7.4 Longitudinal muscle – Comprises smooth muscle cells continuous with the outer layer of the rectal wall, and striated muscle from various pelvic floor muscles. The longitudinal muscle lies between the internal and external anal sphincters in the inter-sphincteric space. (NEW)

4.2.7.5 External anal Sphincter – It is made up of striated muscle and surrounds the longitudinal muscle forming the outer border of the inter-sphincteric space. The external sphincter is divided into

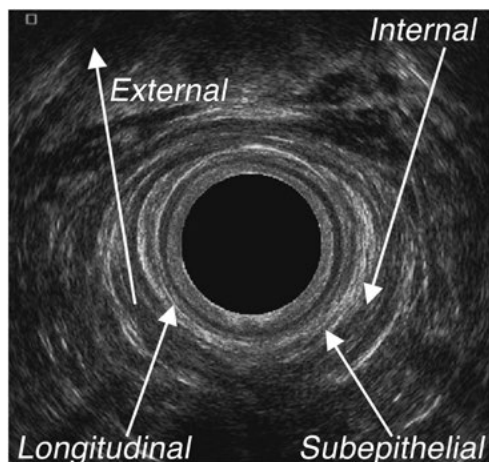


FIGURE 18 Normal anal canal anatomy as seen on anal endosonography (AES)

deep, superficial and subcutaneous parts, with the deep and subcutaneous parts of the sphincter forming rings of muscle, between them elliptical fibres from the superficial part of the external anal sphincter run anteriorly from the perineal body to the coccyx posteriorly. (NEW)

- 4.2.7.6 Puborectalis** – is formed from the most anterior fibres of the pubococcygeus muscle, this forms a sling pulling the rectum forward. (NEW)

4.3 Radiography

4.3.1 Modalities in current routine clinical use

- 4.3.1.1 Intravenous urography (IVU):** This provides an anatomical outline of the upper urinary tract, ureters and bladder as well as the evaluation of the kidney function and excretion of contrast media. IVU consists of at least 3–4 abdominal images: one plain x-ray, one almost immediately after injection to evaluate for renal vascular uptake, one image 7 min and one image 15 min after infusion of contrast media (and bladder emptying). The preliminary plain x-ray may show calcification in kidney, ureter, bladder, seminal vesicles or vasa. (NEW)

- 4.3.1.2 Retrograde urethrocytography and voiding cystourethrography:** Unidirectional or combined contrast imaging of the urethra in a patient in the 30 degree oblique position to visualize the lumen, mainly to diagnose urethral strictures or diverticula (Figure 19). It is also of use to diagnose and stage urethral trauma. (NEW)

- 4.3.1.3 Voiding cystourethrography:** imaging of the bladder neck, urethra and prostate during voiding (Figure 20). The principal use is determining the site of any obstruction, for example, bladder neck or prostate. It can detect vesico-ureteric reflux, vesical or urethral fistulae, vesical or urethral diverticula and strictures. (NEW)

- 4.3.1.3.1 Videocystourethrography (VCU):** Synchronous radio-

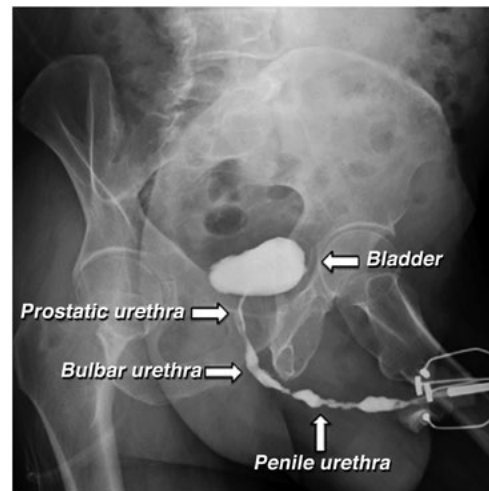


FIGURE 19 Retrograde urethrocytography of a patient with a penile urethral stricture

logical screening of the bladder and urethra during filling and voiding (Figure 21). The only difference between

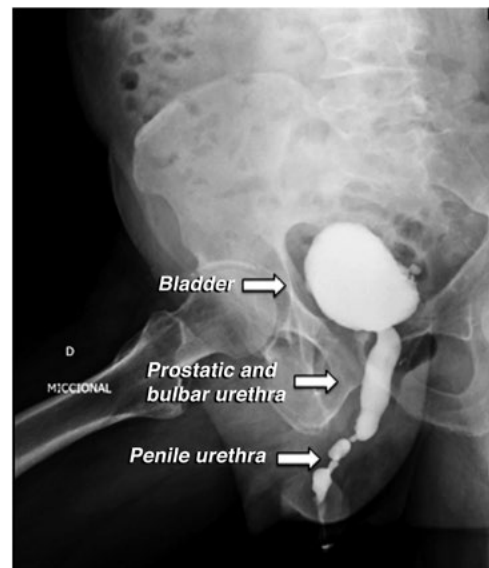


FIGURE 20 Voiding cystourethrography: Shows bladder diverticula, open bladder neck and prostatic urethra till stricture of penile urethra

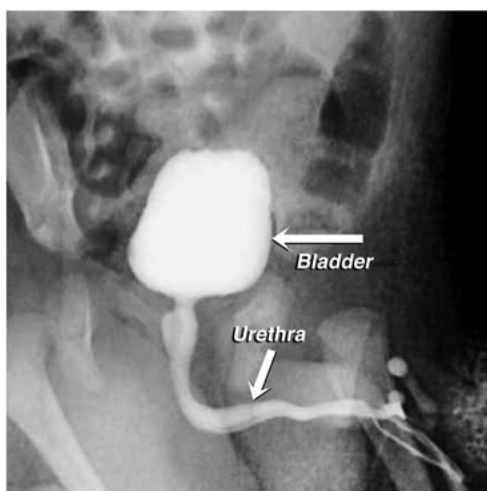


FIGURE 21 Example of Videocystourethrography

VCU and 4.3.1.3. is continuous image capture. (NEW)

4.3.4 Videourodynamics¹¹²: Videourodynamics refers to videocystourethrography with synchronous pressure and flow rate recordings. It is a dynamic study with function, during bladder filling and emptying. (NEW) See also Figure 12.

Video-urodynamics has two defining characteristics:

- It is a kinetic technique that records morphological and functional changes of the lower urinary tract as a function of time. This feature distinguishes this technique from the static images obtained by cystography.
- It is a technique that is applied simultaneously with conventional urodynamic studies.

Image acquisition for the urinary tract can be performed with X-rays (fluoroscopy) or by ultrasound. Although in a strict sense, the “video” prefix refers to the recording of the images and not to their acquisition.

4.3.5 Defecography (Evacuation proctography): This demonstrates the anatomy of the anorectum as well as disorders of rectal evacuation. Barium

paste is inserted rectally prior to defecation over a translucent commode. (NEW)

4.4 Computerized Tomography (CT)

4.4.1 CT Urogram (CT-U): CT study of the urinary tract system using injected contrast, used to clarify diagnoses such as (i) tumors; (ii) renal disease; (iii) abnormal fluid collections/abscesses (iv) bladder diseases. (NEW)

4.4.2 CT Kidneys, ureter, bladder (CT-KUB): Non-contrast study aimed primarily at identifying stones but may identify other diseases. Aka “stone protocol.” (NEW)

4.5 Magnetic Resonance Imaging¹¹³

4.5.1 Magnetic resonance imaging (MRI) in male lower urinary tract and pelvic floor dysfunction: MRI provides the opportunity to examine the soft tissue structures of the pelvic support apparatus. It is non-invasive, has excellent soft tissue contrast resolution without exposure to ionizing radiation and allows the study of function of pelvic floor structures under different dynamic conditions. Several anatomical landmarks used for pelvic measurements are also easily identified in MRI and most measurements are thus highly reproducible. T-weighting assists enhancement of fluid-filled structures. (NEW)

4.5.2 Current possible measurements using MRI in male lower urinary tract and pelvic floor dysfunction. FN4.2

4.5.2.1 Bladder abnormalities: For example, tumor, foreign body, bladder wall abnormalities, intestine-vesical fistulae. (NEW)

4.5.2.2 Urethral abnormality: For example, diverticulum, recto-urethral fistulae. (NEW)

4.5.2.3 Urethral sphincter length:¹¹⁴ prediction of post-prostatectomy incontinence. (NEW)

4.5.2.4 Prostate abnormalities: For example, benign enlargement, cancer, cysts, prostatorectal fistulae. (NEW)

4.5.2.5 Intercurrent abnormalities: For example, rectum – rectal dynamics are assessed during evacuation after adding ultrasound gel to the rectum. Anorectal and pelvic floor motion can be imaged

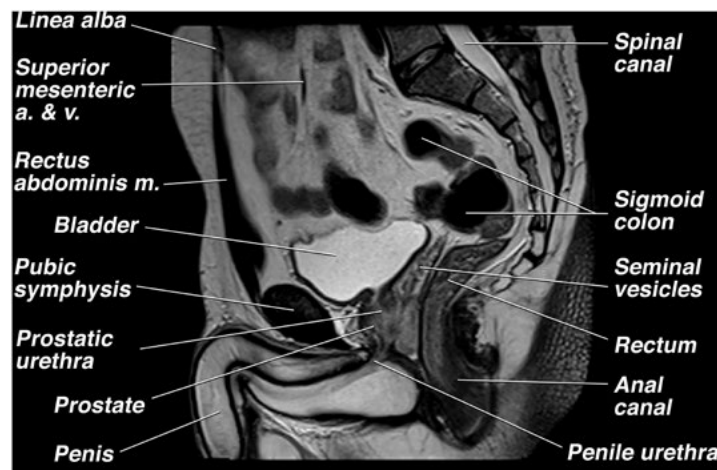


FIGURE 22 MRI (sagittal) of male lower abdomen and pelvis

providing pelvic images at rest and when the subject strains. (NEW)

4.5.2.6 Congenital abnormalities: Detection of Mullerian duct remnants, aberrantly inserted ureters and duplicated pelvic structures. (NEW)

4.5.2.7 Standardised MRI prostate imaging: PI-RADS – prostate imaging reporting and data system (Figures 22–24).^{FN4.4, FN4.5} (NEW)

Footnotes for Section 4

4.1: The “cut-off” value for obstruction has been suggested as 35 g (adult Asian men).¹⁰⁶

4.2: The potential of 3D and 4D ultrasound in male lower urinary tract and pelvic floor dysfunction is

currently being researched with validated applications likely to be included in future updates of this Report and/or separate ultrasound reports.

4.3: Diagnostic ability may be enhanced by the use of 3D MRI. New techniques with high speed sequence of pictures allows for a functional MRI.

4.4: Prostate imaging has over the last 5 years become more standardised with the introduction of PI-RADS (Prostate Imaging Reporting and Data System), currently version 2. The recommended MRI prostate protocol consists of multiparametric study which consists at least of a diffusion sequence (DWI), high resolution anatomical sequences (T2 weighted) and dynamic contrast enhanced sequences (perfusion imaging). A score is given according to each sequence finding and an overall PI-RADS score is finally given based on a structured

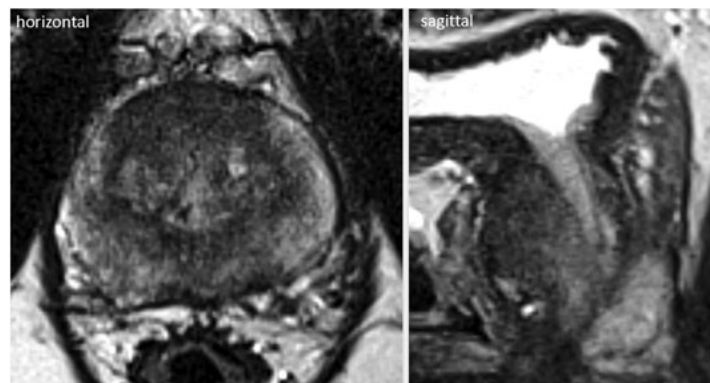


FIGURE 23 MRI of prostate showing low grade inflammatory changes in the peripheral zone

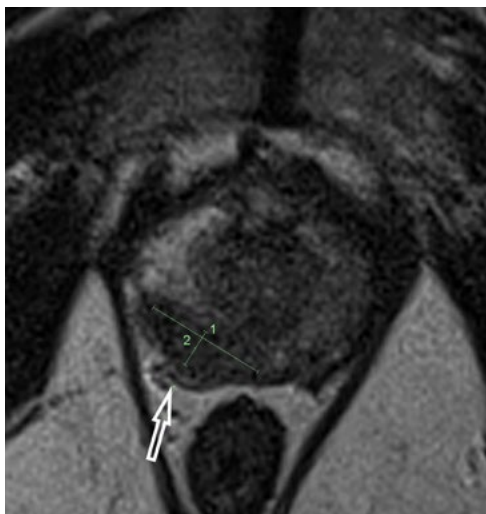


FIGURE 24 MRI of prostate showing prostate cancer in the right posterolateral peripheral zone

reporting scheme. A score of 1–5 is given with one being benign and five being highly suspicious of malignancy. Ideally the MR studies are performed on a three Tesla strength MR scanner negating the need for an endorectal coil to achieve adequate resolution. MR spectroscopy imaging on the prostate is now rarely performed as it rarely adds value to the above multiparametric study.

SECTION 5: DIAGNOSES (MOST COMMON)

This report, like previous ones,^{2,3,5} highlights the need to base diagnoses for male lower urinary tract and pelvic floor dysfunction on the correlation between a man's symptoms, signs and any relevant diagnostic investigations. We include EMG and imaging as possible diagnostic investigations. The diagnoses are categorized according to three subgroups that reflect the function of the lower urinary tract, namely storage, voiding dysfunction and mixed storage and voiding dysfunction. *It should be noted that prevalence data for the relative frequency of the different male diagnoses are scarce.* ^{FNS.1} *More studies are required.* (NEW)

STORAGE DYSFUNCTION (SD) ^{FNS.1} Those diagnoses related to abnormal changes in bladder sensation, detrusor pressure or bladder capacity during filling cystometry. (NEW)

5.1 Bladder Factor

5.1.1 Bladder Oversensitivity (BO)⁵ ^{FNS.2 FN 5.3}
(NEW – Male)

5.1.1.1 Definition: Bladder oversensitivity, a clinical diagnosis made by *symptoms and urodynamic investigations*, most likely to occur in individuals with symptoms of increased daytime frequency and nocturia. A frequency-volume chart shows a clearly reduced average voided volume (by day and night). As noted in section (3.4.3.6), it can be defined as: increased perceived bladder sensation during bladder filling with specific cystometric findings of: (i) early first desire to void (3.4.3.2); (ii) early strong desire to void, which occurs at low bladder volume (3.4.3.4); (iii) low maximum cystometric bladder capacity (3.4.4.2); and (iv) no abnormal increases in detrusor pressure. Specific bladder volumes at which these findings occur vary in different populations. ^{FNS.3}

5.1.2 Detrusor Overactivity (DO) ^{FN 5.1 FNS.4 FNS.5}

^{FNS.6}

5.1.2.1 Definition: As noted in section 3.4.5.2, this diagnosis by *symptoms and urodynamic investigations* is made in individuals with lower urinary tract symptoms (more commonly OAB symptoms – section 1.1.7) when detrusor muscle contractions occur during filling cystometry. (CHANGED)

5.1.2.2 Subtypes

- (i) **Idiopathic (primary) detrusor overactivity:** As noted in 3.4.5.2.1, no identifiable cause for the involuntary detrusor contraction(s). (CHANGED)
- (ii) **Neurogenic (secondary) detrusor overactivity:**^{3,5,13} As noted in 3.4.5.2.2, there is detrusor overactivity and evidence (history; visible or measurable deficit) of a relevant neurological disorder. (CHANGED)
- (iii) **Non-neurogenic (secondary) detrusor overactivity:** As noted in 3.4.5.2.3, an identifiable possible non-neurological cause exists for involuntary detrusor contraction (s) during bladder filling. For example, functional (obstruction); stone, tumor (eg, carcinoma in situ), UTI. (CHANGED)

5.1.3 Reduced compliance storage dysfunction (RCSD): this diagnosis by *symptoms and urodynamic investigations* is made in individuals with lower urinary tract symptoms, more commonly storage symptoms, when there is a non-phasic (at times linear or exponential) rise in detrusor pressure during filling cystometry with generally reduced capacity indicating reduced compliance (**section 3.4.6**). (*NEW*)

5.1.3.1 Reduced compliance (RCSD) incontinence: urinary incontinence directly related to the RCSD. (*NEW*)

5.2 Outlet Factor (Urethra/Sphincter Dysfunction – decreased urethral resistance – incompetence /insufficiency)

5.2.1 Urodynamic Stress Incontinence (USI) ^{FN5.7}

5.2.1.1 Definition: As noted in section (3.6.2.1), this clinical diagnosis by *symptom, sign and urodynamic investigations* involves the finding of involuntary leakage during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor muscle contraction.

^{FN5.7–FN5.10}

5.2.1.2 Subtype: Intrinsic sphincter deficiency (ISD (See 3.6.2.1.1): Very weakened urethral closure mechanism. (*CHANGED*)

VOIDING DYSFUNCTION (VD) Those diagnoses related to abnormally slow and/or incomplete bladder emptying manifest as an abnormally slow urine flow rate (3.1.10) and/or an abnormally high post-void residual (3.2.2), with confirmation by pressure-flow studies (including any related imaging). (*NEW – Male*)

5.3 Bladder factor – (poor or absent detrusor activity)

5.3.1 Detrusor Underactivity (DUA) ^{FN5.11}

5.3.1.1 Definition of DU: As per 3.7.3.2 A diagnosis based on *urodynamic investigations* generally (but not always) with relevant *symptoms, signs* manifest by low detrusor pressure or short detrusor contraction in combination with a low urine flow rate (3.1.10) resulting in prolonged blad-

der emptying and/or a failure to achieve complete bladder emptying within a normal time span, with or without a high postvoid residual (3.2.2) (c.f. “hypocontractile detrusor” – detrusor contraction of reduced strength) (*CHANGED*)

5.3.2 Detrusor Acontractility (DAC) ^{FN5.11}

5.3.2.1 Definition of DAC: As per 3.7.3.3. a diagnosis by *urodynamic investigation*, generally (but not always) with relevant *symptoms, signs* manifest by the absence of an observed detrusor contraction during voiding studies resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span. Voiding in men with DAC is usually achieved by straining or manual pressure on the bladder resulting generally in an abnormally slow urine flow rate (3.1.10) and/or an abnormally high postvoid residual (3.2.2) (*CHANGED*)

5.3.2.2 Subtypes:

- Neurogenic detrusor acontractility (See 3.7.3.3.1)
- Non-neurogenic detrusor acontractility (See 3.7.3.3.2)

5.4 Outlet Factor (Urethral/Sphincter dysfunction)

5.4.1 Bladder Outlet Obstruction (BOO) ^{FN 5.1 FN5.12}

5.4.1.1 Definition of BOO: A diagnosis based on *urodynamic investigations (pressure-flow studies ± imaging)*, generally (but not always) with relevant *symptoms* and/or *signs*, manifest by an abnormally slow urine flow rate (3.1.10) ^{FN5.12} with evidence of abnormally high detrusor voiding pressures and abnormally slow urine flow (3.8.2.1) during voiding cystometry with or without an abnormally high PVR. (3.2.2). ^{FN5.13} (*CHANGED*)

5.4.1.2 Possible sites/causes of BOO: Can be:

5.4.1.2.1 Functional

bladder neck obstruction, detrusor sphincter dysfunctions, pelvic floor overactivity. (*NEW*)

5.4.1.2.2 Mechanical: benign prostatic enlargement, urethral stricture, meatal stenosis). ^{FN5.14-FN5.19}

Imaging of the lower urinary tract especially video-urodynamics and EMG can be required to evaluate location/cause. *(NEW)*

5.4.2 Alternate presentations of Voiding Dysfunction

5.4.2.1 Acute retention of urine: An individual is unable pass any urine despite having a full bladder, which on examination is painfully distended, and readily palpable and/or percussible. *(CHANGED)*

5.4.2.2 Chronic retention of urine: Generally (but not always) painless and palpable or percussible bladder, where there is a chronic high PVR. The patient experiences slow flow and chronic incomplete bladder emptying but can be asymptomatic. Overflow incontinence can occur. Some men with retention present with impaired renal function and/or hydronephrosis. *(CHANGED)*

5.4.2.3 Acute on chronic retention: An individual with chronic retention goes into acute retention and is unable to void. *(NEW)*

5.4.2.4 Retention with overflow: Involuntary loss of urine directly related to an excessively full bladder in retention. *(NEW)*

5.5 MIXED STORAGE AND VOIDING DYSFUNCTION

5.5.1 Bladder Outlet Obstruction and Detrusor Underactivity (BOO-DU)

5.5.1.1 Definition: Urodynamic BOO (3.8.2.1) occurring synchronous with urodynamic DU (3.7.3.2) in pressure-flow analyses. FN5.20 *(NEW)*

5.5.2 Detrusor Overactivity and Bladder Outlet Obstruction (DO-BOO)_{FN5.1}

5.5.2.1 Definition: Urodynamic DO (3.4.5.2) on filling cystometry in the presence of BOO (3.8.2.1) on pressure-flow studies. FN5.21 *(NEW)*

5.5.3 Detrusor Overactivity with Detrusor Underactivity (DO-DU)

5.5.3.1 Definition: Urodynamic DO (3.4.5.2) on filling cystometry) in combination with urodynamic DU (3.7.3.2) on pressure-flow studies. This diagnosis is intended to supersede the old expression “detrusor hyperactivity with impaired contractility” (DHIC) and detrusor overactivity with impaired contractility (DOIC). It is most common in the elderly group. *(NEW)*

Footnotes for Section 5

5.1: Large series data on the relative frequency of diagnoses in men presenting with symptoms of LUT/PF dysfunction are scarce. The relative prevalence of six main diagnoses is known in women.^{4,5} In a series of 504 consecutive men⁶⁴ aged 49-94 years, referred for urodynamic studies including videocystourethrography (VCU) and department review of results because of urological symptoms. The following diagnoses were made:

Detrusor overactivity (DO) 149 (29.6%)

DO plus obstruction (BOO) 124 (24.6%)

i.e. Total DO (54.2%)

Obstruction (BOO) alone 161 (31.9%)

i.e. Total Obstruction (56.5%)

Normal/ No Specific Dx 70 (13.9%) Some more recent diagnoses may not have been present in 1990.

5.2: Prevalence of Bladder Oversensitivity (BOS): In the EPIC study,¹¹⁵ the prevalence rate for men who void with frequencies of greater than eight times per day is approximately 12%. The presence of bladder oversensitivity in urogynaecology patients is 10-13%.⁵

5.3: There should be no known or suspected urinary tract infection. Bladder oversensitivity is often a diagnosis after other more serious conditions such as lower urinary tract malignancy, including carcinoma-in-situ of the bladder, are excluded.

5.4: Prevalence of overall urinary incontinence in men by age:¹¹⁶ 19-44 (4.8%); 45-64 (11.2%); 65-79 (21.1%); >80 (32.2%)

5.5: Prevalence of urgency (urinary) incontinence in men by age¹¹⁷: 19-44 (3.1%); 45-64 (7.8%); 65-79 (11.7%); >80 (18.1%)

5.6: Abnormal detrusor contractions can be, at times, observed during filling cystometry without the patient being symptomatic.

5.7: Prevalence of urodynamic stress incontinence (USI): Prevalence of stress (urinary) incontinence in men by age:¹¹⁵ 19-44 (0.7%); 45-64 (3.8%); 65-79 (2.7%); >80 (N/A) or overall for men over 18 years¹¹⁷ (1.4%).

5.8: Men, unlike women, do not develop significant urethral hypermobility (with radical prostatectomy a possible exception), and hence urodynamic stress incontinence is most often associated with intrinsic sphincter deficiency, rather than urethral hypermobility. Sphincter deficiency is most commonly a result of either pelvic trauma or post-prostatectomy, either transurethral or radical, or neurological disorder.

5.9 Prevalence for urinary incontinence after transurethral prostatectomy (TURP) for benign prostatic disease appears between 0.5% and 3%.^{118–122}

5.10: Prevalence for post radical prostatectomy: The rates of post radical prostatectomy incontinence varies depending on the definition used and the duration of follow-up. However, the long-term incidence ranges between 4% and 8%.^{117–122}

5.11: Prevalence of either detrusor underactivity (DU) or acontractility (DAC): In a study involving a review of urodynamic data of 1179 patients aged 65 and older, Jeong et al. reported the prevalence of DUA of 40.2 % in men.¹²³

5.12: Urodynamic BOO can be diagnosed using the ICS Nomogram⁸⁹. The formula used, known as the bladder outlet obstruction index (BOOI) is calculated by detrusor pressure at maximum flow ($P_{det.Qmax}$) minus two times the maximum urinary flow ($BOOI = P_{det.Qmax} - 2 Q_{max}$). A BOOI with a value of >40 defines BOO, less than 20 defines absence of BOO, and in between denotes equivocal BOO. Alternative classifications for BOO are the Schäfer grades (0-VI)^{90,91} and CHES classification.⁹²

5.13 The evidence in men regarding PVR and BOO is not clear. Urodynamic studies in adult male patients with clinical BPH demonstrated that approx. 30% of men with PVR ≥ 50 mL do not have BOO/BPO, independent on the magnitude of PVR¹²⁴ and, vice versa, 24% of men with urodynamically confirmed BOO/BPO have PVR < 50 mL or even 0 mL.^{124–125}

5.14: The level of obstruction can usually be diagnosed during voiding video cysto-urethrography. It may be aided by sphincter or pelvic floor EMG during voiding.

5.15: Bladder outlet obstruction from an enlarged prostate: BOO where the cause is benign prostatic enlargement (BPE) with clinical or imaging evidence.

5.16: Bladder outlet obstruction from the bladder neck: BOO where the cause is at the level of the bladder neck (clinical or radiological). The pelvic floor electromyogram (EMG) trace should be quiet during voiding in these patients.

5.17: Bladder outlet obstruction from pelvic floor muscular overactivity: Bladder outflow obstruction where the cause is at the level of the pelvic floor musculature (clinical, urodynamic or radiological). The pelvic floor electromyogram (EMG) trace may not be positive during voiding.

5.18: Bladder outlet obstruction from the rhabdosphincter (external urinary sphincter): BOO where the cause is at the level of rhabdosphincter (clinical, urodynamic or radiological). The pelvic floor electromyogram (EMG) trace may not be positive during voiding.

5.19: Bladder outlet obstruction from stenosis of bladder neck or urethra due to fibrosis: Bladder neck stenosis may occur secondary to prostate surgery for benign disease, radical prostate surgery, radiotherapy or trauma.

5.20: Currently, although many experts in this field agree that this entity exists, there is currently no consensus on its

definition because there is currently no consensus on defining detrusor underactivity. There is a Maastricht-Hannover Nomogram¹²⁶ may be used to diagnose reduced detrusor contractility in the presence of obstruction (or vice versa).

5.21: Up to 83%¹²⁷ of men with urodynamic BOO may have concomitant urodynamic DO. Both BOO-grade and advancing age were independent factors of DO in men. The more severe BOO, the higher the chance of DO.

AREAS FOR FURTHER RESEARCH

In the preparation of this document, the following “gaps” in knowledge in male LUT/PF dysfunction have been noted compared to the equivalent for female LUT/PF dysfunction:⁵

- Post-void residuals in men with symptoms of LUT/PF dysfunction.
- Male diuresis data.
- Bladder compliance – normal and abnormal values in men.
- Additional large patient series for the prevalence data and the relative frequency of the most common male diagnoses.⁶⁴

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An International Continence Society (ICS) report on the terminology for adult neurogenic lower urinary tract dysfunction (ANLUTD)

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Introduction: The terminology for adult neurogenic lower urinary tract dysfunction (ANLUTD) should be defined and organized in a clinically based consensus Report.

Methods: This Report has been created by a Working Group under the auspices and guidelines of the International Continence Society (ICS) Standardization Steering Committee (SSC) assisted at intervals by external referees. All relevant definitions for ANLUTD were updated on the basis of research over the last 14 years. An extensive process of 18 rounds of internal and external review was involved to exhaustively examine each definition, with decision-making by collective opinion (consensus).

Results: A Terminology Report for ANLUTD, encompassing 97 definitions (42 NEW and 8 CHANGED, has been developed. It is clinically based with the most common diagnoses defined. Clarity and user-friendliness have been key aims to make it interpretable by practitioners and trainees in all the different groups involved not only in lower urinary tract dysfunction but additionally in many other medical specialties.

Conclusion: A consensus-based Terminology Report for ANLUTD has been produced to aid clinical practice and research.

KEYWORDS

adult, dysfunction, neurogenic, terminology, urinary tract

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1 | INTRODUCTION

“Adult” refers to “a fully grown and physically mature individual”^{1,2} “Neurogenic” refers to “originating in the nervous system.”² “Lower Urinary Tract (LUT)” refers to the bladder, urethra (and prostate in men).² “Dysfunction”

refers to abnormal or difficult function. “Adult neurogenic lower urinary tract dysfunction (ANLUTD)” refers to abnormal or difficult function of the bladder, urethra (and/or prostate in men) in mature individuals in the context of clinically confirmed relevant neurologic disorder. There is currently no single document focusing on the definitions related to ANLUTD. Many ANLUTD symptoms and signs have been defined in core current terminology reports for lower urinary tract and pelvic floor dysfunction.^{3,4,5} With the advantage of ongoing research into ANLUTD epidemiology, pathophysiology as well as pharmacological initiatives by generalist and specialist medical practitioners, it is timely to reconsider the different definitions.

2 | METHODOLOGY

This document was developed according to the published methodology of the International Continence Society Standardization Steering Committee.⁶ This document aligns with the previous standardizations of the ICS on lower urinary tract dysfunction and is adapted to a group of patients with ANLUTD. Thus, ANLUTD can be diagnosed in the presence of neurological disease only. The intent is to supersede older terminology of “Neurogenic Bladder” or “Neurogenic Bladder Dysfunction”: these definitions are misleading, because the dysfunction(s) may involve not only the bladder but also the urethral sphincter competence or relaxation. Furthermore, using a single term to indicate a broad spectrum of dysfunctions is restrictive and unclear. For instance, there are many differences, in terms of investigations needed, treatment and prognosis, between a male patient with spinal cord injury (SCI) at cervical level and a female patient with Parkinson’s disease, both complaining of Lower Urinary Tract Symptoms (LUTS) and “labeled” as having a “Neurogenic Bladder.” Finally, these definitions could lead to the conviction that the dysfunction may be due to a problem of the bladder, whilst the primary defect is in the central or peripheral nervous system. The document contains some original standardization of LUTS-related definitions, some modified with designation “CHANGED” and some newly defined — “NEW.”

This Terminology Report is inherently and appropriately a definitional document, collating the definitions of those terms, that is, “words used to express a defined concept in a particular branch of study,”⁷ here ANLUTD. Emphasis has been on comprehensively including those terms in current use in the relevant peer-reviewed literature. The definitions of those terms will be reviewed with all available evidence. The aim is to assist clinical practice and research. Some new and revised terms have been included. Explanatory notes on definitions have been referred, where

possible, to the “Footnotes” section. Like all the other joint ICS terminology reports, every effort has been made to ensure this Report is:

1. User-friendly: It should be able to be understood by all clinical and research users.
2. Clinically based: Refers to the relevant clinical practice.
3. Origin: Where a term’s existing definition (from one of multiple sources used) is deemed appropriate, that definition will remain and be duly referenced. A large number of these, because of their long-term use, have now become generic, as apparent by their listing in medical dictionaries.
4. Able to provide explanations: Where a specific explanation is deemed appropriate to describe a change from earlier definitions or to qualify the current definition, this will be included as Footnote to this paper. Wherever possible, evidence-based medical principles will be followed.

This document has involved 18 rounds of full review, by co-authors, of an initial draft (Version 1) completed 16.09.2014. Comments for each round of review were collated and debated as necessary in order to form a subsequent version. Live meetings on the document took place in Zurich and Tokyo.*

This document covers symptoms, signs, urodynamic observations and definitions, clinical diagnoses, and treatment.

3 | RESULTS

1 ANLUTD SYMPTOMS:

Symptom: Any morbid phenomenon or departure from the normal in structure, function, or sensation, experienced by individual and indicative of disease or a health problem.² Symptoms are either volunteered by, or elicited from the individual or may be described by the patient’s caregiver.^{3,4,5} LUTS are classified as neurogenic in the presence of a relevant neurological disease ONLY. Symptoms are a subjective indicator of, or change in disease as perceived by the patient, carer, or partner that may lead the patient to seek help from healthcare professionals. They are usually qualitative. In general, LUTS cannot be used to make a definitive diagnosis. LUTS in people with neurological disease can also indicate pathologies other than NLUTD, such as urinary infection.

*14th International Neuro-Urology Meeting, Zürich 2016 and International Continence Society Meeting, Tokyo, 2016.

Three groups of LUTS are: storage, voiding, and post micturition symptoms.

1.1. Storage Symptoms are experienced during the storage phase of the bladder, (CHANGED).[†]

1.1.1. Increased daytime urinary frequency: Complaint that micturition occurs more frequently during waking hours than previously deemed normal.⁵

1.1.2. Nocturia is waking to pass urine during the main sleep period.⁸ (CHANGED)

1.1.3. Urgency is the complaint of a sudden compelling desire to pass urine, which is difficult to defer.⁴

1.1.4. Urinary incontinence: Complaint of involuntary loss of urine.⁵ ‡

1.1.4.1. Stress Urinary Incontinence is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.⁴

1.1.4.2. Urgency Urinary Incontinence is the complaint of involuntary loss of urine associated with urgency.⁵

1.1.4.3. Mixed Urinary Incontinence is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing.⁵

1.1.4.4. Enuresis: Complaint of intermittent incontinence that occurs during periods of sleep⁸ (NEW).

1.1.4.4.1. Primary enuresis has been present lifelong (NEW).

1.1.4.4.2. Acquired enuresis is an enuresis developed in adults (NEW).[§]

1.1.4.5. Continuous (urinary) incontinence: Complaint of continuous involuntary loss of urine⁵

1.1.4.6. Impaired cognition urinary incontinence: Complaint of periodic urinary incontinence that the individual with cognitive impairment

reports to have occurred without being aware of it. (NEW)

1.1.4.7. Impaired mobility urinary incontinence: Complaint of inability to reach the toilet on time for voiding because of physical or medical disability (NEW).^{||}

1.1.4.8. Sexual activity urinary incontinence is the individual report of urinary incontinence associated with or during sexual activity (NEW).[¶]

1.1.4.9. Other situational types of urinary incontinence may exist, for example giggle incontinence, or incontinence associated with epileptic seizures, sphincter denervation in cauda equina and in the Onuf's nuclei lesions in Multiple system atrophy (NEW).

1.1.5. Bladder Sensation can be defined, during history taking by following categories.

1.1.5.1. Normal: the individual is aware of bladder filling and increasing sensation up to a strong desire to void.⁴

1.1.5.2. Increased: Increased bladder sensation: complaint that the desire to void during bladder filling occurs earlier or is more persistent to that previous experienced. N.B. This differs from urgency by the fact that micturition can be postponed despite the desire to void.⁵

1.1.5.3. Reduced: Reduced bladder sensation: complaint that the definite desire to void occurs later to that previously experienced despite an awareness that the bladder is filling.⁵

1.1.5.4. Absent: the individual reports no sensation of bladder filling or desire to void.⁴

1.1.5.5. Non-specific bladder awareness: the individual reports no specific bladder sensation, but may perceive, for example, abdominal fullness,

[†]Some symptoms in NLUTD cannot be defined properly when there is a significant reduction in motor and/or sensory function. "Complaint" is intended to mean the patient (or sometimes caregiver) expresses the symptom is present, regardless of whether it also causes them bother.

[‡]Loss of urine can result from: (a) incontinence; (b) involuntary passing of urine; (c) incontinence that is not derived from an abnormality in the lower urinary tract or its innervation, but from immobility, cognitive disability, and decreased motivation impaired patient's mobility enhances likelihood of being incontinent.

[§]Mature CNS regulation ensures voiding (detrusor contraction with outlet relaxation) is under voluntary control. Abnormal voiding reflexes, or disinhibition, may result in the person passing urine without voluntary control. Confirming the precise underlying mechanism(s) is often not possible in routine clinical practice. Enuresis is considered different from urgency urinary incontinence.

^{||}This inability includes (any combination of) the individual's physical as well as social causes or reasons. Other signs or symptoms of LUTD should not be present, or should be reported by the professional (as primary or as accessory) (eg, "Urgency urinary incontinence" with "mobility impairment"; or "Mobility impairment urinary incontinence" with "stress urinary incontinence.")

[¶]Sexual activity urinary incontinence may be reported as a single symptom, but may also be reported in association with other LUTD. Sexual activity urinary incontinence is documented (in combination with other symptoms) as being the primary or the as the associated symptom (or vice versa) based on the individual's expression of predominance.

vegetative symptoms, urethral sensations or spasticity as bladder filling awareness or a sign of bladder fullness. (CHANGED).

- 1.1.5.6. Abnormal sensations:** awareness of sensation in the bladder, urethra or pelvis, described with words like “tingling,” “burning,” or “electric shock,” in the setting of a clinically relevant neurologic disorder (eg, incomplete spinal cord lesion) (NEW).
- 1.1.5.7. Bladder Pain:** Complaint of suprapubic or retropubic pain, pressure or discomfort, related to the bladder, and usually increasing with bladder filling. It may persist or be relieved after voiding.⁴
- 1.2. Voiding symptoms:** A departure from normal sensation or function, experienced by a person during the act of micturition.^{2 #}
- 1.2.1. Slow stream:** Complaint of a urinary stream perceived as slower compared to previous performance or in comparison with others.⁵
- 1.2.2. Spraying (splitting)** of the urinary stream: Complaint that the urine passage is a spray or split rather than a single discrete stream.⁵
- 1.2.3. Intermittent stream (Intermittency)** is the term used when the individual describes urine flow, which stops and starts on one or more occasions, during micturition.⁴
- 1.2.4. Hesitancy:** Complaint of a delay in initiating micturition.⁵
- 1.2.5. Straining to void:** Complaint of the need to make an intensive effort (by abdominal straining, Valsalva or suprapubic pressure) to either initiate, maintain or improve the urinary stream.⁵
- 1.2.6. Terminal dribble** is the term used when an individual describes a prolonged final part of micturition, when the flow has slowed to a trickle/dribble.⁴
- 1.3. Post Micturition Symptoms** are experienced immediately after micturition.⁴
- 1.3.1. Feeling of incomplete emptying:** Complaint that the bladder does not feel empty after micturition.⁵
- 1.3.2. Post micturition leakage:** Complaint of a further involuntary passage of urine following the completion of micturition.^{4,5}

[#]Some symptoms in NLUTD cannot be defined properly when there is a significant reduction in motor and/or sensory function.

2 ANLUTD SIGNS

Sign: Any abnormality indicative of disease or a health problem, discoverable on examination of the patient; an objective indication of disease² or a health problem. Signs are observed by the physician including simple means to verify symptoms and quantify them.

Measuring the frequency, severity and impact of lower urinary tract symptoms by asking the patient to record micturitions and symptoms for a period of days provides invaluable information. The recording of “micturition events” can be in three main forms.^{**}

- 2.1. Micturition Time Chart:** this records only the times of micturitions, day and night, for at least 24 h.⁴
- 2.2. Frequency Volume Chart (FVC):** this records the volumes voided as well as the time of each micturition, day and night, for at least 24 h.⁴
- 2.3. Bladder Diary:** this records the times of micturitions and voided volumes, incontinence episodes, pad usage, and other information such as fluid intake, the degree of urgency, and the degree of incontinence.^{4,9 ††}

3 ANLUTD URODYNAMIC OBSERVATIONS AND DEFINITIONS

3.1 Filling cystometry definitions

Bladder storage function should be described according to bladder sensation, detrusor activity, bladder compliance and bladder capacity. Storage abnormalities identified may or may not be the result of a clinically relevant neurologic disorder.

3.1.1. Bladder sensation during filling cystometry

3.1.1.1. Normal bladder sensation can be judged by three defined points (as per ICS recommendations) noted during filling cystometry: First sensation of bladder filling, First desire to void and Strong desire to void, and evaluated in relation to the bladder volume at that moment and in relation to the patient's symptomatic complaints.^{4,7}

3.1.1.2. Reduced Bladder Sensation: Bladder sensation perceived to be diminished during filling cystometry.⁵

^{**}Validated questionnaires are useful for recording symptoms, their frequency, severity and bother, and the impact of LUTS on QoL. The instrument used should be specified. Some instruments were not validated in NLUTD or are impossible to implement because of sensory or motor deficiency in NLUTD.

^{††}Recommended minimum duration of 3 days.⁹ Some information could be difficult or impossible to collect because of sensory or motor deficiency in NLUTD.

- 3.1.1.3. Absent Bladder Sensation:** The patient reports no bladder sensation during filling cystometry.⁵
- 3.1.1.4. Bladder oversensitivity:** Increased perceived bladder sensation during bladder filling with: an early first desire to void; an early strong desire to void, which occurs at low bladder volume; a low maximum cystometric bladder capacity and no abnormal increases in detrusor pressure.⁵
- 3.1.1.5. Abnormal sensations:** awareness of sensation in the bladder, urethra or pelvis, described with words like “tingling,” “burning,” or “electric shock,” in the setting of a clinically relevant neurologic disorder (eg, incomplete spinal cord lesion) (NEW).
- 3.1.1.6. Non-specific bladder awareness:** perception of bladder filling as abdominal fullness, vegetative symptoms, spasticity or other “non-bladder awareness,” in the setting of a clinically relevant neurologic disorder (eg, incomplete spinal cord lesion) (NEW).
- 3.1.1.7. Bladder Pain:** An unpleasant sensation (pain, pressure, discomfort) perceived to be related to the urinary bladder. (CHANGED).^{‡‡}
- 3.1.2. Bladder capacity during filling cystometry**
- 3.1.2.1. Cystometric capacity** is the bladder volume at the end of the filling cystometry, when “permission to void or to empty the bladder” is usually given. The end point should be specified, for example, if filling is stopped when the patient has a normal desire to void. The cystometric capacity is the volume voided together with any residual urine.^{4§§}
- 3.1.3. Detrusor function during filling cystometry**
- 3.1.3.1. Neurogenic detrusor overactivity** is an urodynamic observation characterized by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked in the setting of a clinically relevant neurologic disease.^{4|||}
- Specific types of neurogenic detrusor overactivity include:
- 3.1.3.1.1. Phasic detrusor overactivity** is defined by a characteristic wave form, and may or may not lead to urinary incontinence.^{4¶¶}
- 3.1.3.1.2. Terminal detrusor overactivity** is defined as involuntary detrusor contraction occurring near or at the maximum cystometric capacity, which cannot be suppressed, and results in incontinence or even reflex bladder emptying (reflex voiding) (CHANGED).^{###}
- 3.1.3.1.3. Sustained detrusor overactivity** is defined as a continuous detrusor contraction without returning to the detrusor resting pressure (NEW).
- 3.1.3.1.4. Compound detrusor contraction** is defined as a phasic detrusor contraction with a subsequent increase in detrusor and base pressure with each subsequent contraction (NEW).
- 3.1.3.1.5. High pressure detrusor overactivity** is defined as a phasic, terminal, sustained or compound high maximal detrusor overactivity with the high detrusor pressure perceived by investigator to be potentially detrimental to the patient's renal function and/or health and the value should be defined in the report (NEW).

^{‡‡}The pain may be felt suprapubically or retropubically. It usually increases with bladder filling, and may persist after voiding. Bladder pain may or may not relate to clinically relevant neurologic disorder.

^{§§}In certain types of dysfunction including neurogenic LUTD, the cystometric capacity cannot be defined in the same terms. In the absence of sensation, the cystometric capacity is the volume at which the clinician decides to terminate filling. The reason(s) for terminating filling should be defined in the report, for example, high detrusor filling pressure, large infused volume or pain. If there is uncontrollable voiding/bladder emptying, it is the volume at which this begins. In the presence of sphincter incompetence the cystometric capacity may be significantly increased by occlusion of the urethra, for example, by a Foley catheter balloon.⁴

^{|||}Provoked contraction may be elicited by cough, change of position etc., or by urethral/sphincter to bladder reflex.

^{¶¶}Phasic detrusor contractions are not always accompanied by any sensation, or may be interpreted as a first sensation of bladder filling, or as a normal desire to void. In neurogenic LUTD phasic detrusor contraction may elicit autonomic dysreflexia or abnormal bladder sensation.

^{###}Terminal detrusor overactivity is typically associated with reduced bladder sensation, for example in the elderly stroke patient when urgency may be felt as the voiding contraction occurs. However, in neurogenic LUTD phasic detrusor contraction may elicit autonomic dysreflexia or abnormal bladder sensation and in complete spinal cord injury patients there may be no sensation whatsoever.

3.1.3.1.6. Neurogenic Detrusor Overactivity Incontinence is incontinence due to involuntary neurogenic detrusor overactivity (NEW).^{***}

3.1.3.2. Leak point pressures:

3.1.3.2.1. Detrusor Leak Point Pressure (DLPP) is defined as the lowest detrusor pressure at which urine leakage occurs in the absence of either a detrusor contraction or increased abdominal pressure.⁴

3.1.3.2.2. Detrusor Overactivity Leak Point Pressure (DOLPP) is defined as the lowest detrusor pressure rise with detrusor overactivity at which urine leakage first occurs in the absence of voluntary detrusor contraction or increased abdominal pressure (NEW).

3.1.3.2.3. Detrusor Leak Point Volume (DLPV) is defined as a bladder volume at which first urine leakage occurs, either with detrusor overactivity or low compliance (NEW).

3.1.3.2.4. Abdominal Leak Point Pressure (ALPP) is the intravesical pressure at which urine leakage occurs due to increased abdominal pressure in the absence of a detrusor contraction.^{4 †††}

3.1.3.2.5. Bladder compliance during filling cystometry describes the relationship between change in bladder volume

and change in detrusor pressure.^{4 †††}

3.2. Pressure Flow Study Definitions

3.2.1. Detrusor function during the voiding phase in people that can initiate voluntary voiding

3.1.3.2.1. Normal detrusor function is a voluntarily initiated continuous detrusor contraction that leads to complete bladder emptying within a normal time span, and in the absence of obstruction. For a given detrusor contraction, magnitude of the recorded pressure rise will depend on the degree of outlet resistance.⁴

3.1.3.2.2. Neurogenic detrusor underactivity is defined as a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span in the setting of a clinically relevant neurologic disorder (NEW).

3.1.3.2.3. Neurogenic acontractile detrusor is one that cannot be demonstrated to contract during urodynamic studies in the setting of a clinically relevant neurologic lesion (NEW).

3.1.3.2.4. Balanced bladder emptying is a bladder emptying with physiological detrusor pressure and low residual as perceived by the investigator, and should be defined in the report (NEW).

^{†††}Compliance is calculated by dividing the volume change (ΔV) by the change in detrusor pressure (Δp_{det}) during that change in bladder volume ($C = \Delta V / \Delta p_{det}$). It is expressed in mL/cm H₂O. The normal value are not well defined however any report on compliance must include reference to the rate of filling and position of patient. A variety of means of calculating bladder compliance has been described. The ICS recommends that three standard points should be used for compliance calculations: the investigator may wish to define additional points. These points are measured excluding any detrusor contraction. The standards points are: (1) The detrusor pressure at the start of bladder filling and the corresponding bladder volume (usually zero). (2) The detrusor pressure at the bladder volume when the bladder pressure rises significantly and decreased compliance commences (Low compliance starting volume). (3) The detrusor pressure (and corresponding bladder volume) at cystometric capacity or immediately before the start of any detrusor contraction that causes significant leakage (and therefore causes the bladder volume to decrease, affecting compliance calculation).

^{***}Incontinence can occur with or without any sensation of urgency or awareness.

^{†††}This test can be applied to both neurogenic and non-neurogenic patients with stress urinary incontinence.

3.2.2. Detrusor function during pressure flow studies in people that cannot initiate voluntary voiding.

3.2.2.1. Initiated reflex bladder emptying is an artificially elicited LUT reflex comprised of various manoeuvres (exogenous stimuli) performed by the patient or the therapist, resulting in complete or incomplete bladder emptying (NEW).^{§§§}

3.2.3 Sphincter function during pressure flow studies

3.2.3.1. Detrusor-Sphincter Dyssynergia (DSD): describes a detrusor contraction concurrent with an involuntary contraction of the urethral and/or periurethral striated muscle. Occasionally flow may be prevented altogether.^{¶¶¶¶}

3.2.3.2. Non-relaxing urethral sphincter is characterized by a non-relaxing, obstructing urethral sphincter resulting in reduced urine flow.^{¶¶¶¶¶}

3.2.3.3. Delayed relaxation of the urethral sphincter is characterized by impaired and hindered relaxation of the sphincter during voiding attempt resulting in delay of urine flow (NEW).^{###}

4 ANLUTD CLINICAL DIAGNOSES

Clinical diagnoses are the clinical manifestation of symptoms and signs, which are characterized by specific urodynamic findings and/or non-urodynamic evidence defined by the presence of urodynamic observations associated with characteristic symptoms or signs and/or non-urodynamic evidence of relevant pathological process.

^{§§§}Spontaneous reflex bladder emptying is termed Detrusor Overactivity Incontinence

^{¶¶¶¶}Neurological disease that impairs the ability of the PMC or its pathways to co-ordinate function of the LUT spinal centres, leading to detrusor contraction against a contracting outlet. Detrusor sphincter dyssynergia (DSD) typically occurs in patients with a supra-sacral lesion, and is uncommon in lesions of the lower cord. DSD is responsible for bladder outlet obstruction and occasionally flow may be prevented altogether.

^{¶¶¶¶¶}Non-relaxing sphincter obstruction is found in individuals with a neurological lesion (sacral and infra-sacral lesions such as meningomyelocele) and after radical pelvic surgery. It may relate to both smooth and striated muscle sphincter.

^{###}This can occur in some patients with Parkinson's disease or muscular dystrophy

This depends on the extent of loss of neurological function and depends on which part(s) of the nervous system is affected. Neural lesions are described according to time of onset, risk of neurological progression, completeness, and neurological level.

4.1. Spinal Shock Phase is usually temporary following acute neurologic insult or SCI that is characterized by loss of sensory, motor and reflex activity below the level of injury. NLUTD in Spinal Shock: is usually a temporary complete painless urinary retention (NEW).

4.2. Suprapontine Lesion (SPL) is a neurological lesion above the pons (forebrain or midbrain). NLUTD in SPL: there is a reflex contraction of the detrusor with impaired cerebral regulation and central inhibition and usually synergistic voiding/bladder emptying (NEW)^{****}

4.3. Suprasacral spinal cord/pontine lesion (SSL) is a neurological lesion in suprasacral spine and/or pons. NLUTD in SSL: Detrusor overactivity (DO) and DO incontinence are common, with or without detrusor-urethral sphincter dyssynergia (DSD), often resulting in a significant post void residual (PVR) and "high pressure" bladder (NEW).^{††††}

4.4. Sacral Spinal Cord Lesion (SSCL) is a neurological lesion in the sacral spinal cord. NLUTD in SSCL; findings include acontractile detrusor with or without decreased bladder compliance and usually with impaired sphincter activity. (NEW).^{****}

^{****}Lesions resulting from cerebral or brainstem lesion with preservation of the pontine micturition center (PMC), that is, cerebrovascular disease, degenerative disease, hydrocephalus, intracranial neoplasms, traumatic brain injury (the list is incomplete). This may lead to inability to initiate voiding, inappropriate timing of bladder emptying, detrusor overactivity (DO), and DO incontinence.

^{††††}Lesion persists after resolution of the spinal shock. Bladder sensation may be somewhat preserved (incomplete lesions) but voluntary control of the micturition reflex arc is lost. Altered function of the sympathetic spinal centre in the thoraco-lumbar spinal cord may alter blood pressure control. Complete SSL above T6 may be associated with autonomic dysreflexia when there is residual sympathetic nucleus function; this should be included in the description of the lesion.

^{****}There is a loss of parasympathetic control of the detrusor and a somatic denervation of the external urethral sphincter. Sensory impairment is typically associated with a complete lesion. Some afferent pathways remain intact due to potential preservation of hypogastric afferents. Some patients may have stress urinary incontinence (SUI) due to sphincter deficiency (loss of Onuf's nuclei).

- 4.5. Infrasacral (cauda equina and peripheral nerves) Lesion (CEPNL)** is a neurological lesion affecting the cauda equina and/or peripheral nerves. NLUTD in CEPNL: acontractile detrusor and/or SUI may be present. In diabetic neuropathy, detrusor overactivity can be seen in combination with the above (NEW).^{§§§§}
- 4.6. Mixed Neuronal Lesion** is resulting from lesions of the neural pathway at different levels of the central nervous system concurrently (NEW)
- 4.7. Autonomic Dysreflexia** is a syndrome resulting from upper thoracic or cervical spinal cord injury above T6, elicited by a stimulus in the field of distribution of the autonomous sympathetic nucleus, characterized by unregulated sympathetic function below the lesion and compensatory autonomic responses (NEW).^{|||||}
- 4.7.1. Asymptomatic Autonomic Dysreflexia:** increase of blood pressure without any other symptoms (NEW).^{¶¶¶¶}
- 4.8. Neurogenic Overactive Bladder** is characterized by urgency, with or without urgency urinary incontinence, usually with increased daytime frequency and nocturia in the setting of a clinically relevant neurologic disorder with at least partially preserved sensation (NEW).^{####}
- 4.9. Voiding dysregulation** is urination in situations which are generally regarded as socially inappropriate, such as while still fully dressed, or in a public setting away from toilet facilities (NEW).
- 4.10. Involuntary voiding** is both a symptom and a diagnosis of sporadic bladder emptying

when awake, without intention to void (NEW).^{*****}

- 4.11. Urinary retention** is an inability to properly empty the bladder and can be divided into acute, chronic, complete and incomplete (NEW).
- 4.11.1. Acute retention** of urine is defined as an acute event of painful, palpable or percussable bladder, when the patient is unable to pass any urine when the bladder is full.^{5 †††††}
- 4.11.2. Chronic retention** of urine is defined as a non-painful bladder, which remains palpable or percussable after the patient has passed urine. Such patients may be incontinent.^{4†††††}
- 4.11.3. Complete urinary retention** is an inability to empty any amount of bladder volume (or the requirement for use of a catheter, consciously or unconsciously due to anatomical or functional bladder outlet obstruction, detrusor underactivity or both (NEW).
- 4.11.4. Incomplete urinary retention** is impaired bladder emptying due to anatomical or functional bladder outlet obstruction, detrusor underactivity or both, when the voided volume is smaller than Post Void Residual.
- 4.11.5. Post void residual (PVR)** is defined as the volume of urine left in the bladder at the end of micturition.⁴

^{§§§§}The peripheral nerves and the lower spinal centres are often grouped under the term "lower motor neurones," as damage to these structures causes loss of contractile function. Elsewhere, the neurological lesions are termed "upper motor neuron lesions," where the consequences are impaired co-ordination and reflex function. This is a considerable simplification, and anatomically inaccurate, so the committee considers categorization into lower versus upper motor neuron lesions should no longer be supported.

^{|||||}It is potentially a medical emergency characterized by hypertension, bradycardia, severe headaches, and flushing above, with pallor below the cord lesion, and sometimes convulsions.¹⁰

^{¶¶¶¶}This can happen during routine urodynamic bladder studies or bowel program.¹¹

^{####}These symptom combinations in case of preserved sensation, are suggestive of urodynamically demonstrable detrusor overactivity, but can be due to other forms of LUTD. These terms can be used if there is no proven infection or other obvious non neurological disease.

^{*****}Usually the voiding reflex is preserved, and there is only lack of proper inhibition of the voiding reflex. If that happens when asleep it is called Acquired Enuresis.

^{†††††}Although acute retention is usually thought of as painful, in certain circumstances pain may not be a presenting feature, for example, when due to prolapsed intervertebral disc, post-partum, or after regional anaesthesia such as an epidural anaesthetic. The retention volume should be significantly greater than the expected normal bladder capacity. In patients after surgery, due to bandaging of the lower abdomen or abdominal wall pain, it may be difficult to detect a painful, palpable, or percussable bladder.⁴

^{†††††}The ICS no longer recommends the term "overflow incontinence" This term is considered confusing and lacking a convincing definition. If used, a precise definition and any associated pathophysiology, such as reduced urethral function, or detrusor overactivity/low bladder compliance, should be stated. The term chronic retention, excludes transient voiding difficulty, for example, after surgery for stress incontinence, and implies a significant residual urine; a minimum figure of 300 mls has been previously mentioned.⁴

5 ANLUTD TREATMENTS DEFINITIONS

5.1 Bladder Reflex Triggering comprises various manoeuvres performed by the patient or the therapist to elicit reflex bladder emptying by exteroceptive stimuli (relating to, being, or activated by stimuli received from outside of the bladder).^{4 §§§§§}

5.2 Bladder Expression refers to various compression manoeuvres aimed at increasing intravesical pressure to facilitate bladder emptying with or without obvious sensation from the bladder. (CHANGED).^{¶¶¶¶¶}

5.3 Catheterization is a technique for bladder emptying employing a catheter to drain the bladder or a urinary reservoir.⁴

5.3.1. Indwelling catheterization; an indwelling catheter remains in the bladder, urinary reservoir or urinary conduit for a period longer than one emptying.^{4 ¶¶¶¶¶}

5.3.2. Intermittent Catheterization (IC) is defined as drainage of the bladder or a urinary reservoir with subsequent removal of the catheter mostly at regular intervals. (CHANGED)

5.3.2.1. Clean IC (CIC): use of a clean technique. This implies ordinary hand and genitals washing techniques and use of disposable or cleansed reusable catheters. (CHANGED)

5.3.2.2. Aseptic IC: This implies genital antiseptic preparation and the use of sterile (single-use) catheters and instruments/gloves in a designated clean area. (NEW)

5.3.2.3. Sterile IC: Complete sterile setting, including genital skin antiseptics, sterile gloves, forceps, gown and mask (NEW).^{#####}

5.3.2.4. No-touch technique IC: This was introduced as an easier way for the patient to perform self-intermittent catheterization with a ready-to-use catheter (pre-lubricated catheter, usually a hydrophilic catheter). A pull-in aid or special packages

are used to handle the catheter without directly touching the sliding surface of the hydrophilic catheter (NEW).^{*****}

5.4 Electrostimulation

5.4.1. Direct electrical neurostimulations a direct stimulation of the nerves or neural tissue to effect function of the end organ. It is done through electrodes implanted directly or near the nerve or neural tissue (NEW).^{†††††}

5.4.2. Electrical neuromodulation is the stimulation of the nerves or neural tissue to modulate function and induce therapeutic response of the LUT (NEW).^{§§§§§}

5.4.3. Transcutaneous electrical nerve stimulation (TENS) is electrical stimulation of the nerves through intact skin to modulate function and induce therapeutic response of the LUT (NEW).^{§§§§§}

5.4.4. Pelvic electrical stimulation is the application of electrical current to stimulate the pelvic viscera or their nerve supply (NEW).^{¶¶¶¶¶}

4 | CONCLUSIONS

Standardized terminology is an important aspect on research and communication in NLUTD. The International Continence Society (ICS) continues to have a key role in standardizing terminology related to lower urinary tract and pelvic organ dysfunction.

^{*****}The ICS Working Group recognizes that there is a lack of uniformity and consensus on the classification of aseptic technique in previously published studies, especially with regard to genital hygiene. Thus, it is strongly recommended that all aspects related to the technique of intermittent catheterization are described as completely as possible in the context of clinical research, including the environment in which catheterization is performed, the type of lubricant, the catheter characteristics, the use of gloves, as well as the genital hygiene mode.

^{†††††}For example, stimulation of the anterior sacral roots, that is, Brindley's stimulator.

^{§§§§§}It is done through electrodes implanted directly on or near the nerves or neural tissue: Sacral Neuromodulation (SNM), Pudendal Nerve Stimulation (PNS), Percutaneous Tibial Nerve Stimulation (PTNS), Spinal cord stimulation (SCS), Deep brain stimulation (DBS).

^{#####}This is done by skin surface electrode(s), as touch plate(s) or superficial needle(s). Long-term or chronic electrical stimulation is delivered below the sensory threshold. Maximal electrical stimulation is using a high-intensity stimulus (just below the pain threshold). This can be done intermittently.

^{¶¶¶¶¶}The aim of electrical stimulation may be to directly induce a therapeutic response or to modulate lower urinary tract, bowel, or sexual dysfunction through transvaginal or transrectal stimulation.

^{§§§§§}The most commonly used manoeuvres are; suprapubic tapping, thigh scratching, and anal/rectal manipulation.

^{¶¶¶¶¶}The most commonly used manoeuvres are; abdominal straining (Valsalva's manoeuvre) and exerting manual suprapubic pressure (Crede's manoeuvre).

^{†††††}Indwelling catheterization may be performed transurethral, suprapubic or trans-conduit.

^{#####}Usually performed in the surgical theatre or during diagnostic procedures.

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SOUNDING BOARD

International Continence Society (ICS) report on the terminology for nocturia and nocturnal lower urinary tract function

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Introduction: The terminology for nocturia and nocturnal lower urinary tract function is reviewed and updated in a clinically and practically-based consensus report.

Methods: This report has been created by a Working Group under the auspices and guidelines of the International Continence Society (ICS) Standardisation Steering Committee (SSC). All relevant definitions were updated on the basis of research over the last 16 years since the publication of the first nocturia standardization document in 2002. An extensive process of 16 rounds of internal and external reviews was involved to examine each definition exhaustively, with decision-making by collective opinion (consensus).

Results: A clinically-based terminology report for nocturia and nocturnal lower urinary tract function, encompassing five key definitions divided into signs and symptoms has been developed. Clarity and user-friendliness have been key aims to make it interpretable by healthcare professionals and allied healthcare practitioners involved in the care of individuals with nocturnal lower urinary tract function.

Conclusion: A consensus-based terminology report for nocturia and nocturnal lower urinary tract function has been produced to aid clinical practice and research.

KEYWORDS

enuresis, International Continence Society, nocturia, nocturnal polyuria, terminology

1 | INTRODUCTION

In 2002, the International Continence Society (ICS) defined nocturia as the complaint that the individual has to wake at night one or more times to void.¹ Since that original

publication, several studies have been conducted looking at the epidemiology, pathophysiology and treatment of nocturia, leading to a wealth of new information.^{2,3} The time has now come to review the terminology in the original publication since it has been established that nocturia may not be a

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Marcus J. Drake and Jane Meijlink: Standardisation Steering Committee ICS. At time of publication, Marcus Drake was an ICS Trustee.

complaint and that people can get up at night to void for various reasons which may or may not be pathological.⁴ Nocturia can also occur as a clinical entity in its own right due to non-medical reasons such as a baby crying, or a partner snoring, causing the individual to wake up at night to pass urine. In these latter scenarios, nocturia would have been excluded in the 2002 definition as the person would have not woken up to void due to a complaint, but rather due to a convenience void.

Nocturia may also be present as part of other conditions which may or may not be directly related to the urinary tract, for example, heart failure or sleep apnea. Therefore, patients can present to and consult not only urologists but also other clinicians such as gynecologists, geriatricians, neurologists, sleep experts, endocrinologists, cardiologists, immunologists, rheumatologists, and/or general practitioners. Each specialist is likely to approach nocturia in a different way depending on the presentation. However, it is important that all healthcare providers speak the same “language” and refer to the same condition using specific definitions, in order to avoid confusion and any misunderstandings.

The ICS therefore formed a new working group to revise and update the 2002 standardization document on nocturia and make new recommendations on terminology based on the published literature over the last 16 years. This terminology report is inherently and appropriately a definitional document, collating the definitions of those terms, that is, “words or phrases used to describe a thing or to express a concept, especially in a particular kind of language or branch of study,”⁵ here nocturia and nocturnal lower urinary tract function. Emphasis has been on comprehensively including those terms in current use in the relevant peer-reviewed literature. The definitions of those terms will be reviewed with all available evidence and aim to assist clinical practice and research. Some new and revised terms have been included. Explanatory notes on definitions have been referred, where possible, to the “footnotes” section. This document does not address the epidemiology, pathophysiology or treatment of nocturia or any of its sub-categories, as that is not the main aim of the Standardisation Steering Committee (SSC) or the nocturia working group, is beyond the scope of this article, and is covered in several other publications.^{2,3,6–11}

Like all other joint ICS terminology reports, every effort has been made to ensure this report is:

User-friendly: It should be understandable by all clinical and research users.

Clinically-based: The definitions should be applicable to clinical practice.

Original: Where a term's existing definition (from one of multiple sources used) is deemed appropriate, that definition will remain and be duly referenced.

Able to provide explanations: Where a specific explanation is deemed appropriate to describe a change from earlier definitions or to qualify the current definition, this will be included as an addendum to this paper (*Footnote [FN] 1,2,3...*). Wherever possible, evidence-based medical principles will be followed.

It is suggested that acknowledgement of these standards in written publications related to nocturia and nocturnal lower urinary tract function be indicated by a footnote to the section “Methods and Materials” or its equivalent, to read as follows: “Methods, definitions and units conform to the standards recommended by the International Continence Society Nocturia and Nocturnal Lower Urinary Tract Function Terminology Standard 2018, except where specifically noted”.

Relevant ICS 2002 and 2010 definitions are highlighted for ease of reference and comparison. The 2018 definitions (Table 1) will be added if there are any changes to the previous definitions.

2 | GENERAL DEFINITIONS

2.1 | Symptom(s)

2002: The subjective indicator of a disease or change in a condition as perceived by the patient, carer or partner, and may lead him/her to seek help from healthcare professionals. Symptoms may either be volunteered or described during the patient interview. They are usually qualitative. In general, Lower Urinary Tract Symptoms (LUTS) cannot be used to make a definitive diagnosis. LUTS can also indicate pathologies other than lower urinary tract dysfunction (LUTD), such as urinary tract infection.¹²

2010: Any morbid phenomenon or departure from the normal in structure, function, or sensation; experienced by the person and indicative of disease or a health problem. Symptoms are either volunteered by, or elicited from the person, or may be described by the person's caregiver.^{13,14}

2018: The previous definitions have not been changed.

2.2 | Sign(s)

2002: Signs are observed by the physician including simple means, to verify symptoms and quantify them. For example, a classic sign is the observation of leakage on coughing. Observations from frequency/volume charts, pad tests and validated symptom and quality of life questionnaires are examples of other instruments that can be used to verify and quantify symptoms.¹²

2010: Any abnormality indicative of disease or a health problem, discoverable on examination of the

TABLE 1 Definitions of terms related to nocturia and nocturnal lower urinary tract function (2018)

Term	Definition
Main sleep period (new)	The period from the time of falling asleep to the time of intending to rise for the next “day.”
First morning void (changed)	The first void after the main sleep period.
Enuresis (changed)	Symptom: complaint of intermittent incontinence that occurs during periods of sleep. If it occurs during the main sleep period, then it could be qualified by the adjective “nocturnal.” Sign: Intermittent incontinence (“wetting”) that occurs during periods of sleep (while asleep). If it occurs during the main sleep period then it could be preceded by the adjective “nocturnal.”
Night-time (changed)	Commences at the time of going to bed with the intention of sleeping and concludes when the individual decides they will no longer attempt to sleep and rise for the next “day.” It is defined by the individual’s sleep cycle, rather than the solar cycle (from sunset to sunrise).
Night-time frequency (changed)	The number of voids recorded from the time the individual goes to bed with the intention of going to sleep, to the time the individual ends their main sleep period with the intention of rising.
Nocturia (changed)	Symptom: The number of times urine is passed during the main sleep period. Having woken to pass urine for the first time, each urination must be followed by sleep or the intention to sleep. This should be quantified using a bladder diary. Sign: The number of times an individual passes urine during their main sleep period, from the time they have fallen asleep up to the intention to rise from that period. This is derived from the bladder diary.
Nocturnal polyuria (changed)	Symptom: Passing large volumes of urine during the main sleep period. This should be quantified using a bladder diary. Sign: Excessive production of urine during the individual’s main sleep period. This should be quantified using a bladder diary.
Nocturnal urine volume (changed)	Sign: Total volume of urine produced during the individual’s main sleep period including the first void after the main sleep period. This should be quantified using a bladder diary.
24-h voided volume (changed)	Sign: Total volume of urine passed during a 24-h period excluding the first morning void of the period. The first void after rising is discarded and the 24-h period begins at the time of the next void and is completed by including the first void, after rising, the following day.
24-h polyuria (not changed)	Excessive excretion of urine resulting in profuse and frequent micturition. Defined as >40 mL per kg body weight per 24-h.

patient; an objective indication of disease or a health problem.¹⁴

These can be quantified by a questionnaire or bladder diary.

2018: The previous definitions have not been changed.

Nocturnal: Refers to “Done, occurring, or active at night.”⁵ Therefore, “nocturnal” will refer to signs and symptoms that occur during the night-time.

Night-time (Changed): For the purposes of the nocturia 2018 terminology, night-time will be defined by the individual’s sleep cycle, rather than the solar cycle (from sunset to sunrise). Thus, some shift workers may have their “night-time” period during the daylight hours, as it is the time of their main sleep period. It commences at the time of going to bed with the *intention* of sleeping and concludes when the individual decides they will no longer attempt to sleep and rise for the next “day.”

Main sleep period (New): The period from the time of *falling asleep* to the time of *intending to rise* for the next “day.”

Frequency: The frequency is the number of times an event occurs during a stated period.

3 | NOCTURNAL SYMPTOMS

3.1 | Nocturia

2002: The complaint that the individual has to wake at night one or more times to void.¹

2010: Complaint of interruption of sleep one or more times because of the need to micturate.¹⁴ Each void is preceded and followed by sleep.

2018: The number of times urine is passed during the main sleep period. Having woken to pass urine for the first time, each urination must be followed by sleep or the intention to sleep. This should be quantified using a bladder diary.^a

3.2 | Core reasons for change

The 2002 and 2010 definitions of nocturia have caused much debate and controversy, including the fact that getting up once at night to void may not be bothersome and is therefore not a “complaint.” Furthermore, it can be difficult to determine the “reason for waking” and to confirm that waking was indeed in order to pass urine. What clinicians and researchers wanted

was to define a clinical condition. Also, the previous ICS definitions of nocturia did not take into account the voiding episodes at night during the main sleep period of several groups of people, including but not limited to:

1. those who need to void multiple times in the night after falling asleep, often several times in a row, small amounts at a time, and may not be able to get back to sleep again,
2. those whose bladder does not empty fully, and who consequently need to void again several times soon after going to sleep,
3. those who suffer from insomnia or have difficulty going back to sleep due to causes other than their bladder problem,
4. those who wake up and then are unable to sleep due to painful or sensitive bladders.

Furthermore, while various studies have been published on nocturia, only few have critically discussed the definition of nocturia. In fact, nocturia has not been defined at all in many studies. The new definition reflects the fact that nocturia is first a symptom, which may or may not be a complaint (ie, of an abnormality), with mixed and multiple etiologies and a prevalence in the general population which is well described for men and women of different ages worldwide.^{2,15,16}

Night-time frequency can sometimes be confused with nocturia. However night-time frequency includes voids when an individual goes to bed, with the intention of sleeping, but cannot sleep and needs to void at least once before falling asleep (2002 nocturia document). For example, if an

individual goes to bed at 10 pm and passes urine three times before falling asleep at 11pm, then the three episodes are not part of nocturia, as nocturia starts when the person falls asleep but these are part of night-time frequency (Figure 1).

Another, scenario that may cause confusion is if an individual wakes up at, for example, 3 am from sleep and could not sleep although they want to sleep, and passes urine at 4 and 6 am, and then decides to end his/her sleep period at 7 am, then these voids are part of nocturia episodes.

In other words, nocturia episodes begins when the individual falls asleep and ends with the intention of getting up for the day. These, and other scenarios, will be highlighted by careful analysis of the bladder diary, which is a mandatory first-line investigation tool for the management of patients with LUTS (Figure 2). This document aims is to generalize the definitions to apply to all groups of patients with the symptom of nocturia.^b

3.3 | Analysis of bladder diary

1. Nocturia by 2002/2010 definition: 1 (the only void that was preceded and followed by sleep was the one at 23.00). It could also be argued that nocturia could be three episodes as the voids at 1.00am and 3.00am were preceded and followed by sleep but the return to sleep was delayed. This depends on whether the definition is strictly applied or not. Either way, the definition misses out on nocturia episodes.
2. Nocturia by 2018 definition: 4 (the total number of voids after falling asleep at 22.30 and before the individual decides to get up for the day at 08.00).

Time	Scenario				
	1	2	3	4	5
10pm	Bed & Sleep	Bed	Bed	Bed	Bed
11pm		X	X	X	X
12am		Sleep	Sleep	Sleep	Sleep
1am					
2am	Wake to void X Sleep after Void	Wake to Void X Sleep after Void	Wake to Void X	Wake to Void X	Wake to Void X Sleep after Void
3am				X	
4am	Wake to Void X Sleep after Void	Wake to Void X Sleep after Void	X Sleep after Void	X Sleep after Void	Wake to Void X
5am					X Intention to Sleep but not able to
6am					
7am	Wake & Rise for the day	Wake & Rise for the day	Wake & Rise for the day	Wake & Rise for the day	Rise for the day
	NF: 2 N2002: 2 N2018: 2	NF: 3 N2002: 2 N2018: 2	NF: 3 N2002: 0 N2018: 2	NF: 4 N2002: 0 N2018: 3	NF: 4 N2002: 1 N2018: 3

FIGURE 1 Different scenarios highlighting difference between the different definitions of night-time frequency (NF), previous nocturia definition (N2002), and new nocturia definition (N2018). (X denotes micturition)

Night-time	
Time	Voided volume (mL)
Time of falling asleep: 22.30	
23.00	100 (woke up to void and went back to sleep)
01.00	150 (woke up to void but could not sleep after void although wanted to sleep)
03.00	100 (voided again and then fell asleep)
06.00	200 (woke up to void but could not sleep after void although wanted to sleep)
08.00	100 (decision to get up for the day)

FIGURE 2 Example of nocturia using a single night extracted from a bladder diary^c

3.4 | Nocturnal polyuria (NP)

2002: Not defined as a symptom.

2010: Not defined as a symptom.

2018: Passing large volumes of urine during the main sleep period. This should be quantified using a bladder diary.

3.5 | Core reasons for change

The previous standardization reports have not highlighted nocturnal polyuria as a symptom, but looked at it as a sign. However, we know from clinical practice that patients can report passing large volumes of urine at night, especially relative to the day, and hence we have defined the symptom of nocturnal polyuria.

3.6 | Enuresis

2002: Any involuntary loss of urine. If it is used to denote incontinence during sleep, it should always be qualified with the adjective “nocturnal.”¹

2010: Complaint of involuntary loss of urine which occurs during sleep.¹⁴

2018: Complaint of intermittent incontinence that occurs during periods of sleep. If it occurs during the main sleep period, then it could be qualified by the adjective “nocturnal.” The patient has to be asleep when enuresis happens and is usually unaware of it. If the patient is woken from sleep and then leaks or has incontinence then this would be classified according to the pathophysiology of incontinence while awake, for example, stress urinary incontinence, urgency urinary incontinence, mixed urinary

incontinence, etc. The timing of leakage, whether during sleep or after being woken up and then leaking, is established when taking a detailed clinical history from the patient by asking them, for example, “Does the wetting/leakage occur while you are asleep and unaware of it or do you get woken up and then leak?”^d

3.7 | Core reasons for change

Enuresis is a symptom reflecting several different pathologies, previously believed to be a complete emptying of the bladder, but later identified as both complete and incomplete emptying of the bladder. The International Children’s Continence Society (ICCS) defined nocturnal enuresis as both a symptom and a condition of intermittent incontinence that occurs during periods of sleep.^{17–19} Previously it was wetting in discrete portions while asleep after the age of five. To ensure consistency between the ICCS and the ICS definitions, the ICS has adapted the ICCS definition.

4 | NOCTURNAL SIGNS

4.1 | Nocturia

2002: Not specifically defined.

2010: Not specifically defined.

2018: The number of times an individual passes urine during their main sleep period, from the time they have fallen asleep up to the intention to rise from that period. This is derived from the bladder diary.

In order to capture the frequency of nocturia, a bladder diary is needed on which the patient indicates the time of

falling asleep, the time when they decided they would no longer attempt to sleep, and all intervening voids. A bladder diary is needed to ascertain nocturnal urine production, with complete recording of all volumes voided during the main sleep period. Measurement of the frequency of nocturia begins after sleep and concludes before the first void following intention of getting up for the day.^c The individual can also note why they went to void, for example, due to urgency, pain, etc.

4.2 | Nocturnal polyuria (NP)^{3–5}

2002: Nocturnal urine volume output greater than 20% of the daily total urine output in the young and 33% in the elderly, with the value for middle age probably falling somewhere in the middle. Increased proportion of a 24-h urine output occurring at night (normally during the 8 h while the patient is in bed).¹²

2010: Excess (over 20–30%—age dependent) proportion (nocturnal voided volume/total 24 h voided volume \times 100%) occurs at night (or when patient is sleeping).¹⁴

2018: Excessive production of urine during the individual's main sleep period. The definition used by the health-care provider to quantify “excessive” will need to be highlighted in both clinical and research settings and should be derived from a bladder diary.

4.3 | Core reasons for change

There have been numerous ways of classifying nocturnal polyuria.²⁰ From clinical practice, we have learned that the 20% and 33% numbers (the nocturnal polyuria index) are not well supported, as they were not based on normal distributions and were not properly validated. They also assumed that the index person is 70 kg and sleeps 8 h a day, irrespective of gender or age. Regardless of what definition is applied, the diagnosis of NP includes a differential diagnosis encompassing congestive heart failure, diabetes mellitus, obstructive sleep apnea, peripheral edema, excessive night-time fluid intake and “normal” ageing. Other factors which have been implicated in the causation of nocturnal polyuria are an abnormality in nocturnal secretion or action of arginine vasopressin (AVP) (this describes the classical nocturnal polyuria syndrome) and any edema-forming state (in addition to congestive heart failure, chronic renal disease, nephrotic syndrome, hypoalbuminemia, liver failure), co-morbidities such as autonomic nervous system dysfunction, Alzheimer's disease, multisystem atrophy, stroke, and Parkinsonism. Hence the need for standardization!

Terms that can be used to define urine production at night include:

1. 24-h urine production rate (mL/h): volume of urine produced per hour in a 24 h period.
2. nocturnal urine production rate (mL/h): nocturnal urine volume/length of time of main sleep period (mL/h).
3. nocturnal urine production rate index: nocturnal urine production rate/24-h urine production rate.

Absolute and normal values are yet to be defined for the above terms, but will be dependent on fluid input, the population defined, and the gender. There are several definitions in the literature that could be used to indicate nocturnal polyuria^f including:

1. Nocturnal urine production based on body weight of greater than 10 mL/kg.²¹
2. Rate of nocturnal urine production >90 mL/h.²² This figure is suggestive of nocturnal polyuria in *men* only (about 450 mL per 8 h sleep).²³ There are no studies looking at the rate of nocturnal urine production in women and this may well be different from that in men.
3. Nocturnal polyuria index is the most commonly used definition for nocturnal polyuria²⁰ (nocturnal urine volume/24-h voided volume)¹ based on nocturnal urine volume as part of total 24-h urine volume. It is age dependent; however the age groups have not been clearly defined:
 - a. 33% in elderly, for example, >65.
 - b. >20% in younger individuals.
 - c. 20–33% in “middle age.”
4. Nocturia index (nocturnal urine volume/maximum voided volume).²⁴
 - a. >1: nocturia occurs because maximum voided volume is smaller than nocturnal urine volume.
 - b. >1.5: nocturia secondary to nocturnal urine overproduction in excess of maximum bladder capacity, that is, nocturnal polyuria.

One confounding issue is that if one uses an amount or volume as the indicator for nocturnal polyuria, then even with a normal distribution of day and night output, virtually all people with 24-h polyuria will have nocturnal polyuria. If one uses a percentage of total 24-h urine output, and if the normal circadian rhythm is preserved, they will not all have nocturnal polyuria. Whatever definition is used, it has to be clearly indicated in both clinical practice and research settings (Figure 3).

4.4 | Enuresis

2002: Not defined as a sign in previous terminology documents.

2010: Not defined as a sign in previous terminology documents.

Daytime		Night-time	
Time	Voided volume (mL)	Time	Voided volume (mL)
Time of waking up: 07.00	200	Time of falling asleep: 22.30	
08.15	175	23.00	150
12.00	375	01.00	275
16.30	325	03.00	400
18.30	225	06.00	350
22.00	225	Woke up at 08.30 next morning and voided 200 mL	

- > Maximum voided volume: 400 mL
- > Daytime frequency: 6 times (200, 175, 375, 325, 225, 225)
- > Nocturia episodes: 4 times (150, 275, 400, 350)
- > 24-hour urine volume: $175+375+325+225+225+150+275+400+350+200=2700$
- > Nocturnal urine volume: $150+275+400+350+200=1375$
- > NPI: $1375/2700 = 50.9\%$ i.e. nocturia due to nocturnal polyuria
- > Ni: $(150+275+400+350+200)/400 = 3.4$ i.e. nocturia due to nocturnal polyuria
- > NBCi (Actual nightly voids (ANV) minus Predicted nightly voids (PNV = Ni-1) (24): $3-(3.4-1) = 0.6$ i.e. nocturia is probably *not* due to reduced bladder capacity.
- > 24-hr urine production rate (mL.s/hr) = $2700/24 = 112.5$ mL.s/hr
- > Nocturnal urine production rate (mL.s/hr) = $1375/10 = 137.5$ mL.s/hr
- > Nocturnal urine production rate index = $137.5/112.5 = 1.22$

FIGURE 3 Example of Nocturnal Polyuria using a one-day bladder diary^c

2018: Intermittent incontinence (“wetting”) that occurs during periods of sleep (while asleep).

NB. As in the symptoms section previously, this occurs while the patient is asleep and has not been woken up from sleep and then leaks. If it occurs during the main sleep period then it could be preceded by the adjective “nocturnal.”

4.5 | Core reasons for change

Previous definitions were not available for enuresis as a sign. Enuresis as a symptom has been defined as a complaint of intermittent incontinence that occurs during periods of sleep. As a sign, enuresis could be related to or be a manifestation of several different pathologies that the healthcare provider

would need to investigate, for example, high pressure urinary retention, overactive bladder, or neurogenic causes. Depending on the severity, it could be “wetting” the underclothes, outer clothes, or the bed.

4.6 | Nocturnal urine volume

2002: The total volume of urine passed during the night, including the first morning void.¹

2010: Cumulative urine volume from voids after going to bed with the intention of sleeping to include the first void at the time of waking with the intention of rising (excludes last void before sleep).¹⁴

2018: Total volume of urine produced during the individual's main sleep period, including the first void after the main sleep period.

Volume measurement begins after the last void preceding sleep and concludes after the first morning void. The first morning void follows the individual's decision they will no longer attempt to sleep.

4.7 | Core reasons for change

Wording of previous definitions has been confusing. The new definition is practical and takes into account the fact that if an individual does not empty his/her bladder before falling asleep, then for pragmatic reasons it would be reasonable to include any volume produced after the last void before falling asleep as part of nocturnal urine produced. Alternatively, it would be best to advise individuals who are filling out a bladder diary or frequency/volume chart to void before going to sleep to make assessment of volumes passed easier by the healthcare provider when analyzing the diary or chart.

4.8 | 24-h voided volume

2002: Total volume of urine voided during a 24 h period (1st void to be discarded; 24 h begin at the time of the next void).¹

2010: Summation of all urine volumes voided in 24 h.¹⁴

2018: Total volume of urine passed during a 24-h period excluding the first morning void of the period. The first void after rising is discarded and the 24-h period begins at the time of the next void and is completed by including the first void, after rising, the following day.

4.9 | Core reasons for change

Previous definitions needed further clarification to avoid confusion with regard to when the 24-h period begins and when it ends. The new definition clarifies this matter.

4.10 | 24-h polyuria

2002: 24-h urine output >40 mL/kg, in men and women, causing daytime urinary frequency and nocturia occasioned by a general increase in urine output, outstripping even normal bladder capacity.¹

2010: Excessive excretion of urine resulting in profuse and frequent micturition. It has been defined as over 40 mL/kg body weight during 24 h or 2.8 L urine for an individual weighing 70 kg.¹⁴

2018: The previous definitions have not been changed.

4.11 | Core reasons for change

Since there was no new research or information on defining polyuria, the working group has decided to retain the previous definitions as volumes passed daily vary considerably, and are influenced by environmental, physiological, and pathological factors; which can affect the amount of fluid loss by other means, such as perspiration, and the amount of fluid intake.

5 | CONCLUSION

This standardization document on nocturia and nocturnal lower urinary tract function aimed to update previous standardization documents with emphasis on pragmatism and practicality when coming up with new definitions. These new definitions can be used both clinically and in research, allowing better communication and understanding between healthcare providers and researchers.



This document has involved 16 rounds of full review by co-authors of an initial draft (Version 1) completed on 3 October, 2014. Comments for each round of review were collated and debated as necessary in order to form a subsequent version. Live meetings on the document took place at the ICS annual meetings in Brazil (2014) and Tokyo (2016). The document was then sent to six experts for comments before the final version was produced. The document was also subject to general ICS membership review and reviews by the SSC and ICS Board.

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ENDNOTES

^a The first nocturia episode must be preceded by sleep. Subsequent nocturia episodes must be followed by the intention of getting back to sleep. The quality of life impact of nocturia is not an element in its definition but will be appropriately evaluated during its assessment by fully validated quality of life questionnaires.

^b Definition of nocturia does not take into account whether this is bothersome or not, whether it is affecting quality of life or whether it needs treatment. The aim is to have a global pragmatic definition, rather than defining or suggesting a clinical pathological entity. For the healthcare provider, it is prudent that they state the cause of nocturia when reporting it clinically or for research purposes for each individual, in other words it has to be reported why the nocturia occurred, for example, due to urgency, pain, habit, etc.

^c A 3-day bladder diary is the standard of care for the assessment of patients with lower urinary tract symptoms including nocturia and nocturnal polyuria.

^d Enuresis can be primary (has been present lifelong) or acquired (developed in adults).

^e The frequency with which a person passes urine during their main sleep period can be used as an indicator of the severity of their nocturia. It is known that this does not necessarily correspond with the quality of life impact of nocturia. The first void after the main sleep period follows the individual's decision that they will no longer attempt to sleep.

^f The working group recognizes the limitations and difficulties that exist in defining nocturnal polyuria. It believes that there is not enough data in the literature to make a recommendation to adopt a new definition of nocturnal polyuria as a "sign" or to recommend one method of calculation over the other. Further research is needed into this field before adopting one of the methods of calculation as every definition above has limitations. However, the working group believes that the way forward for new research is to have an absolute number based on rate of urine production during the main sleep period or when the patient has gone to sleep, relative to the urine production rate in 24 h, for the various age groups and both genders. Ultimately, the definition will be used to aid treatment of a bothersome condition and the treatment will target the cause rather than the definition. The definition should also be easily usable in research. Whichever definition is used, the healthcare provider or researcher should specify exactly which parameter and method of calculation they have used to diagnose nocturnal polyuria.

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A Standard for Terminology in Chronic Pelvic Pain Syndromes: A Report From the Chronic Pelvic Pain Working Group of the International Continence Society

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Aims: Terms used in the field of chronic pelvic pain (CPP) are poorly defined and often confusing. An International Continence Society (ICS Standard for Terminology in chronic pelvic pain syndromes (CPPS) has been developed with the aim of improving diagnosis and treatment of patients affected by chronic pelvic pain syndromes. The standard aims to facilitate research, enhance therapy development and support healthcare delivery, for healthcare providers, and patients. This document looks at the whole person and all the domains (organ systems) in a systematic way. **Methods:** A dedicated working group (WG) was instituted by the ICS Standardisation Steering Committee according to published procedures. The WG extracted information from existing relevant guidelines, consensus documents, and scientific publications. Medline and other databases were searched in relation to each chronic pelvic pain domain from 1980 to 2014. Existing ICS Standards for terminology were utilized where appropriate to ensure transparency, accessibility, flexibility, and evolution. Consensus was based on majority agreement. **Results:** The multidisciplinary CPPS Standard reports updated consensus terminology in nine domains; lower urinary tract, female genital, male genital, gastrointestinal, musculoskeletal, neurological aspects, psychological aspects, sexual aspects, and comorbidities. Each is described in terms of symptoms, signs and further evaluation. **Conclusion:** The document presents preferred terms and definitions for symptoms, signs, and evaluation (diagnostic work-up) of female and male patients with chronic pelvic pain syndromes, serving as a platform for ongoing development in this field. *NeuroUrol. Urodynam.* © 2016 Wiley Periodicals, Inc.

Key words: bladder pain syndrome; chronic pelvic pain syndromes; comorbidities; condition; disease; domain; female genital pain; gastrointestinal pain; Hunner lesion; hypersensitive bladder; interstitial cystitis; lower urinary tract pain; male genital pain; musculoskeletal pain; neurological aspects; phenotype; psychological aspects; sign; sexual aspects; symptom; syndrome

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INTRODUCTION

This is the first International Continence Society (ICS published Standard of Chronic Pelvic Pain Syndromes (CPPS). Global standardization of terms and clear definitions are essential for scientific and clinical progress. Furthermore, meaningful coding of diseases, nationally and internationally, depends on accepted terminology. Inappropriate and unclear coding and definitions have negative effects not only on diagnosis, but also on the patient's ability to obtain appropriate treatment, reimbursement, and social benefits. The International Continence Society (ICS) has led the way in the development of Standards for terminology of lower urinary tract function and dysfunction,¹ and the need for a Standard in CPPS was identified by the ICS Standardisation Steering Committee (SSC).

Chronic pelvic pain (CPP) is the most common indication for referral to women's health services, and accounts for 20% of all outpatient appointments in secondary care.² This leads to a substantial burden on limited health care resources. For example, \$881.5 million are spent per year on its outpatient management in the USA, while an estimated £158 million are spent annually on management in the United Kingdom National Health Service.² CPPS are multifactorial and multidisciplinary conditions, and terminology can vary according to which specialist is looking at the patient. This document is an endeavour to look at the whole person and to consider all the domains involved. Each domain is described separately.

Pain in the pelvic area potentially includes urologic, gynecologic, gastrointestinal, musculoskeletal, neurologic and/or rheumatologic etiology, with psycho-social aspects, and hence must be regarded as a multidisciplinary issue. A taxonomy of the relevant elements of CPP was provided by the International Association for the Study of Pain (IASP).^{3,4} Complementing the taxonomy, the European Association of Urology (EAU) Guidelines on Chronic Pelvic Pain provide a comprehensive overview of basic science pertaining to pelvic pain, clinical workup and management of CPPS.⁵ This ICS Standard should be seen as complementary to other CPPS standards and guidelines. Its aims are to:

1. Describe the nine clinical domains involved in CPPS (summarized in Tables I–XI).
2. Define terminology.
3. Develop an evaluation guideline for each domain.
4. Establish a process for evolving terminology in response to scientific and clinical development and patient need.

This Standard for CPPS Terminology should facilitate future research and therapy development, improve cost effectiveness, and ensure access by the patient to appropriate treatment, reimbursement, and social benefits.

METHODS

The CPPS Standard was developed according to the published methodology of the ICS Standardisation Steering Committee (SSC).⁶ The Working Group (WG) and Chairperson were selected by an independent SSC sub-committee following an open advertisement. The WG comprised a multi-disciplinary group of health care providers, a basic science researcher, and a patient advocate. Activities of the WG and contributions of individual members were recorded in an open forum on the ICS website. The WG developed an outline of proposed content at an open workshop at the ICS annual scientific meeting in Beijing (2012). Successive iterations of the draft standard involved electronic communications, teleconferences, and face-to-face meetings. The WG reviewed documents that provided historical and research insight into the multidisciplinary approach to the evaluation of female and male CPPS.

A literature review covered the period 1980–2015 and extracted sources from electronic database searches, including MEDLINE and Cochrane. In addition, cross-referencing was done for existing relevant guidelines and consensus documents, notably:

- The EAU Guidelines on Chronic Pelvic Pain,^{5,7} which place CPP in the clinical context.
- The American Urological Association (AUA) guidelines for the diagnosis and the treatment of IC/BPS.^{8,9}
- The International Continence Society (ICS) joint/ICS joint report on the terminology for female pelvic floor dysfunction,¹⁰ which covers terminology for female sexual dysfunction, genital pain, and pudendal neuralgia.
- The IASP Taxonomy, which classified pain on the basis of "organ + pain + syndrome" and applied it to pain of urogenital origin.³
- In 2008, the International Society for the Study of Bladder Pain Syndrome (ESSIC) published diagnostic criteria, classification, and nomenclature for bladder pain syndrome (BPS).¹¹
- The East Asian IC Study Group/Society of Interstitial Cystitis of Japan (SICJ) guidelines, which revived the concept of hypersensitive bladder.¹²
- The Functional Gastro-Intestinal Disorder Society (FGIDS) Rome III Diagnostic Criteria¹³ for gastro-intestinal disorders.

RESULTS

The WG identified the following nine domains, each of which are considered in terms of symptoms, signs, and further evaluation.

I. Lower Urinary Tract Domain

- A. Bladder.
- B. Urethra.

II. Female Genital Domain

- A. Vulva, vestibule, and clitoris.
- B. Intra-abdominal female genital pain.
- C. Pelvic floor muscle pain.

III. Male Genital Domain

- A. Prostate.
- B. Scrotum.
- C. Epididymis.
- D. Testicle.
- E. Penis.
- F. Urethra.
- G. Sexual Pain.

IV. Gastro-Intestinal Domain

- A. Anorectum.
- B. Colorectum.

V. Musculoskeletal Domain

- A. Pelvic muscle pain.
- B. Coccyx pain syndrome.
- C. Pelvic Joint, ligament, or bony pain.

VI. Neurological Domain

- A. Complex Regional Pain Syndrome (CRPS).
- B. Somatic neuropathic pain.
- C. Pain following mesh surgery.

VII. Psychological Domain

- A. Worry, anxiety, and fear.
- B. Depression and depressed mood.
- C. Catastrophizing.

VIII. Sexual Domain

- A. Sexual desire disorder.
- B. Sexual arousal disorder.
- C. Orgasmic disorder.
- D. Sexual pain disorder.

IX. Comorbidities

- A. Allergies.
- B. Chronic pain and fatigue syndromes.
- C. Systemic autoimmune syndromes/disease.
- D. Extraintestinal manifestations of inflammatory bowel disease.

TAXONOMY

A. Pain—A subjective phenomenon described as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.¹⁴

- a. Nociceptive pain: arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors.
- b. Somatic pain: arises from bone, joints, muscles, skin, or connective tissue and is normally achy or throbbing and well localized.
- c. Visceral pain: arises from visceral organs, with involvement of the organ capsule with aching, and is localized. There is obstruction of hollow viscus, causing intermittent cramping, which is poorly localized.¹⁵
 - i. Nociceptive: direct injury or lesion of an internal organ such as: bladder stone, surgical injury.
 - ii. Inflammatory: acute/chronic inflammation of an internal organ such as urinary tract infection, pelvic inflammatory disease, colitis, endometriosis.
 - iii. Neuropathic: primary lesion of visceral nerves such as neuritis following mesh placement.

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- d. Centrally generated pain/deafferentation pain: may result from injury to either the peripheral or central nervous system, leading to burning pain below the level of the lesion. It can be sympathetic-nervous system maintained pain, which may result in chronic regional pain syndrome (CRPS). There is increased responsiveness of nociceptive neurons in the central nervous system to normal or sub-threshold afferent input.
- e. Hypersensitivity: increased nerve activity from a standardized stimulus with an expected tissue/clinical response. The underlying mechanism remains to be defined.
- f. Central sensitization:¹⁶ nociceptor sensitization results in synaptic strengthening by incoming afferent volleys (sensitization) and is expressed as hyperalgesia (a form of non-associative learning characterized by an increase in responsiveness upon repeated exposure to a stimulus).¹⁷

B. Pain Experience—According to the most common views, pain constitutes the internal perception of bodily damage. It is unknown whether chronic pelvic pain syndromes (CPPS) are primarily an abnormal perception of a normal stimulus or a normal perception of an abnormal physiologic sensory stimulus.^{14 FN1}

C. Psychology of Pain—Pain is modulated by cognitive factors and emotional experience, memory, attention, and context represented in descending modulation of pain, affecting pain experience from moment to moment and longer term. Pain has an impact on many aspects of daily life, affecting mood, sleep, relationships, and activities. Therefore, attention to the psychological aspects of pain is an important part of effective assessment and treatment.^{18,19}

D. Neurobiology of Pain—Alterations in gut and bladder motility, visceral perception and central processing of pain and motor function due to abnormalities in the visceral and central nervous systems may account for the symptoms.^{18 FN2}

E. Chronic Pelvic Pain—Chronic pelvic pain is characterized by persistent pain lasting longer than 6 months or recurrent episodes of abdominal/pelvic pain, hypersensitivity or discomfort often associated with elimination changes, and sexual dysfunction often in the absence of organic etiology.²⁰

F. Symptoms and Signs of Chronic Pelvic Pain Syndromes

- a. Symptoms: The subjective indicator of a disease or change in condition/syndrome/phenotype as perceived by the patient, caregiver or partner which may lead him/her to seek help from healthcare professionals.²¹ The main symptom in CPPS is pain and will be described in relation to its domain and its perception. Complaint: what the patient describes when prompted by the physician.
- b. Signs are observed by the physician including simple means to verify symptoms and quantify them. To evaluate and discover all the signs, a full evaluation of the pelvis and body is necessary as multiple intra and extra-pelvic domains (organ systems) are commonly involved. It is necessary to attempt to identify all of the pain generators.^{11,21}

G. Condition, Disease, Syndrome

- a. A condition is defined by the presence of observations associated with characteristic symptoms or signs and/or evidence of relevant pathological processes.⁷
- b. A disease is a disordered or incorrectly functioning organ, part, structure, or system of the body resulting from the effect of genetic or developmental errors, infection, poisons, nutritional deficiency or imbalance, toxicity, or unfavourable environmental factors; illness; sickness; ailment.
- c. A syndrome is a complex of concurrent symptoms and signs that is collectively indicative of a disease, dysfunction or disorder in the absence of obvious pathology. (NEW) Example: Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS) is one of the Chronic Pelvic Pain Syndromes.^{1 FN3}

H. Characteristics

- a. Duration of pain: Six months or more of persistent pain.^{FN4}
- b. Location of pain: Pelvis, lower abdomen, low back, medial aspect of thigh, inguinal area, perineum.
- c. Perception of pain: Patients may describe the pain as sharp, burning, aching, shooting, stabbing, pressure or discomfort, sexual pain (dyspareunia).^{22 FN5}
- d. Modality of pain (7): Persistent and/or continuous, recurrent and/or episodic and/or cyclic (related to menstrual cycle).

^{FN1}Diagnosis is often based on the presence of clinical symptoms. The diagnosis of CPP is confirmed by applying symptom-based criteria and pursuing further diagnostic evaluation to exclude organic disease. Validation of symptom-based criteria is a process; it is not carved in stone and is easy to change as new data on its underlying pathophysiology emerge.³

^{FN2}The brain-visceral axis and biopsychosocial model have been used to explain how intrinsic and extrinsic stimuli modulate disease expression.^{14,18}

^{FN3}This is an update of the ICS Standardisation Sub-committee report on the Standardisation of Lower Urinary Tract Function.¹

^{FN4}In different guidelines and standardisation documents, the duration varies from 6 weeks to 6 months.

^{FN5}Some patients describe pain as an ache, soreness or simply discomfort, while cultural differences may influence perception of pain. For example, some patients describe an unpleasant sensation or pressure or discomfort, but do not consider these to be true pain. Memories, emotions, thoughts, expectations and culture are now believed to influence how people perceive pain.²²

I. Phenotype—Subgroup of patients within a condition, disease, or syndrome that share similar expression of specific symptoms, signs and diagnostic parameters: Example: Irritable bowel syndrome has three phenotypes: constipation, diarrhea, or mixed constipation/diarrhea.^{5,23,24 FN6}

Phenotyping is currently in its infancy with regard to evidence and will increase in importance in the future to aid in identifying specific patient pools for research and treatment.^{5,23}

J. Domain (organ system)—Lower urinary tract, female genital, male genital, gastro-intestinal, musculoskeletal, neurological, psychological, sexual, and comorbidities are domains involved in chronic pelvic pain syndromes (CPPS).

Tables I–IX are a summary of the appropriate domain for domains I–IX and appear in the Symptoms section.^{25 FN7}

INDIVIDUAL PATIENT ASSESSMENT

Section 1: Symptoms

The first and most important step is to obtain a thorough history of the patient's perception of her/his pain or discomfort. The common complaints are the most prevalent symptoms.

Ask about duration (at least 6 months), perception (identify inciting event and/or triggers), and modality (persistent/recurrent).

I. Lower Urinary Tract Domain (Table I)

A. Bladder

Common complaints include: increased urinary frequency day and night, urgency, hypersensitivity, pain, pressure, discomfort, pain with filling, hesitancy, intermittency, feeling of incomplete emptying. Pain/hypersensitivity related to the bladder provides an umbrella for hypersensitive bladder, interstitial cystitis/bladder pain syndrome, and interstitial cystitis with Hunner lesion.^{26–28} Urgency: A compelling need to urinate which is difficult to defer (pain, pressure, discomfort).^{1,5,11,21,30–33 FN8 FN9} The Working Group identified the following adjustments as applying more descriptively, for example, to Interstitial Cystitis/Bladder Pain Syndrome patients: a compelling need to urinate, due to pain or an unpleasant sensation, that is difficult to defer.^{FN10 FN11 FN12}

As there are differences in symptoms as well as in the perception and experience of pain, the WG agreed to distinguish:

- a. Hypersensitive Bladder (HSB)(Japanese and East Asian guidelines). Hypersensitive bladder symptoms (increased bladder sensation, usually associated with increased urinary frequency day and night, with or without bladder pain) in the absence of pathology explaining the symptoms.^{29,30 FN13}
- b. Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS). Persistent or recurrent chronic pelvic pain, pressure or discomfort perceived to be related to the urinary bladder accompanied by at least one other urinary symptom such as an urgent need to void or urinary frequency.¹¹
- c. Interstitial Cystitis (IC) with Hunner lesion has the same symptoms as IC/BPS.^{31 FN14 FN15} Pain in IC/BPS and IC with Hunner lesion may be pain, pressure or discomfort, which may increase with bladder filling. Possible locations of perceived discomfort and pain are the pelvis, lower abdomen/suprapubic area, low back, medial aspects of the thigh, inguinal area, or multiple pain sites.¹¹ Descriptors/Perception of pain⁵ include: “Sharp, burning, ache, shooting, stabbing, pressure, discomfort.”

B. Urethra

Urethral pain is perceived to be in the urethra, usually when voiding, with increased day- and night-time frequency. It may be combined with a feeling of dull pressure, and sometimes radiates toward the groin, sacrum and perineum.^{1,7} The terms “chronic urethritis” and “urethral syndrome” are no longer recommended.^{5,23}

- i. Persistent or recurrent pain.
- ii. No history of current infection or other obvious pathology.
- iii. May be subsequent to a previous urinary tract infection.

^{FN6}This has been adapted from the European Association of Urology Guidelines on Chronic Pelvic Pain.⁵

^{FN7}Domains I–V involve intrapelvic organs, VI–IX involve overlying aspects including comorbidities.

^{FN8}In the previous ICS LUTS document of 2002, urgency was defined as: the sudden complaint of a compelling desire to pass urine, which is difficult to defer.¹

^{FN9}This was a change from a previous definition in 1988 which stated that urgency may be associated with two types of dysfunction: (i) Overactive detrusor function (motor urgency), and (ii) Hypersensitivity (sensory urgency).³⁰

^{FN10}The change in definition in 2002 with introduction of the word “sudden” effectively restricted this term to overactive bladder syndrome and there was no mention of another sensation of urgency (urgent need to void) due to pain or hypersensitivity.

^{FN11}The term hypersensitive bladder is a revival of an earlier ICS Document.³⁰

^{FN12}Hunner lesion is preferable to Hunnefs ulcer.

^{FN13}There is currently global discussion as to whether Hunner lesion should/could be completely separated from IC/BPS and if so what it should be called. It is felt that more research is needed to provide sufficient evidence for such a step.³¹

^{FN14}The term vulvodynia is no longer recommended.³

^{FN15}The terms Dyesthetic vulvodynia and Essential vulvodynia are no longer recommended.^{3,34}

TABLE I. Lower Urinary Tract Domain

Symptoms	Signs	Evaluation	Syndrome/disease
Increased daytime frequency Increased night-time frequency	Suprapubic tenderness Tenderness of the bladder	Questionnaires Voiding diary	Hypersensitive bladder Interstitial cystitis/bladder pain syndrome
Urgency	Tenderness of the pelvic floor muscles	Urine analysis	Interstitial cystitis/hunner lesion
Hypersensitivity		Optional: urine culture/cytology	
Pain, pressure, discomfort with bladder filling		Intravesical anesthetic challenge	
Hesitancy		Urodynamics	
Intermittency		Cystoscopy (biopsy)	
Feeling of incomplete bladder emptying			
Frequency/urgency painful urination	Tenderness of the urethra	Urine analysis	Urethral pain

II. Female Genital (Table II)

Common complaints: painful menstruation, abnormal bleeding, pain with intercourse (dyspareunia), discharge, burning, itching, stabbing pain, voiding/defecatory pain, abdominal/pelvic pain (unilateral or bilateral, persistent or cyclic).

Female genital pain is defined as pain perceived in the pelvis, pelvic organs, the vagina and/or the female external genitals.^{5,34}

A. Vagina (Vulva, Vestibule, and Clitoris)

1. Pain in the vagina or the external genital organs (vulva, which includes the labia, clitoris and entrance to the vagina).^{5 FN14}
2. Generalized vulvar pain syndrome.⁴
 - i. Diffuse vulvar pain perceived to be in the vestibule or beyond.
 - ii. Dyspareunia.
 - iii. Provocation of pain with touch, pressure or friction.^{3,34 FN15}

3. Localized vulvar pain syndrome.⁴

Pain is usually provoked with touch, pressure, or friction; example: tight clothing, bicycle riding, tampon use, sexual activity.

- i. Vestibular pain syndrome—Pain localized to one or more portions of the vulvar vestibule.^{3,34 FN16 FN17}
- ii. Clitoral pain syndrome—Pain localized to or perceived in the clitoris.

B. Intra-Abdominal Female Genital

1. Ovary
 - i. Unilateral or bilateral abdominal/pelvic pain.
 - ii. Persistent.
 - iii. Cyclic.
2. Pelvic Congestion Syndrome
 - i. Pressure, heaviness, dull aching pain in the pelvis and/or in the back.
 - ii. Dysmenorrhea.

C. Pelvic Floor Muscle⁵ (See Domain V Musculoskeletal Pain)

- i. Urinary/defecatory dysfunction.
- ii. Dyspareunia (see also VIII sexual aspects).
- iii. Pain with sitting.
- iv. Bulging sensation.

D. Female Sexual Pain (See Domain VIII)

^{FN16}The terms vulvar vestibulitis, vestibulodynia, and focal vulvitis are no longer recommended.³⁴

^{FN17}Differential diagnosis and treatable diseases: A history of infection (Pelvic Inflammatory Disease, sexually transmitted diseases, endometriosis, adenomyosis or fibroids, and Mullerian abnormalities should be excluded.

TABLE II. Female Genital Domain

Dyspareunia	Tenderness	Pain Mapping	Vaginal/vulvar/perineal pain
Sharp burning and/or stabbing Provocation of pain with touch	Erythema	Q-tip touch sensitivity test	
Dysmenorrhea Abnormal menstrual bleeding Dyspareunia Itching, stabbing, burning pain Cyclic, (episodic or persistent)	Tenderness: uterine, adnexal	Laboratory testing Pelvic ultrasound Laparoscopy/biopsy CT-scan	Intra-abdominal: Ovarian Pain Pelvic congestion Uterine pain Tubal pain

III Male Genital Domain (Table III)

Male genital pain syndromes are often associated with symptoms suggestive of lower urinary tract and sexual dysfunction. Common complaints: genital pain, uncomfortable urination, dysuria, sensation of residual urine, increased daytime frequency, slow stream, urgency, dyspareunia.^{4,5} Absence of infection, previous operations, or other obvious pathology.

A. Prostate

Persistent or recurrent prostate pain, associated with symptoms suggestive of urinary tract and/or sexual dysfunction. No proven infection or other obvious pathology is present to account for the symptoms.^{3,35 FN18 FN19 FN20}

Bladder, perineal, testicular, penile and/or groin pain.

- i. Perception of pain: variable.
- ii. Persistent or recurrent.
- iii. Dyspareunia or erectile dysfunction.
- iv. Voiding and post micturition symptoms (for example: hesitancy, intermittency, feeling of incomplete emptying).

B. Scrotum

Chronic scrotal pain (generic term used when site of pain is not clearly in the testis or epididymis).^{23 FN21}

- i. Persistent or recurrent episodic pain, unilateral or bilateral.
- ii. Spontaneous, or reproduced by digital pressure and physical activities.
- iii. Pain is not in the skin of the scrotum but perceived within its contents.
- iv. Lower urinary tract symptoms or sexual dysfunction.

C. Epididymis

Pain is specific/localized to the epididymis.^{FN22}

- i. Persistent or recurrent episodic pain.
- ii. Spontaneous, or reproduced by digital pressure and physical activities.
- iii. Lower urinary tract symptoms or sexual dysfunction.

D. Testicle^{23 FN23}

- i. Persistent or recurrent episodic pain.
- ii. Spontaneous, or reproduced by digital pressure and physical activities.
- iii. Lower urinary tract symptoms or sexual dysfunction.

E. Penis

Pain within the penis that is not primarily in the urethra^{FN24} and may be:

- i. Persistent or recurrent.
- ii. Spontaneous, or reproduced by digital pressure and physical activities.
- iii. Lower urinary tract symptoms or sexual dysfunction.

F. Urethra

(See Domain I Lower Urinary Tract)

^{FN18}Using the National Institutes of Health classification system, prostate pain syndrome may be subdivided into type A (inflammatory) and type B (non-inflammatory).³⁵ Nickel JC. Prostatitis and related conditions, orchitis and epididymitis. In: Campbell-Walsh, editor. Urology. Philadelphia: Elsevier; 2012.

^{FN19}Based on a more general definition, the term prostate pain syndrome (PPS) is used by the European Association of Urology (EAU) instead of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) term chronic prostatitis/chronic pelvic pain syndrome.

^{FN20}The terms "Chronic Prostatitis" and "Prostatodynia" are no longer recommended.

^{FN21}It may be associated with a congestive epididymitis. Example: after vasectomy. It can result from a mechanical pressure more often than an inflammatory process.

^{FN22}It may occur at any age, but the majority of cases are in the mid to late thirties and it may be disabling and associated with anxiety about cancer.³⁶

^{FN23}Pain is localized to the testis and could be explained by neural plasticity when subsequent to a trauma or disease and this phenomenon can result from the amplification of the pain messages at all levels of nervous system.²² The previous terms "Chronic Orchitis," "Orchalgia," or "Orchiodynia" are no longer recommended.

^{FN24}The most common site for referral to the penis is from the bladder outlet.

TABLE III. Male Genital Domain

Symptoms	Signs	Evaluation	Syndrome/disease
Pain	Tenderness on rectal/genital examination	Questionnaires	Prostate pain
LUTS	Urethral discharge	Culture	
Dyspareunia		PSA/biopsy	
Erectile dysfunction		Cystoscopy/biopsy	
Persistent or episodic		Ultrasound	
	Tenderness on physical examination	Questionnaires	Scrotal pain
	Scars	Ultrasound	Epididymal pain
			Testicular pain
			Penile pain

G. Sexual Pain

(dyspareunia; (see Domain VIII))

i. Penile

1. Prior to penetration (example: pain with erection).
2. With penetration.
3. Post coital.

ii. Perineal

1. During intercourse.
2. After intercourse.

iii. Orgasmic Pain (during ejaculation)

1. Penile.
2. Anorectal.
3. Pelvic.

IV Gastro-Intestinal (Table IV)

Common complaints: constipation, diarrhea and obstructive defecation, pain with defecation, bleeding, discharge, cramping abdominal pain, recurrent rectal pain, rectal pressure, burning sensation or aching episodes.^{37 FN25}

A. Anorectum (7) (4)

1. Chronic Proctalgia—rectal pain, more than 20 min of duration per episode, for at least 3 months with symptom onset at least 6 months prior to diagnosis.
 - i. Persistent or recurrent rectal pain.
 - ii. Rectal pressure or aching episodes.
 - iii. In the absence of other causes of rectal pain.
2. Levator Ani Syndrome (the term may refer to the same syndrome as “pelvic floor muscle pain syndrome”/“tension myalgia of the PFM”—see Domain V).
 - i. Pain with sitting.
 - ii. Pain with defecation.
3. Proctalgia Fugax
 - i. Severe recurrent episodic pain localized in the anus or lower rectum.
 - ii. Duration seconds to minutes.
 - iii. No pain between episodes.

Consider the Symptoms of the Following Treatable Diseases, as They Need to Be Excluded4. Anal Fissure³⁸

- i. Bright red bleeding with bowel movements.
- ii. Anal pain or spasms that can last hours after bowel movements.³⁸
- iii. Pain with sitting.

5. Abscess

- i. Pelvic rectal pain.

^{FN25}Chronic Gastro-Intestinal pain includes syndromes and diseases that have obvious pathologies, but similar symptoms.

TABLE IV. Gastro-Intestinal Domain

Symptoms	Signs	Evaluation	Syndrome/disease
Pain with defecation	Tenderness on rectal examination	Questionnaire	Ano-rectal pain
Evacuation dysfunction		Culture	
Pain/pressure with sitting		Colonoscopy/biopsy	
Abdominal pain	Abdominal tenderness		Colo-rectal pain
Nausea	Bloating	Ultrasound	
Constipation/diarrhea		CT/barium enema/MRI	
Persistent or episodic			

- ii. Tenesmus³⁹ (persistent painful need to defecate despite an empty colon).
- iii. Pain with sitting.

6. Hemorrhoids^{40–42}

- i. Anal discomfort with engorgement.
- ii. Pain and itching.
- iii. Lump in perianal area.
- iv. Pain with defecation.
- v. Internal hemorrhoids—Painless bleeding, mucus discharge, incomplete evacuation.
- vi. External hemorrhoids—Anal discomfort with engorgement, pain, and itching.
- vii. Thrombosed External Hemorrhoids- Exquisitely painful lump in the perianal area. The pain tends to be acute at onset. Typically following straining at the time of bowel movement or physical exertion.

7. Anorectal Crohn's Disease—May be asymptomatic, with possible anal pain during flare.⁴³

B. Colorectum (ROME III Criteria)

Rome III Criteria are a standard for functional gastrointestinal disorders. The Rome III Criteria are a system developed to classify the **functional gastrointestinal disorders (FGIDs)** of the digestive system, in which symptoms cannot be explained by the presence of structural or tissue abnormality, based on clinical symptoms. Some examples of FGIDs include irritable bowel syndrome, functional dyspepsia, functional constipation, and functional heartburn.¹³

1. Irritable Bowel Syndrome (IBS) Functional (non-inflammatory)

- i. Recurrent episodes of abdominal pain.
- ii. Changes in frequency, form or consistency of the stool.
- iii. Sensation of incomplete evacuation, straining, fecal urgency.⁴⁴
- iv. Sensation of nausea, fatigue, fullness, vomiting.
- v. Recurrent abdominal pain or discomfort at least 3 days/month in the last 3 months associated with two or more of the following:
 1. Improvement of pain with defecation.
 2. Onset associated with change in frequency of stool.
 3. Onset associated with a change in the form (appearance) of stool.⁴⁵

Note: Consider the Symptoms of the Following Disease

Inflammatory Bowel Disease (IBD)—Complaint of recurrent abdominal pain and discomfort of at least 3 days per month in the last 3 months. The majority of IBD patients experience periods of flares and remission.

- i. Abdominal and anal pain, diarrhea which may be associated with blood, suggestive of ulcerative colitis.
- ii. Abdominal pain, fatigue, prolonged diarrhea with crampy abdominal pain, weight loss, and fever, with or without gross bleeding. Irregular bowel habits, with possible blood in the stool, are suggestive of Crohn's disease.⁴⁵

V. Musculoskeletal Domain (Table V)

Musculoskeletal pain may originate from muscles, fascia, ligaments, joints, or bones.

TABLE V. Musculoskeletal Domain

Symptoms	Signs	Evaluation	Syndrome/disease
Abdomino-pelvic-perineal pain	Altered muscle tone Tension; muscle spasms and muscle compliance	Questionnaires Pain mapping	Pelvic muscle pain syndrome Coccyx pain syndrome
Pain at rest, with movement, with sitting, with sexual activity	Stiffness muscle tightness	Ultrasound	Pelvic joint, ligament or bony pain
Pain with voiding or bowel evacuation	Trigger point tenderness		
Unilateral or bilateral pain	Tender taut band		
Persistent or episodic	Twitch response, referred pain		

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Common complaints: abdominal/pelvic pain, pain with sitting or with movement or with change of posture, with sexual activity, unilateral or bilateral pain. Possible pain with voiding or bowel evacuation.

A. Pelvic Muscle Pain^{10,46} (See also Domain IV)

1. Pelvic Floor Muscle Pain (Pelvic Floor Myalgia)^{FN26}
 - i. Pain in the muscles of the pelvic floor (perineal or levator ani).
2. Intra-pelvic Muscle Pain
 - i. Pain in the pelvic side wall muscles (obturator internus, piriformis, coccygeus).
3. Anterior Pelvic/Lower Abdominal Muscle Pain
 - i. Pain in the rectus abdominus, oblique or transverse abdominus muscles, described below the umbilicus.
4. Posterior Pelvic/Buttock Muscle Pain
 - i. Pain in the gluteal muscles.

B. Coccyx Pain Syndrome

- i. Complaint of chronic or recurrent pain in the coccyx or sacro-coccygeal joint.

C. Pelvic Joint, Ligament, or Bony Pain

1. Joint pain
 - i. Sacroiliac or pubic symphysis joint.
2. Ligament pain
 - i. Sacro-spinous or Sacro-tuberous ligament.
3. Bony pain
 - i. Pain described in or along the margins of the pubic ramus, ilium, ischial spine or ischial tuberosity.

VI Neurological Aspects Domain⁴⁷ (Table VI)

Common complaints: Burning, throbbing, stabbing, electric shock-like sensation, tingling, stinging and/or paresthesia pain in the pelvis and/or perineal region.

A. Complex Regional Pain Syndrome⁴⁸ (CRPS)

Sympathetic, centrally generated pain.

1. CRPS 1- Triggered by tissue injury with no underlying nerve injury.
2. CRPS 2- Associated with nerve injury.
 - i. Burning pain.
 - ii. Increased skin sensitivity.
 - iii. Changes in skin temperature, color, and/or texture.

Note: Consider Differential Diagnosis:**B. Somatic Neuropathic Pain**—Nerve injury (stretching, blunt trauma, compression, entrapment, suture ligature).

1. Sacral nerve (disease)⁴⁹
- iv. Pudendal neuralgia is a disabling form of pelvic pain. It is related to a ligamentous nerve compression mechanism. This pain is associated with the second stage of labor, sacrospinous vault suspension, vaginal laceration repairs, prostatectomy, straddle injuries, prolonged motorcycle riding, and laser treatment to the vulva, scrotum and/or perineum.
 1. Unilateral or bilateral.
 2. Lancing burning pain in the clitoris, penis, urethra, labia, scrotum, perineum and/or anus.
 3. Worse with sitting.
 4. Relieved by standing or supine position.
3. Thoracolumbar nerve (disease)^{50 FN27}

^{FN26} International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative management of female pelvic floor dysfunction (under review).⁵¹

^{FN27} Irritation of the thoracolumbar facet joints causes pain referred to the distribution of nerves T12, L1, and L2. This results in pain to the iliac crest and buttock. Frequently seen after abdominal and/or pelvic surgery.⁵⁰

TABLE VI. Neurological Aspects Domain

Symptoms	Signs	Evaluation	Syndrome/disease
Characteristic sensation descriptions: burning, throbbing, stabbing, tingling, stinging, shooting, electric shock-like sensation paresthesia, atrophy, persistent or episodic	Tenderness (nerve distribution)	Questionnaires	Somatic neuropathic pain
	Referred pain	Quantitative sensory testing	Complex regional pain syndrome
	Possible skin change (color, temp, texture)	Pain mapping Nerve block imaging Ultrasound MRI	

i. Ilioinguinal nerve.

1. Pulling or throbbing that limits physical activity (groin, labia scrotum inner thigh).

ii. Iliohypogastric nerve.

1. Pulling or throbbing sensation that limits physical activity (suprapubic area and groin).

iii. Genitofemoral nerve⁵²

1. Burning, paresthesia and pain (groin, labia or scrotum, medial thigh).

iv. Obturator nerve

1. Medial thigh or groin pain.
2. Weakness with adduction of the thigh.

C. Pain Following Mesh Surgery^{34,53}

- i. Pain during physical activity.
- ii. Dyspareunia.
- iii. Vaginal discharge.
- iv. Exposure of mesh in vagina or elsewhere.

VII Psychological Aspects Domain (Table VII)

Common complaints: worry, anxiety, low mood, frustration, sleep disturbance, helplessness, hopelessness, difficulty in concentrating, pain impairing enjoyment. These all have biopsychosocial aspects.⁵⁴

The **biopsychosocial model** in pain medicine was introduced with the publication of the Gate Control Theory of Pain. It is suggested that in the perception of pain three different inputs are involved: the sensory-nociceptive, the affective-motivational and the cognitive-evaluation input. These could differ within individuals, but all of these are involved in the human experience of pain.⁵⁵

Psychological distress as a biopsychological aspect is most often a consequence of persistent pain, although existing distress is likely to exacerbate the experience of pain and difficulties dealing with it. Findings support growing evidence that the negative affective, cognitive and psychosocial state of chronic pain is universal, regardless of a neuropathic, or nociceptive nature. Emotions, thoughts and behavior involve many different locations in the brain and multiple psychological processes are involved in neuromodulation of pain.^{18,54}

A. Worry, anxiety, fear: Pain is interpreted as a message of something seriously wrong with the body at the point where the pain is felt, consistent with models of severe acute pain. Without an explanation for chronic pain, anxiety is likely to persist and results in attempts to avoid activities which exacerbate the pain or are expected to do so.

B. Depression and depressed mood: This is predominantly pain-related and concerns loss of valued activities and roles as a result of pain. Difficulty sleeping, difficulty concentrating, helplessness, and hopelessness about finding a solution to the pain or a way of living a worthwhile life despite pain are common.

C. Catastrophizing: a tendency to overattend (magnification) to pain stimuli, with overestimation of the threat value and underestimation (hopelessness and helplessness) of the capacity to deal with the threat.

TABLE VII. Psychological Aspects Domain

Symptoms	Signs	Evaluation	Syndrome/disease
Worry, anxiety, fear	Helplessness	Formal psychological assessment	Worry/anxiety/fear
Catastrophizing	Hopelessness	Asking the patient what is wrong and what worries her/him about pain	Depression
Persistent or episodic	Avoidance of certain activities	Questionnaires	

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VIII Sexual Aspects Domain (Table VIII)

Common Complaints: Low sex drive, inability to become aroused, pain with intercourse, difficulty reaching orgasm.

Sexual dysfunction is a disturbance in the sexual response cycle or pain associated with sexual intercourse, and can take a heavy psychological toll; it is associated with depression, anxiety, and debilitating feelings of inadequacy.⁵⁶ It is appropriate to investigate for possible history of sexual/physical abuse.

Dyspareunia is a biopsychosocial phenomenon that can have physical and psychosocial implications for the individual as well for the relationship.⁵⁷ Decrease in self-esteem, depression, anxiety, fatigue, and the need to use pain medication and other medications increase the likelihood of one or more of the disorders.

Superficial or entry dyspareunia is often associated with provoked vaginal-vulvar pain syndrome. Deep or thrusting dyspareunia often occurs in association with lower urinary tract pain, musculoskeletal pain, gastrointestinal pain, as well as abdominal/pelvic pain.^{58,59}

Female and male sexual function is adversely affected in most patients with chronic pelvic pain, resulting in more than one comorbid disorder. More than 50% of partners are significantly affected and develop sexual dysfunction.

A. Sexual Desire Disorder

The following definitions form part of the DSM IV TR^{60,61 FN28}

1. Hypoactive Sexual Desire Disorder (HSDD)

- i. Low sex drive.
- ii. An absence of sexual fantasizing or erotic thoughts.
- iii. No longer feeling aroused or excited during sex.
- iv. A substantial decrease in sexual activity with partner, persisting for more than 6 months.

2. Sexual aversion disorder

- i. Persistent or recurrent aversion to, or avoidance of, sexual activity.
- ii. When presented with a sexual opportunity, the individual may experience panic attacks or extreme anxiety.

B. Sexual Arousal Disorder

- i. Persistent or recurrent inability to become sexually aroused.
- ii. Often characterized by inadequate vaginal lubrication for penetration (female).
- iii. Inability to achieve or maintain an adequate erection for penetration (male).
- iv. Symptoms present for more than 6 months.

C. Orgasmic Disorder

- i. Difficulty or delay in reaching orgasm, after sufficient sexual stimulation (female).
- ii. Premature or delayed ejaculation (male).
- iii. Present for more than 6 months.

D. Sexual Pain Disorder

1. Dyspareunia

- i. Female sexual pain: Burning, ripping, tearing, or aching sensation associated with penetration. The pain can be at the vaginal opening, deep in the pelvis, or anywhere between. It may also be felt throughout the entire pelvic area and the sexual organs and may occur only with deep thrusting.
- ii. Male sexual pain: Sexual activity may induce a central sensitization process characterized by hypersensitivity or hyperalgesia.

History should include duration of symptoms, identification of disorder, impact on quality of life, and partner relationship. Partner interviews may be very helpful as erectile dysfunction, delayed or premature ejaculation in males with hypoactive sexual desire disorder result in a 4–30 times increased risk of female partner desire, arousal or orgasmic disorder.

TABLE VIII. Sexual Aspects Domain

Symptoms	Signs	Evaluation	Syndrome/disease
Lack of desire, arousal, orgasm Dyspareunia Persistent or episodic	Depression Relationship issues	Questionnaires Laboratory (hormonal and complete metabolic panel) Doppler ultrasound	Sexual dysfunction

IX Comorbidities (Table IX)

Patients with chronic pelvic pain syndromes, and in particular those with interstitial cystitis/bladder pain syndrome (IC/BPS), have a higher prevalence of one or multiple comorbid syndromes and diseases than the general population. These include: allergies, non-cancer chronic pain, fatigue syndromes and systemic autoimmune diseases. The risk of a comorbidity in patients

^{FN28} Minimal data are available utilizing DSM 5 criteria, DSM IV TR was thus utilized. The Diagnostic and Statistical Manual of Mental Disorders, published by the American Psychiatric Association, offers a common language and standard criteria for the classification of mental disorders.⁶⁰

TABLE IX. Comorbidities

Symptoms	Signs	Evaluation	Syndrome/disease
Allergies	Fatigue	General medical evaluation	Allergies
Fatigue	Skin lesions	Laboratory	Chronic pain and fatigue syndrome
Widespread muscular and joint pain	Dry eye	Imaging	Systemic autoimmune diseases
Irritation of the eyes	Muscular skeletal tenderness		
Dryness			
Sleep disorder			

affected by IC/BPS is usually between two and ten times higher than in a healthy population. However, data from studies on comorbidities in chronic pelvic pain patients are difficult to interpret as the composition of study populations and methodology are highly variable. Information on the prevalence of comorbidities is therefore often obtained from studies on IC/BPS.^{62–66}

A. Allergies

Allergies are a heterogeneous group of diseases with involvement of the airways, skin, and sometimes of other organs. Symptoms are caused by an immunologic reaction to some kind of trigger (e.g., inhaled allergens such as dust mite allergen, pet dander, pollen, mold, food, drugs). Nonallergic reactions to drugs or food may cause symptoms similar to allergic reactions.⁶⁷ Examples include allergic asthma, allergic rhinitis (hay fever), atopic dermatitis (eczema), allergic drug reactions and allergic food reactions (tingling mouth, swelling of the lips, tongue, face or throat), hives, anaphylaxis, and atopic dermatitis.⁶⁸

B. Chronic Pain and Fatigue Syndromes

Chronic pain and fatigue syndromes are characterized by pain, often widespread; fatigue; sleep disturbances; and disability. The symptoms are usually medically unexplained, have no known pathophysiology or organic basis and show no abnormal laboratory or imaging investigations. The literature suggests that many of these conditions share demographic characteristics, clinical course and psychosocial profiles.⁶⁹ Examples are:

1. Fibromyalgia: symptoms are widespread musculoskeletal pain, fatigue, non-restorative sleep, psychological distress, and regions of localized tenderness.
2. Temporomandibular Joint Disorders: symptoms consist of complaints of facial, jaw, neck, or shoulder pain. The pain is experienced in or around the ear with chewing, speaking, or opening the mouth, with or without migraine.
3. Chronic Fatigue Syndrome: is defined as clinically evaluated, unexplained, persistent or relapsing fatigue plus four or more specifically defined associated symptoms (self-reported impairment in short term memory or concentration; sore throat; tender cervical or axillary nodes; muscle pain; pain in multiple joints without redness or swelling; headaches of a new pattern or severity; unrefreshing sleep).⁷⁰

C. Systemic Autoimmune Syndromes/Diseases

Systemic or generalized autoimmune diseases are a heterogeneous group of diseases with multi-organ involvement and evidence indicating a role played by the immune system in the pathogenesis. Examples are systemic lupus erythematosus (SLE), Sjögren's syndrome, and rheumatoid arthritis (RA). Many patients can be diagnosed with more than one of these diseases, or also with fibromyalgia and irritable bowel syndrome.

1. Systemic Lupus Erythematosus (SLE). Most frequent symptoms are debilitating fatigue, arthritis, red skin lesions after sun exposure such as a red butterfly lesion of the face, pericarditis and pleuritis, glomerulonephritis. The prevalence is 10× higher in females than in males and 2× more frequent in non-white people.
2. Sjögren's Syndrome is a systemic autoimmune disease characterized by a functional disorder of the tear and salivary glands, with or without signs of inflammation. The most common symptoms are irritation of the eyes, a dry mouth, muscle and joint pain, (debilitating) fatigue and Raynaud phenomenon.
3. Rheumatoid Arthritis (RA) is a disease characterized by chronic symmetric polyarthritis resulting in painful swelling of the joints. Other symptoms are morning stiffness, rheumatoid nodules and typical changes on hand and wrist radiographs.

D. Extraintestinal Manifestations of Inflammatory bowel disease (IBD) include non-destructive arthritis of large joints or axial arthritis such as sacroiliitis, inflammation of the eyes (uveitis, scleritis), or inflammation of the skin (erythema nodosum, pyoderma gangrenosum).⁷¹

Section 2: Signs

Generalized Physical Examination

A comprehensive physical examination should be performed, including palpation of the lower abdomen for bladder fullness and tenderness, and a complete pelvic exam to identify pain generators and referred pain patterns:

1. Observe posture, gait and protective behavior (avoiding sitting on flat surface or standing to avoid sitting, neck folding posture).
2. Standing: kyphosis, scars, hernia.
3. Supine: abduction/adduction of the hips, hyperaesthetic areas, scars, hernia.
4. Comprehensive pelvic examination for female and male.
5. Pain mapping (identification of pain generators/trigger points and referred pain).⁷²

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I Lower Urinary Tract

A. Bladder/Urethra

1. Suprapubic tenderness.
2. Tenderness of the bladder.
3. Tenderness of the urethra.
4. Tenderness of the pelvic floor muscles and identification of trigger points.⁴⁶ (See Domain V).

II Female Genital⁵

A. Vulva, Vestibule, and Clitoris

Generalized vulvar pain syndrome refers to a vulvar pain syndrome where the pain/burning cannot be consistently and precisely localized by point-pressure “mapping” via probing with a cotton-tipped applicator or similar instrument. Tenderness is diffuse and may affect all locations of the vulva.^{FN29}

1. Localized and Generalized Vulvar Pain Syndrome
 - i. Tenderness, Q-Tip touch sensitivity test.⁷²
 - ii. Erythema (localized or generalized).
 - iii. Fissures.
 - iv. Ulcers.

B. Intra-Abdominal Female Genital

1. Uterus and Fallopian Tube
 - i. Uterine tenderness.
 - ii. Cervical discharge, cervical excoriation, tenderness, adnexal tenderness, erythema.
 - iii. Extrauterine tenderness, decreased uterine mobility, adnexal mass.
 - iv. Enlarged uterus, nonspecific tenderness.
 - v. Abdominal or pelvic scars, neuroma.
2. Ovary; adnexal mass, tenderness, abdomino-pelvic scar.
3. Pelvic Congestion Syndrome: Labia varicosities, non-specific abdominal tenderness.
4. Cervix: Erosion, Nabothian follicles, discharge, bleeding.

C. Pelvic Floor Muscle (See Domain V)

1. Perineal scarring, neuroma, dermal cutaneous allodynia.
2. Tenderness (local and/or referred to another pelvic location).
3. Vaginal discharge, mesh extrusion.⁵³
4. Bulging.
5. Mass, radiation changes.

III Male Genital

A comprehensive physical examination should be performed in standing (example: exclusion of varicocele) and supine positions, including observation and palpation with pain mapping (identification of pain generators) of the external male genitals, and rectal examination.^{FN30}

A. Prostate

1. Prostate tenderness on rectal examination.
2. Possible urethral discharge.

B. Scrotum

1. Tenderness on physical examination.
2. Change in color.
3. Masses on palpation.
4. Scars post-vasectomy.
5. Allodynia (increased perception of pain).

C. Epididymis

1. Tenderness.

^{FN29}The vulvar vestibule (part of the vulva which lies between the labia minora into which the urethral meatus and vaginal introitus open) may be involved, (but the discomfort is not limited to the vestibule and may include referred pain from the other CPPS domains).

^{FN30}Tenderness might be graded as mild, moderate, or severe.

2. Masses, nodules.

D. Testicle

1. Tenderness.
2. Masses, nodules.

E. Penis

1. Tenderness.
2. Curvature.
3. Nodules/plaque.

F. Urethra

1. Tenderness.
2. Discharge.

IV Gastro-Intestinal

A. Anorectum

1. Chronic Proctalgia—Identification of tenderness on rectal exam³
2. Levator Ani Syndrome—Identification of tenderness during posterior traction on the puborectalis.
3. Proctalgia Fugax—Usually there is no evident sign on physical examination.⁴⁰
4. Anal Fissure—Identification of separation of the anoderm, sentinel tag at the external apex, exposed internal sphincter muscle, hypertrophic anal papilla at the internal apex.³⁸
5. Abscess—Identification of fluctuant collections in the perianal tissues, drainage (fistula).³⁹
6. Hemorrhoids—Identification of skin tags, thrombosis, prolapse on straining (reducible and irreducible).
 - i. Internal: Located proximal to the dentate line and covered by columnar epithelium.
 - ii. External: Located distal to the dentate line and covered by modified Squamous epithelium (anoderm)
 - iii. Thrombosed: Painful lump in the perianal area.^{41,42}
7. Anorectal Crohn's Disease—Identification of skin tags, hemorrhoids, fissures, anal ulcers, strictures, abscess, fistula, severe proctitis.⁴³

B. Colorectum (IBS, IBD)

1. Abdominal tenderness.
2. Watery or bloody diarrhea.
3. Rectal bleeding.
4. Weight loss.
5. Fever.

V. Musculoskeletal

The musculoskeletal structures are examined for signs of tenderness and altered tension or abnormal movement.^{73–76} FN31

1. Muscle tone: State of the muscle, usually defined by its resting tension, clinically determined by resistance to passive movement. Muscle tone has two components: (i) the contractile component, created by a low-frequency activation of a small number of motor units; (ii) the viscoelastic component, which is independent of neural activity and reflects the passive physical properties of the elastic tension of the muscle fiber elements and the osmotic pressure of cells.⁴⁶ In normally innervated skeletal muscle, tone is comprised of both “active” (contractile) and “passive” (viscoelastic) components.^{46,77,78} FN32
 - a. Hypertonicity is a general increase in muscle tone that can be associated with either elevated contractile activity and/or passive stiffness in the muscle.^{5,77–79} FN33
 - b. Hypotonicity is a general decrease in muscle tone that can be associated with either reduced contractile activity and/or passive stiffness in the muscle.^{FN34} As the cause is often unknown, the terms neurogenic hypotonicity and non-neurogenic hypotonicity are recommended.

FN31 Varying reliability has been found from pelvic floor muscle (PFM) studies assessing pain and tension using digital palpation scales.^{73–76} Patients who present with alteration in the musculoskeletal structure need to be referred to a Physical Therapist well trained in the treatment of CPPS.

FN32 Muscle tone is evaluated clinically as the resistance provided by a muscle when a pressure/deformation or a stretch is applied to it.^{46,77,78} Muscle tone may be altered in the presence or absence of pain. There is no single accepted or standardized way of measuring muscle tone, and there are no normative values.

FN33 As “hypertonicity” can also be used to describe increased muscle tone of neurogenic origin, the term “increased tone” is preferred when the cause is non-neurogenic.

FN34 As “hypotonicity” can also be used to describe decreased muscle tone of neurogenic origin, the term “decreased tone” is preferred when the cause is non-neurogenic.

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2. Stiffness: Stiffness is the resistance to deformation.^{80,81 FN35}
3. Compliance: Passive compliance is defined as the reciprocal of muscle stiffness.^{80,81 FN36}
4. Tension: may have a similar meaning to tone and stiffness.^{FN37}
5. Spasm: persistent contraction of striated muscle that cannot be released voluntarily.^{82 FN38}
 - a. Contracture: is an involuntary tightening of a muscle. Clinically, a muscle cramp and contracture may appear similar, however contractures are electrically silent.⁸³
6. Cramp: a muscle cramp is a painful involuntary muscle contraction that occurs suddenly and can be temporarily debilitating.^{83,84 FN39}
7. Fasciculation: A fasciculation is a single, spontaneous, involuntary discharge of an individual motor unit.^{83 FN40}
8. Tender point: tenderness to palpation at soft tissue body sites.⁴⁶
9. Trigger point (TrP): a tender, taut band of muscle that can be painful spontaneously or when stimulated.⁸⁵ The taut band is electrically silent. Local or referred pain may be reproduced.^{86 FN41}

VI Neurological Aspects⁴

1. Tenderness on palpation corresponding to the nerve distribution.
2. Pain mapping (reproduce pain on palpation).
3. Identify referred pain by palpation.
4. Possible skin changes (color, blistering, temperature).

VII Psychological Aspects

Observation by the provider may reveal:

1. Anxiety and/or depressed mood, and avoidance or reduction of activities which exacerbate pain, or are believed by the patient to carry a risk of increasing the pain or causing harm.
2. Expression of helplessness and hopelessness (feeling of despair and representing 'the internal belief that one cannot manage one's pain').^{18,54}

VIII Sexual Aspects (59)

A patient with sexual pain often has one or more other sexual dysfunctions including desire disorder, arousal disorder or orgasm disorder.

In most cases the physical examination will not identify the specific etiology of sexual dysfunction. However, a focused and comprehensive pelvic examination in females and males is mandated. In addition, assessment of the secondary sexual characteristics should be performed.^{60 FN42} For the specific assessment, see the relevant Domains.

Section 3: Further Evaluation

Pain Evaluation and Measurement (7)

Pain rating(s) are essential in patient evaluation, including; Baseline and ongoing regular evaluation of severity, quality of life, questions about thoughts, emotions and behavior associated with the pain (questionnaires).

Pain Measurement

1. One of the most commonly used tools is the visual analogue scale (VAS)(85), which is a 10 cm line from "0" no pain to "10" extreme pain.^{5 FN43}

0	1	2	3	4	5	6	7	8	9	10
No pain										Extreme pain
Not unpleasant										Extremely unpleasant

^{FN35} Passive elastic stiffness is defined as the ratio of the change in the passive resistance or passive force (ΔF) to the change in the length displacement (ΔL) or $\Delta F/\Delta L$.⁸¹ The term should only be used if stiffness is measured quantitatively such as with instruments like dynamometry or myotonometry.

^{FN36} It represents the compressibility of a muscle, clinically assessed by pressing a finger into it (palpation) to determine how easily it is indented and how "springy" it is.

^{FN37} Muscle tension can be increased or decreased due to exogenous factors such as the amount of pressure applied and endogenous factors such as thickness/ cross sectional area of the muscle itself, fluid present within the muscle (swelling, inflammation), position (e.g., standing vs. sitting) or increased neural activity.

^{FN38} Occurs at irregular intervals with variable frequency and extent. Spasm over days or weeks may lead to a contracture.

^{FN39} Pain is intense and localized. It tends to occur when the muscle is in the shortened position and contracting, is generated by the motor unit, and displays a high firing rate (20–150 Hz).⁸³ Muscle cramp either during or immediately after exercise is commonly referred to as "exercise-associated muscle cramping."⁸⁴ However, cramps are not specific to exercise.

^{FN40} The source generator is the motor unit or its axon, prior to its terminal branches. Fasciculations display an irregular firing pattern of low frequency (0.1–10 Hz).⁸³ Clinically, fasciculations are recognized as individual brief twitches. They may occur at rest or after muscle contraction and may last several minutes.

^{FN41} An active TrP is said to have a characteristic "twitch" response when stimulated; however, the twitch response to palpation has been shown to be unreliable.

^{FN42} The most reliable sign of a TrP is sensitivity to applied pressure.⁸⁶

^{FN43} Blood pressure, heart rate, peripheral pulses, edema, lower extremity strength, and vibratory sensation is almost always helpful.⁶⁰

^{FN44} A simple verbal rating scale can also be used, for example, "none," "mild," "moderate," "severe."

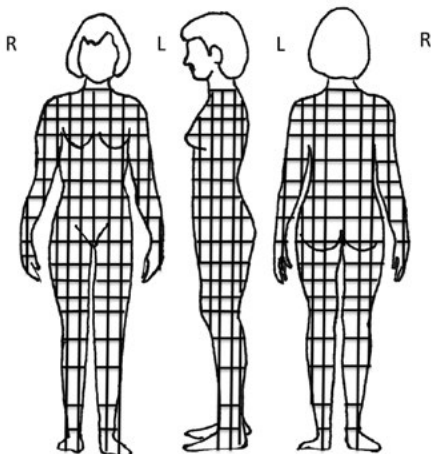
2. Pain Mapping Utilizing a Pain Body Chart^{87 FN44}

PAIN MAPPING

Instructions

Put highest intensity in each square that is applicable

May use color codes for different pains



Pain evaluation involves additional pain mapping by identifying pain generators through diagnostic procedures.^{FN45} These include EMG, Q-tip touch sensitivity testing,^{88,89} trigger point injections, nerve blocks and imaging.^{88 FN46}

I Lower Urinary Tract**A. Questionnaires^{FN47}**

- a. Voiding diary with volume intake and output for 3 days at initial evaluation. Patient sensation at voiding might be recorded. At follow-up only the number of voids during day and night time is necessary. Morning volume might be recorded as a help to monitor highest functional capacity.⁹⁰
- b. Basic symptom severity Questionnaires (condition specific):
 - i. The O'Leary-Sant Symptom Index.⁹¹
 - ii. International Prostate Symptom Score.⁹²
- c. Visual Analogue Scale (VAS)⁸⁷ or a Likert scale for pain during the last 24 hr and over the last month (to fit with the voiding diary).^{FN48}

B. Laboratory Testing

- a. Urine Dipstick (red blood cells, pH, leucocytes, nitrite).
- b. Urine Culture.^{FN49}
- c. Urine Cytology in high risk patients.
- d. Investigations for Ureaplasma and Chlamydia are optional.

^{FN44} Patients color the pain sites on the body chart.

^{FN45} As pain is multidimensional, it can be helpful to assess separately pain intensity, pain distress, and interference of pain with activities of daily life.

^{FN46} Kaufman Q-tip touch sensitivity test. This involves touching all four quadrants of the vulvar and vestibular Skene's gland ostia to evaluate for vestibulodynia, using a visual analog scale to document the level of pain and sensitivity the patient is experiencing.⁸⁹

^{FN47} Many of the questionnaires have not been studied and validated in patients with CPPS. The main assessment is still a thorough history and a full and accurate physical examination followed by pain mapping and other studies as indicated.

^{FN48} Separate scores for the average, mildest and worst pain might be obtained.

^{FN49} If sterile pyuria, culture for tuberculosis, in high risk patients.

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- e. C.T. Urogram for Hematuria.

C. Intravesical Anesthetic Challenge

An Anesthetic Challenge may be useful in pain mapping to identify the bladder and/or the urethra as a pain generator.⁹³ FN50

D. Urodynamic Evaluation (1)

- a. Flowmetry and Post-void Residual
- b. Filling Cystometry^{94,95} FN51
- c. Pressure-Flow Study

It is recommended to perform filling cystometry and pressure flow study if the flowmetry suggests voiding dysfunction. The demonstration of pain may identify the bladder and/or urethra as a pain generator.

In males, bladder outlet obstruction might be a differential diagnosis⁹⁶ and it is recommended to perform flowmetry in all males and consider pressure-flow studies. In males with a peak flow below 20 ml/second. In females, flowmetry and post void residual urine volume should be considered, and pressure-flow study is optional.

E. Cystoscopy

Needs to be done for patients with hematuria⁹⁷ and to identify Hunner lesions.

- a. ESSIC standardized the procedure for cystoscopy and hydrodistension.¹¹ FN52

Cystoscopic findings by hydrodistension are important in subclassification of IC/BPS, see for example the ESSIC classification.^{11,31,98,99} FN53

- i. Glomerulation
During cystoscopy with hydrodistension, glomerulations, with or without waterfall lesions (blood trickling downwards), may often be observed.¹⁰⁰ FN54
- ii. Hunner Lesion Figure 1

A Hunner lesion is not an ulcer, but an inflammatory infiltrate.^{11,101} FN55

- i. Morphologic findings in Hunner Lesion
 1. Inflammatory infiltrate on examination of biopsy taken with electro-resection or by cold cup biopsy.
 2. Lymphocyte-like cells dominate in the infiltrate, but neutrophilic and eosinophilic granulocytes as well as plasma cells and mast cells are also found.
 3. Perineural and perivascular arrangement of lymphocyte-like cell infiltrates
 4. Granulation tissue.^{101–104} FN56

F. Differential Diagnosis (Confusable, treatable diseases):

Criteria for diagnosis are needed as the target disease may be confused with other treatable diseases (confusable diseases) because of similar features.¹¹

- a. Ketamine Cystitis

^{FN50} A solution of lidocaine and sodium bicarbonate administered intravesically results in reduction of pain. Alkalinized lidocaine instillation has not been validated, but may be useful.⁹³

^{FN51} The NIDDK criteria excluded patients with detrusor overactivity at filling cystometry in order not to confuse the picture in clinical trials.⁹⁴ However, this does not mean that detrusor overactivity cannot coexist with interstitial cystitis/bladder pain syndrome. In the interstitial cystitis database, approximately 14% of IC/BPS patients had detrusor overactivity.⁹⁵

^{FN52} A rigid cystoscope is preferred to facilitate taking adequate biopsies. Glycine or corresponding filling fluid should be used to allow for coagulation after biopsies. Infusion height should be approximately 80 cm above the Symphysis Pubis. A dripping chamber is used and the bladder is filled until fluid dribbling stops. If necessary, a digital block is applied around the urethra to prevent leakage. Pre-distension inspection includes observation for radiating vessels, coagulum or fibrin deposits, white spots, hyperaemia, edema, cracks, scars or any other mucosal changes. Continuous inspection while filling the bladder is advised. When maximum capacity is reached, the distension is maintained for 1–3 min. The bladder is emptied and the color of the fluid checked for the degree of bleeding. The total volume drained is the measured maximum bladder capacity. During a second filling, the bladder is filled to approximately 1/3rd to 2/3rds of the bladder capacity to achieve optimal vision for inspection and biopsies. The bladder should not be filled to maximum capacity or distended again to avoid further provocation of changes with doubtful reproducibility.³³

^{FN53} The finding of a Hunner lesion is important because effective treatment is available.^{98,99} The presence of Hunner lesions may be the diagnostic finding of the proposed disease "Interstitial Cystitis."³¹

^{FN54} The significance of the presence of glomerulation remains to be determined.¹⁰⁰

^{FN55} A Hunner lesion is a distinct cystoscopic finding and typically presents as a circumscribed, reddened mucosal area with small vessels radiating towards a central scar, with a fibrin deposit or coagulum attached to this area. This site ruptures with increasing bladder distension, with petechial oozing of blood from the lesion and the mucosal margins in a waterfall manner. A rather typical edema may develop post-distension with varying peripheral extension. Usually, lesions are multiple but occasionally they may be single. It is not unusual for more lesions to be detected at re-inspection than seen at the initial phase of distension.¹¹

^{FN56} To a large extent, the detection rate and the findings on distribution of mast cells have been dependent on laboratory routines and staining as well as fixation techniques. Tryptase staining methods provide a stable result that is not sensitive to laboratory variations.^{103,104}



Fig. 1. Hunner lesion.

Ketamine Cystitis is a new condition not previously described. Caused by recreational ketamine abuse, ketamine cystitis includes increased voiding, frequency, dysuria, bladder pain and hematuria.^{105,106} ^{FNS7}

II Female Genital

A. Vulva, Vestibule and Clitoris

1. Questionnaires
 - i. Visual Analog Scale for pain.⁸⁶
 - ii. Female Sexual Function Index (FSFI).⁶¹
 - iii. Female Sexual Distress Scale (FSDS).¹⁰⁷
2. Laboratory Testing
 - i. Culture.
 - ii. Biopsy.
3. Diagnostic Testing
 - i. Vulvoscopy, with or without biopsy.
 - ii. Quantitative Sensory Testing (Q-tip touch sensitivity test).^{72,89,108}

B. Intra-abdominal Female Genital

1. Questionnaires
 - i. Visual Analog Scale(85) for pain.
2. Laboratory Testing
 - i. Culture.
 - ii. Complete blood count.
3. Laparoscopy (with or without biopsy)
4. Ultrasound (US)
5. MRI
6. Venography (to rule out Pelvic Congestive Syndrome)¹⁰⁹

C. Pelvic Floor Muscle

1. Questionnaires.
 - i. Visual Analog Scale for pain.⁸⁶
 - ii. Pelvic Floor Distress Inventory (PFDI).¹¹⁰

^{FNS7}The molecular mechanism for ketamine-induced cystitis is unknown. The affected bladder exhibits a denudation of the urothelium with inflammatory cell infiltration. The upper urinary tract is also damaged in patients who use a higher dose and with a longer duration. Attention by both medical organizations and social workers for this increasing social phenomenon particularly among young people is now urgently needed.^{105,106}

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- iii. Prolapse and Incontinence Sexual Questionnaire (PISQ).¹¹¹
2. Laboratory Testing
 - i. Wet Mount, Culture.
 - ii. Biopsy.
 3. Imaging References
 - i. Ultrasound (4D if available for visualization of mesh, where applicable).
 - ii. MRI (with or without defecography).
 - iii. Defecography.

III Male Genital

A. Prostate Pain

1. Quantitative assessments.
 - i. Bladder diary.^{90,112}
 - ii. CPSI (Chronic Prostatitis Symptom Index).¹¹³
 - iii. Visual Analog Scale for Pain (VAS).⁸⁶
2. Laboratory Testing
 - i. Urinalysis (including post prostate massage).
 - ii. Urine Culture post prostate massage.
 - iii. Semen Culture.
3. Uroflowmetry, Post voiding residual volume, pressure flow study
4. Cystoscopy
5. Ultrasonography, with or without biopsy.

B. Scrotum, Epididymis, Testicle, Penis

1. Quantitative assessments
 - i. VAS for Pain.⁸⁶
2. Ultrasonography

C. Urethra Pain

1. Quantitative assessments
 - i. Bladder diary.
 - ii. VAS for Pain.⁸⁶
2. Laboratory Testing
 - i. Urinalysis (including post prostate massage, Ureaplasma/Chlamydia as appropriate).
3. Urethroscopy/Urethrography
4. Ultrasonography

D. Sexual Pain (See Domain VIII)

1. Questionnaires
 - i. VAS for Pain.⁸⁶
 - ii. International Index of Erectile Function (IIEF).¹¹⁴

IV Gastro-Intestinal (40)

1. Questionnaires
 - i. Rome III Criteria Questionnaire.¹¹⁵
 - ii. Colorectal Rectal Distress Inventory.¹¹⁶
2. Laboratory Testing
 - i. Culture.

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- ii. Stool Evaluation for ova and parasites.
 - iii. Antibody testing.
 - iv. Biopsy.
3. Diagnostic Testing
- i. Anorectal Manometry (paradoxical contraction of the pelvic floor muscles when instructed to strain during defecation).
 - ii. Rigid or flexible endoscopy (Anorectal sigmoidoscopy) with or without biopsy.
 - iii. Anorectal/Pelvic US, 3D.
 - iv. Barium Enema.
 - v. CT Scan, Defecography, MRI defecography.

V Musculoskeletal¹¹⁷

1. Questionnaires
- i. McGill Pain Questionnaire.¹¹⁸
 - ii. Pelvic Floor Distress Inventory (PFDI).¹¹⁰
 - iii. Female Sexual Function Index (FSFI).⁶¹
 - iv. Female Sexual Distress Scale (FSDS).¹⁰⁷
2. Pain Location Drawing (Pain Mapping)
- i. Pain Chart body map.⁸⁷
3. Evaluation of Muscle Tension There is no single tool which is able to measure all components of muscle tone. Some tools may be able to measure aspects of tone such as contractility, stiffness or elasticity. Instrumented methods may have a role in the valid and reliable evaluation of muscle tone, for example, surface electromyography, dynamometry, real-time ultrasound, elastometry, myotonometry.
- i. Pressure manometry is the measurement of resting pressure or pressure rise generated during contraction of the pelvic floor muscles using a pressure device (a manometer) inserted into the urethra, vagina or anus.^{119,120 FN58}
 - ii. Surface electromyography (sEMG) refers to the bioelectrical activity generated by muscle fibres.^{121,122 FN59}
 - iii. Dynamometry is the measurement of pelvic floor muscle resting and contractile forces using strain gauges mounted on a speculum (a dynamometer), which is inserted into the vagina.¹²³
 - iv. Real-time ultrasound measures pelvic floor muscle morphology and function via a non-invasive (trans-abdominal or trans-perineal) probe.^{124 FN60}
 - v. Elastometry measures the elasticity of a tissue.^{125 FN61}
4. Trigger point injection or needling has been used as a diagnostic test to identify pain generators.^{125 FN62}
5. Imaging
- i. X-Ray.
 - ii. Ultrasound.
 - iii. MRI.

VI Neurological Aspects

A. Neuropathic Pain Questionnaires

1. VAS Pain Score.⁸⁶
2. Pain DETECT (Validated for CPPS evaluation).¹²⁹
3. Leeds Assessment for neuropathic symptoms and signs (not validated for chronic pelvic pain).¹³⁰
4. Douleur Neuropathique 4 Questionnaire.¹³¹

^{FN58} The tool has been used as an outcome measure in intervention studies of pelvic floor pain.^{119,120} However, the tool has not been tested for reliability in this population.

^{FN59} Pelvic floor muscle surface electrodes use either flat interface perineal electrodes or intra-vaginal/intra-anal probes to record sEMG either at rest or during a PFM contraction. Surface EMG is considered to be non-specific to the PFM. Because of the large surface area covered by the electrode, cross-talk from adjacent muscles often occurs.^{121,122} It is therefore not considered reliable as a measure.

^{FN60} Trans-perineal measures of ano-rectal angle and levator plate angle have been tested for reliability in a male pelvic pain population.¹²⁴ Therefore, this tool shows promise as an instrumented method to evaluate pelvic floor muscle changes in pelvic pain.

^{FN61} It has recently been applied to measure the passive stiffness of puborectalis in asymptomatic women and shown to be reliable in this pilot study.¹²⁵ However, it requires testing to establish application in a pelvic pain cohort.

^{FN62} The taut band(s) of sarcomeres within the TrP can be identified by ultrasonography.¹²⁶ and magnetic resonance elastography.¹²⁷ A tissue compliance meter which measures stiffness in the taut band has been shown to confirm the hardness of the discrete band of muscle that harbors the tender region in peripheral skeletal muscle.¹²⁸

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B. Quantitative Sensory Testing

1. 1Q-tip touch sensitivity.
2. Sensory pain mapping.⁷²
3. Reflex evaluation.
4. Electromyography.

C. Nerve Blocks

1. May/may not be done under Computed Tomography, Ultrasound or EMG guidance.^{132,133}

D. Imaging

1. Ultrasound
2. Magnetic resonance Imaging (MRI)

VII Psychological Aspects^{18,54}

The chief purpose of psychological assessment is to get a complete picture of the pain syndrome with all affected dimensions: somatic, affective, cognitive and behavioral, and the individual consequences for the patient. Direct questioning about the patient's view of what is wrong or what worries him/her is more helpful than questionnaires.^{FN63}

1. Questionnaires
 - i. SF-12 or SF-36.¹³⁴
 - ii. Brief Pain Inventory.¹³⁵
 - iii. Catastrophizing Questionnaire can be considered in certain cases.¹³⁶

VIII Sexual Aspects

1. Questionnaires.
 - i. Female Sexual Function Index (FSFI).⁶¹
 - ii. Female Sexual Distress Scale (FSDS).¹⁰⁷
 - iii. International Index of Erectile Function (IIEF).¹³⁷
2. Laboratory Testing
 - i. Hormone Panel.
 - ii. Complete Metabolic Panel.
 - iii. Culture.
3. Imaging
 - i. Doppler US to assess blood flow.

It is also particularly important to work up the partner's potential sexual dysfunction. Early referral to a sexual counsellor is optimal.

IX Evaluation of Comorbidities

If patients have symptoms and signs of comorbidities, evaluation should be undertaken according to relevant guidance, and may be appropriate to refer to the relevant specialist.

SUMMARY

This first ICS Standard for Terminology in Chronic Pelvic Pain Syndromes aims to improve understanding of these syndromes and patient diagnosis. It is hoped that this will help develop the field, through facilitating phenotyping of patients, development of pertinent animal models and new preclinical development of therapeutic strategies.

Evaluation of patients based on the nine domains should be individualized, taking into consideration the patient's personal perception of pain, and also the biopsychosocial aspects of CPPS.

Discussions on nomenclature partly focused on the risk of inadequate patient care if diagnostic terminology is changed without taking into account the practical impact of its application on the patient's access to appropriate treatment, reimbursement, and social benefits.

This Standard for Terminology in CPPS will be reviewed in the future as continuing research, such as the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network, generates new insights.¹³⁸⁻¹⁴⁰ Working with the guideline bodies, such as the AUA, East Asian IC Study Group/SICJ, EAU, ESSIC, FGIDS, and IASP, the ultimate aim should be to achieve international consensus.

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^{FN63} Early referral to a psychological healthcare provider should be considered. Patients with sexual dysfunction may need sexual counseling.

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Any products/companies referred to in this document are not necessarily recommended or endorsed by the ICS.

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An International Urogynecological Association (IUGA) / International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Organ Prolapse (POP)

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Introduction: The terminology for female pelvic floor prolapse (POP) should be defined and organized in a clinically-based consensus Report. **Methods:** This Report combines the input of members of two International Organizations, the International Urogynecological Association (IUGA) and the International Continence Society (ICS), assisted at intervals by external referees. Appropriate core clinical categories and a sub-classification were developed to give a coding to definitions. An extensive process of fourteen rounds of internal and external review was involved to exhaustively examine each definition, with decision-making by collective opinion (consensus). **Results:** A Terminology Report for female POP, encompassing over 230 separate definitions, has been developed. It is clinically-based with the most common diagnoses defined. Clarity and user-friendliness have been key aims to make it interpretable by practitioners and trainees in all the different specialty groups involved in female pelvic floor dysfunction and POP. Female-specific imaging (ultrasound, radiology and MRI) and conservative and surgical managements are major additions and appropriate figures have been included to supplement and clarify the text. Emerging concepts and measurements, in use in the literature and offering further research potential, but requiring further validation, have been included as an appendix. Interval (5-10 year) review is anticipated to keep the document updated and as widely acceptable as possible. **Conclusion:** A consensus-based Terminology Report for female POP has been produced to aid clinical practice and research. *NeuroUrol. Urodynam.* 35:137–168, 2016. © 2016 Wiley Periodicals, Inc., and The International Urogynecological Association

Key words: female; pelvic organ prolapse; standardization report; terminology report

INTRODUCTION

Prolapse (Latin: *Prolapsus* – “a slipping forth”) refers to a falling, slipping or downward displacement of a part or organ. **Pelvic organ** refers most commonly to the uterus and/or the different vaginal compartments and their neighboring organs such as bladder, rectum or bowel. **Pelvic organ prolapse (POP)** is thus, primarily, a definition of anatomical change. Some such changes may well be considered within the range of normality for certain women. A **diagnosis of POP** ideally demands clear clinical evidence, starting with a woman having symptoms related to the “downward displacement” of a pelvic organ.

There is currently no single document encompassing all elements required for diagnoses in the area of female POP. Such a report would require a full outline of the terminology for symptoms, signs, clinical assessments, functional investigations for female POP, the imaging associated with those investigations, the most common diagnoses and terminology for the different conservative and surgical treatment modalities.

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There will be a need to reference considerably the 2010 IUGA-ICS Joint Terminology Report on Female Pelvic Floor Dysfunction¹. An original aim of that report¹ had been to provide a general terminology, forming a “backbone” or “core” terminology to which more specific terminologies can be attached. Reference can also be made to three other published Standardization Reports²⁻⁴ and 6 joint IUGA-ICS Female Terminology Reports⁵⁻¹⁰ subsequent to the 2010 Report¹, three published⁵⁻⁷, three⁸⁻¹⁰ advanced in development.

In terms of the previous standardization document on female POP⁴, now 20 years old, there has been much discussion and debate¹¹⁻¹⁴ on the possible need to update its classification POP-Q, or at least to present it in a refreshed version. The POP Working Group has opted for the latter, with major upgrades to symptoms, signs, investigations and diagnoses, but a conservative approach to the classification itself (apart from adding a validated simplified version), due to the longevity of its use and the lack of any validated, clearly superior alternative classification. Female-specific imaging (ultrasound, radiology and MRI) and conservative and surgical managements are major additions and appropriate figures have been included to supplement and clarify the text. Emerging concepts and measurements, in use in the literature and offering further research potential, but requiring further validation, have been included as an Appendix. This Report acknowledges that POP is often not a diagnosis in isolation but may be associated with POP-related and unrelated voiding, defecatory and/or sexual dysfunctions and/or other diagnoses of pelvic floor dysfunction.

This Terminology Report is inherently and appropriately a definitional document, collating the definitions of those terms, i.e. “words used to express a defined concept in a particular branch of study”¹⁵, here POP. Emphasis has been on comprehensively including those terms in current use in the relevant peer-reviewed literature. The aim is to assist clinical practice and research. Some new and revised terms have been included. Explanatory notes on definitions have been referred, where possible, to the “Footnotes” section.

Like all the other joint IUGA-ICS female-specific terminology reports, every effort has been made to ensure this Report is:

(1) User-friendly: It should be able to be understood by all clinical and research users.

(2) Clinically-based: Symptoms, signs and validated assessments/investigations should be presented for use in forming workable diagnoses for POP and associated dysfunctions. Sections 1-5 will address symptoms, signs, POP quantification, investigations for associated dysfunctions and current POP imaging modalities that may be used to make those diagnoses. A number of related radiological investigations including Magnetic Resonance Imaging (MRI) and Computerized Tomography (CT) have also been incorporated. Section 6 will address POP diagnoses, possible POP-related diagnoses and co-existing diagnoses. The scope of the Report will exclude more invasive investigations requiring an anesthetic. Sections 7 and 8 will list the terminology for evidence-based conservative and surgical treatments for POP.

(3) Origin: Where a term’s existing definition (from one of multiple sources used) is deemed appropriate, that definition will be included and duly referenced. A large number of terms in female pelvic floor prolapse and dysfunction, because of their long-term use, have now become generic, as apparent by their listing in medical dictionaries.

(4) Able to provide explanations: Where a specific explanation is deemed appropriate to describe a change from earlier definitions or to qualify the current definition, this will be included as an addendum to this paper (*Footnote [FN] 1,2,3...*). Wherever possible, evidence-based medical principles will be followed.

It is suggested that acknowledgement of these standards in written publications related to female POP, be indicated by a footnote to the section “Methods and Materials” or its equivalent, to read as follows: “Methods, definitions and units conform to the standards jointly recommended by the International Urogynecological Association and the International Continence Society except where specifically noted”.

SECTION 1: SYMPTOMS:

Symptom: Any morbid phenomenon or departure from the normal in structure, function or sensation, experienced by the woman and indicative of disease or a health problem¹⁶. Symptoms are either volunteered by, or elicited from the woman or may be described by the woman’s caregiver¹⁻³.

¹: In the era of advanced cellphone camera technology, a woman, at times, will bring photographic evidence of the prolapse at its worst. This can add to other clinical evidence, particularly if there is a discrepancy between symptoms and signs.

²: The more formal classification of constipation is as follows:

Rome II diagnostic criteria for constipation:

- At least 12 weeks, which need not be consecutive, in the previous 12 months, of two or more of:
 - (i) Straining in > 1 in 4 defecations.
 - (ii) Lumpy or hard stools in > 1 in 4 defecations.
 - (iii) Sensation of incomplete evacuation in > 1 in 4 defecations.
 - (iv) Sensation of anorectal obstruction/ blockage in > 1 in 4 defecations.
 - (v) Manual manoeuvres to facilitate > 1 in 4 defecations (e.g. digital evacuation, support of the pelvic floor).
 - (vi) Less than 3 defecations per week.
- Loose stools are not present and there is insufficient evidence for IBS (irritable bowel syndrome)

³: A symptomatic-based subdivision of Stage II (see Appendix A) was overlooked at this time in favor of maintaining the current strictly anatomical definition of the “sign of POP”.

Pelvic Organ Prolapse (POP) Symptoms

Prolapse symptoms¹: A departure from normal sensation, structure or function, experienced by the woman in reference to the position of her pelvic organs. Symptoms are generally worse in situations when gravity might make the prolapse worse (e.g. after long periods of standing or exercise) and better when gravity is not a factor e.g. lying supine. Again symptoms may be more noticeable at times of abdominal straining e.g. defecation.

A: Vaginal Prolapse Symptoms

(i) Vaginal bulging¹: Complaint of a “bulge”, lump or “something coming down” or “falling out” through the vaginal introitus. The woman may state she can either feel the bulge by direct palpation or see it, perhaps aided with a mirror. FN1

(ii) Pelvic pressure¹: Complaint of increased heaviness or dragging (pain or discomfort) in the suprapubic area and/or pelvis.

(iii) Bleeding, discharge, infection¹: Complaint of abnormal vaginal bleeding, discharge or infection which may be related to ulceration of the prolapse.

(iv) Splinting / Digitation¹: Complaint of the need to digitally replace the prolapse or to otherwise apply manual pressure, e.g. to the vagina, perineum or perianal area (splinting), or rectally (digitation) to assist voiding or defecation.

(v) Low backache¹ (POP-related): Complaint of low, sacral (or “menstrual-like”) backache associated temporally with vaginal POP and relieved when prolapse is reduced.

B: Urinary Tract Prolapse Symptoms

(i) Urethral Prolapse: Complaint of a “lump” at the external urethral meatus.

C: Anorectal prolapse symptoms

(i) Anorectal prolapse: Complaint of a “bulge” or “something coming down” towards or through the anus/rectum. The woman may state she can either feel the bulge by direct palpation or see it perhaps aided with a mirror. FN1

(ii) Rectal prolapse: Complaint of external protrusion of the rectum.

Effects of Pelvic Organ Prolapse on Bladder, Bowel and Sexual Function.

As demonstrated in Figure 1, higher stage utero-vaginal prolapse will usually cause anatomical distortion to surrounding organs, bladder and rectum most commonly. This can lead to abnormal function, most commonly difficulty with bladder and bowel emptying. Commonly, symptoms related to those surrounding organs are the most bothersome leading to the eventual diagnosis of the POP.

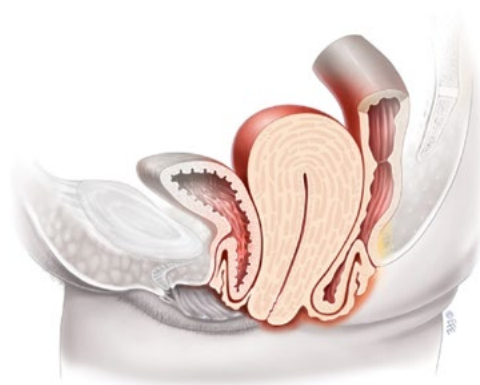


Figure 1. Utero-vaginal prolapse.

D: Potential prolapse-related lower urinary tract symptoms:

(i) Hesitancy¹: Complaint of a delay in initiating micturition.

(ii) Slow stream¹: Complaint of a urinary stream perceived as slower compared to previous performance (particularly prior to the development of POP) or in comparison with others.

(iii) Intermittency¹: Complaint of urine flow that stops and starts on one or more occasions during voiding.

(iv) Straining to void¹: Complaint of the need to make an intensive effort (by abdominal straining, Valsalva or suprapubic pressure) to either initiate, maintain or improve the urinary stream.

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(v) **Spraying (splitting) of urinary stream**¹: Complaint that the urine stream is a spray or split rather than a single discrete stream.

(vi) **Feeling of incomplete (bladder) emptying**¹: Complaint that the bladder does not feel empty after micturition.

(vii) **Need to immediately re-void**¹: Complaint that further micturition is necessary soon after passing urine.

(viii) **Post-micturition leakage**¹: Complaint of a further involuntary passage of urine following the completion of micturition.

(ix) **Position-dependent micturition**¹: Complaint of having to take specific positions to be able to micturate spontaneously or to improve bladder emptying e.g. leaning forwards or backwards on the toilet seat or voiding in the semi-standing position.

(x) **Splinting to micturate**: as above A (iv).

(xi) **Dysuria**¹: Complaint of burning or other discomfort during micturition. Discomfort may be intrinsic to the lower urinary tract or external (vulvar dysuria).

(xii) **(Urinary) retention**¹: Complaint of the inability to pass urine despite persistent effort.

(xiii) **Increased daytime urinary frequency**¹: Complaint that micturition occurs more frequently during waking hours than previously deemed normal by the woman.

(xiv) **Urgency**¹: Complaint of a sudden, compelling desire to pass urine which is difficult to defer.

E: Potential prolapse-related anorectal dysfunction symptoms^{1,8}

(i) **Constipation**⁸: Complaint that bowel movements are infrequent and/or incomplete and/or there is a need for frequent straining or manual assistance to defecate. FN2

(ii) **Feeling of incomplete bowel evacuation**^{1,8}: Complaint that the rectum does not feel empty after defecation and may be accompanied by a desire to defecate again.

(iii) **Straining to defecate**^{1,8}: Complaint of the need to make an intensive effort (by abdominal straining or Valsalva) to either initiate, maintain or improve defecation.

(v) **Sensation of anorectal blockage**⁸: Complaint suggestive of anorectal obstruction.

(vi) **Splinting / Digitation**^{1,8}: Defined above in A (iv).

(vii) **Fecal (rectal) urgency**^{1,8}: Complaint of a sudden compelling desire to defecate that is difficult to defer.

(viii) **Post-defecatory soiling (NEW)**: Soiling occurring after defecation.

F: Potential prolapse-related Sexual dysfunction symptoms^{1,10,17}:

(i) **Dyspareunia**: Complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration.

(ii) **Obstructed intercourse**: Complaint that vaginal penetration is impeded. Possible causes include narrowing or a bulge.

(iii) **Vaginal laxity**: Complaint of excessive vaginal looseness.

(iv) **Libido – loss or decrease**: Complaint of loss or decrease of sexual desire

G: Other Possible Associated Symptoms¹

(i) **Urinary incontinence symptoms**¹: Urinary incontinence (symptom); stress (urinary) incontinence; urgency (urinary) incontinence; postural (urinary) incontinence; nocturnal enuresis; mixed (urinary) incontinence; continuous (urinary) incontinence; insensible (urinary) incontinence; coital (urinary) incontinence.

(ii) **Bladder storage symptoms**¹: nocturia; overactive bladder syndrome.

(iii) **Bladder sensory symptoms**¹: Increased bladder sensation; reduced bladder sensation; absent bladder sensation.

(iv) **Lower Urinary Tract Infection**¹: Urinary tract infection (UTI); recurrent urinary tract infections (UTIs); other related history.

H: More common POP-related symptoms: Table I gives a consensus view of the authors of the more common POP-related symptoms

TABLE I. The symptoms that women with POP would more* and most commonly** describe.

Potential prolapse-related symptoms	
<u>Vaginal prolapse</u>	Bulge sensation /visualization**, pelvic pressure**, low (sacral) backache*
<u>Urinary tract</u>	Frequency**, recurrent UTI**, incomplete emptying/urinary retention*, slow stream*
<u>Ano-rectal</u>	Incomplete defecation**, digitation/splinting*, rectal urgency*, post-defecatory soiling
<u>Sexual</u>	Dyspareunia*, vaginal laxity*
Other possible associated symptoms	
<u>Urinary incontinence**</u>	Stress, urge, postural, nocturnal, coital
<u>Bladder storage*</u>	Urgency, nocturia,

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SECTION 2: SIGNS

Sign: Any abnormality indicative of disease or a health problem, discoverable on examination of the patient; an objective indication of disease¹⁶ or a health problem.

A: Signs of Pelvic Organ Prolapse: All examinations for POP should be performed with the woman's bladder empty (and if possible an empty rectum). An increasing bladder volume has been shown to restrict the degree of descent of the prolapse¹⁸. The choice of the woman's position during examination, e.g. left lateral (Sims), supine, standing or lithotomy is that which can best demonstrate POP in that patient and which the woman can confirm as the maximal extent she has perceived e.g. by use of a mirror or digital palpation. The degree of prolapse may be worse after a lengthy time in the upright position. FN1

(i) Pelvic organ prolapse (anatomical definition of the sign of POP)¹: The descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy). **The presence of any such sign should be correlated with relevant POP symptoms^{13,19-21}**, i.e., patient report of maximal prolapse. More commonly, this correlation would occur at the level of the hymen or beyond¹⁹⁻²¹.

(ii) Pelvic organ prolapse – (POPO) - (staging^{1,3,4}):

Stage 0: No prolapse is demonstrated.

Stage I: Most distal portion of the prolapse is more than 1cm above the level of the hymen.

Stage II: The most distal portion of the prolapse is situated between 1 cm above the hymen and 1cm below the hymen. FN3. See also Appendix.

Stage III: The most distal portion of the prolapse is more than 1cm beyond the plane of the hymen but everted at least 2cm less than the total vaginal length.

Stage IV: Complete eversion or eversion at least within 2 cm of the total length of the lower genital tract is demonstrated.

(iii) Uterine/ cervical prolapse: Observation of descent of the uterus or uterine cervix.

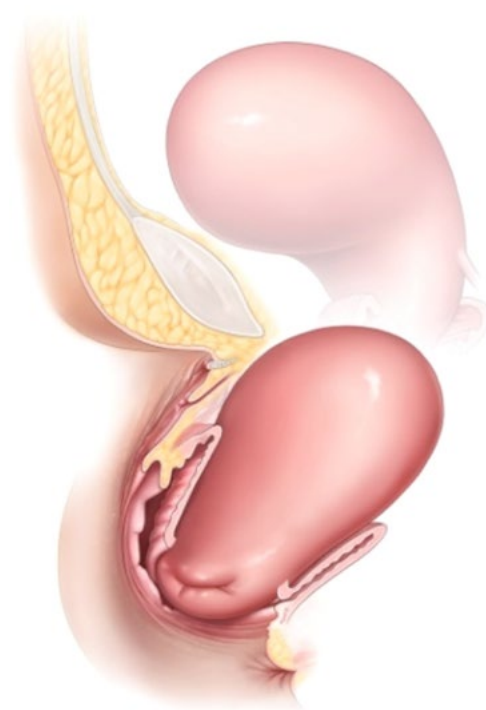


Figure 2. Uterine Prolapse.

(iv) Anterior vaginal wall (compartment) prolapse: Observation of descent of the anterior vaginal wall (compartment). Most commonly this might represent bladder prolapse (cystocele). Higher stage anterior vaginal wall prolapse will generally involve descent of uterus or vaginal vault (if uterus is absent). Occasionally, there might be an anterior enterocele (hernia of peritoneum and possibly abdominal contents), most commonly after prior reconstructive surgery.

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Figure 3. Anterior vaginal wall (compartment) prolapse.

(v) Posterior vaginal wall (compartment) prolapse: Observation of descent of the posterior vaginal wall. Commonly, this would represent rectal protrusion into the vagina (rectocele). Higher stage posterior vaginal wall prolapse after prior hysterectomy will generally involve some vaginal vault (cuff scar) descent and possible enterocele formation. Enterocele formation can also occur in the presence of an intact uterus.

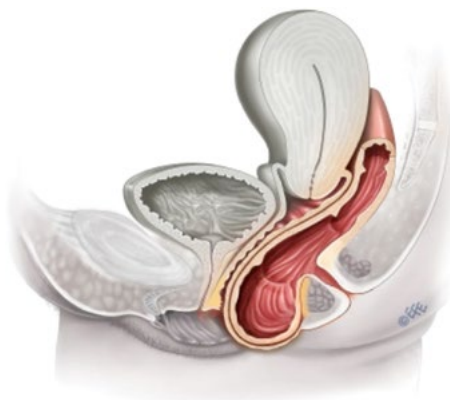


Figure 4. Posterior vaginal (compartment) wall prolapse.

(vi) Vaginal vault (cuff scar) prolapse: Observation of descent of the vaginal vault (cuff scar after hysterectomy).

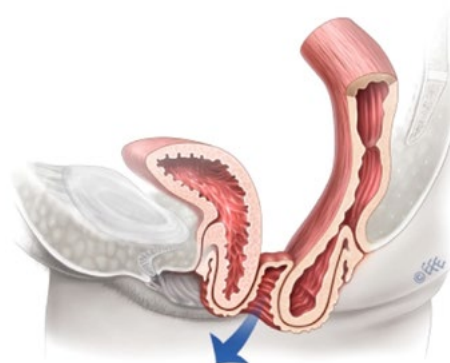


Figure 5. Vaginal vault prolapse.

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B: Clinical Staging⁴:

Each aspect of POP, uterine (cervical) prolapse, anterior vaginal wall (compartment), posterior vaginal wall (compartment), vaginal vault (cuff scar) prolapse can and should be subject to a clinical staging.

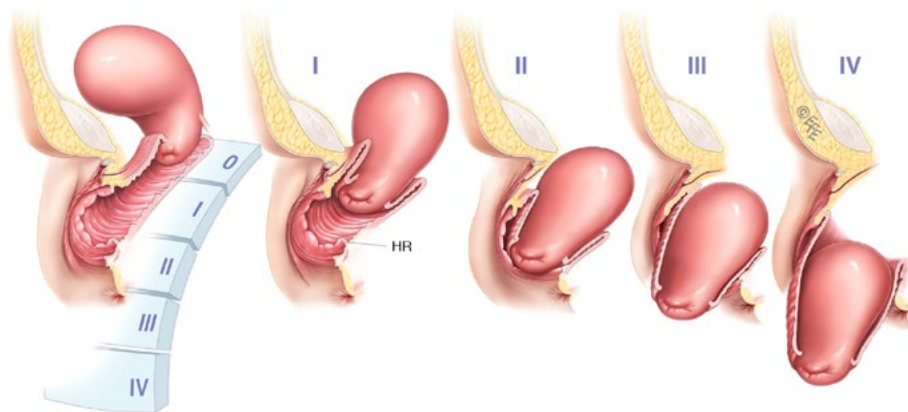


Figure 6. shows prolapse staging⁴ – 0, I, II, III, IV. (uterine – by the position of the leading edge of the cervix).

C: Supplementary Physical Examination Techniques

(i) **Digital rectal-vaginal examination⁴:** While the patient is straining and the prolapse is maximally developed. The aim is to try to differentiate between a high rectocele and an enterocele.

(ii) **Q-tip (urethral) testing⁴:** Measurement of urethral axial mobility at rest and straining to assess degree of mobility.

D: Clinical Assessment of Associations of POP

(i) **Levator Defects / Trauma²²:** Per-vaginal palpation for levator injury/defect/ “avulsion”.

(ii) **Uterine retroversion^{23,24}:** (Turning backward) The axis of the uterus is directed backwards towards the hollow of the sacrum, away from its anteverted position overlying the bladder. Cervix is noted in/ towards the anterior fornix with fundus perhaps palpable in the posterior fornix. FN4

E: Other Possible Signs.

(i) **Urinary incontinence signs¹:** Urinary incontinence; stress (urinary) incontinence; urgency (urinary) incontinence; extraurethral incontinence; stress incontinence on prolapse reduction (occult or latent stress incontinence)

(ii) **Other pelvic examinations/signs¹:** Vulvar examination; urethral inspection/palpation (urethral mucosal prolapse, urethral caruncle; urethral diverticulum); vaginal examination; bimanual pelvic examination; pelvic floor muscle function (normal pelvic floor muscles, overactive pelvic floor muscles, underactive pelvic floor muscles, non-functioning pelvic floor muscles); examination for levator (puborectalis) injury; perineal examination (perineal elevation, perineal descent); rectal examination (anal sphincter tone and strength, anal sphincter tear, fecal impaction present/absent, other rectal lesions, anal lesions, other perianal lesions), vaginal atrophy.

(iii) **Other relevant examinations/Signs¹:** Neurological signs, abdominal signs (bladder fullness/retention; abdominal masses or distension; scars from previous relevant surgery or trauma; renal tenderness or masses).

(iv) **Frequency volume chart / Bladder diary¹**

(v) **Pad testing¹**

SECTION 3: PROLAPSE QUANTIFICATION**A: Pelvic Organ Prolapse Quantification (POP-Q)⁴**

(i) **Fixed Point of Reference.** The hymen is the fixed point of reference used throughout the POP-Q system of quantitative prolapse description.

⁴: The axis of the retroverted uterus is parallel to that of the vaginal axis with less impediment to uterine (cervical) descent. In contrast, the anteverted uterus is perpendicular to the vaginal axis with impediment to descent by the posterior vaginal wall and behind that the rectum.

(ii) Defined Points. The anatomic position of the six defined points (two on the anterior vaginal wall, two in the superior vagina, and two on the posterior vaginal wall) for measurement should be centimeters (cm) above or proximal to the hymen (negative number) or cm below or distal to the hymen (positive number) with the plane of the hymen being defined as zero (0). For example, a cervix that protruded 3 cm distal to the hymen would be +3 cm. All points are measured on maximal straining (except total vaginal length).

(iii) Anterior Vaginal Wall.

(a) **Point Aa.** A point located in the midline of the anterior vaginal wall three (3) cm proximal to the external urethral meatus. By definition, the range of position of Point Aa relative to the hymen is -3 to +3 cm.

(b) **Point Ba.** A point that represents the most distal (i.e., most dependent) position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to Point Aa. By definition, Point Ba is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff (Point C) in women with total uterine prolapse or post-hysterectomy vaginal eversion.

(iv) Superior Vagina. These points represent the most proximal locations of the normally positioned lower reproductive tract. The two superior sites are as follows:

(c) **Point C.** A point that represents either the most distal (i.e. most dependent) edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar) after total hysterectomy.

(d) **Point D.** A point that represents the location of the posterior fornix in a woman who still has a cervix. It is included as a point of measurement to differentiate suspensory failure of the uterosacral-cardinal ligament "complex" from cervical elongation. When the location of Point C is significantly more positive than the location of Point D, this is indicative of cervical elongation which may be symmetrical or eccentric. Point D is omitted in the absence of the cervix.

(v) Posterior Vaginal Wall.

(e) **Point Ap.** A point located in the midline of the posterior vaginal wall three (3) cm proximal to the hymen. By definition, the range of position of Point Ap relative to the hymen is -3 to +3 cm.

(f) **Point Bp.** A point that represents the most distal (i.e., most dependent) position of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to Point Ap. By definition, Point Bp is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in a women with total post-hysterectomy vaginal eversion.

(vii) Other Landmarks and Measurements.

(g) The **genital hiatus** (GH) is measured from the middle of the external urethral meatus to the posterior margin of the hymen.

(h) The **total vaginal length** (TVL) is the length of the vagina (cm) from posterior fornix to hymen when Point C or D is reduced to its full normal position. (See Figure 40 - Appendix).

(i) The **perineal body** (PB) is measured from the posterior margin of the hymen to the mid-anal opening.

(viii) Recording Measurements: (NB: Intraoperative measurements with traction can be quite different from measurements made during Valsalva in clinic, both in regards to cervical location and the vaginal walls). Measurements directly after removing a vaginal pessary are unreliable and will tend to understage the degree of POP.

The position of Points Aa, Ba, Ap, Bp, C, and (if applicable) D with reference to the hymen should be measured (cm) and recorded.

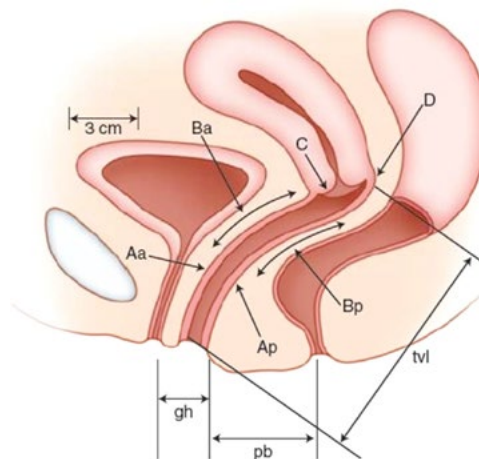


Figure 7. The six sites (Aa, Ba, C, D, Bp and Bp), the genital hiatus (gh), perineal body (pb) and total vaginal length (tvl) used cm above or proximal to the hymen (negative number) or cm below or distal to the hymen (positive number) with the plane of the hymen being defined as zero (0). Alternatively, a three by three grid can be used to organize concisely the measurements as noted in Figure 8.

Anterior wall Aa	Anterior wall Ba	Cervix or Cuff C
Genital hiatus gH	Perineal Body pB	Total Vaginal Length TVL
Posterior wall Ap	Posterior wall Bp	Posterior Fornix D

Figure 8. Grid presentation of POP-Q measurements.

B: Simplified POP-Q^{25,26}

This is based on the POP-Q with similar ordinal staging but with only four points measured instead of nine. There is no Stage 0; it is combined with Stage 1. It is undertaken in the dorsal lithotomy position with patient forcefully bearing down, performing Valsalva or coughing.

(i) Four points used:

- . Anterior vaginal segment: point Ba (estimated around 3cm proximal to hymenal remnants).
- . Posterior vaginal segment: point Bp (estimated around 3cm proximal to hymenal remnants).
- . Cervix point C
- . Apex/posterior fornix: point D (non-hysterectomized); point C (hysterectomized)

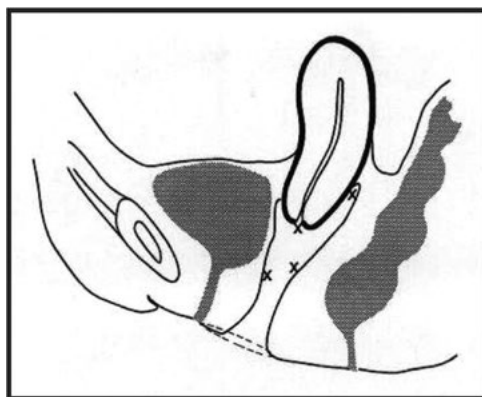


Figure 9. Simplified POP-Q.

(ii) Staging:

I, II, III, IV as for POP-Q above.

C: Additional available measurements awaiting further validation

These have been included as an Appendix after the References

(i): Vaginal Anatomical Levels and Lengths.

(ii): Perineal measurements.

(iii): Vaginal measurements.

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SECTION 4: INVESTIGATIONS

Urodynamics¹: Functional study of the lower urinary tract.

Clinical sequence of testing¹: Urodynamic investigations generally involve a woman attending with a comfortably full bladder for free (no catheter) uroflowmetry and post void residual urine volume (PVR) measurement prior to filling and voiding (with catheter) cystometry.

A: Assessment of Impact of Prolapse on Voiding Function

POP can have a negative impact on voiding function, screening for which importantly involves a postvoid residual and ideally uroflowmetry. Voiding cystometry may clarify the cause of any voiding dysfunction.

(i) Postvoid Residual¹⁻³: Volume of urine left in the bladder at the completion of micturition. **Conditions for PVR measurement:** PVR reading is erroneously elevated by delayed measurement due to additional urine production (1-14 mls/min). Ultrasonic techniques (transvaginal, translabial most accurately) allow immediate²⁷ (within 60 seconds of micturition) measurement and possible repeat measurement (Figure 10). A short plastic female catheter provides the most effective bladder drainage for PVR measurement by catheterization.

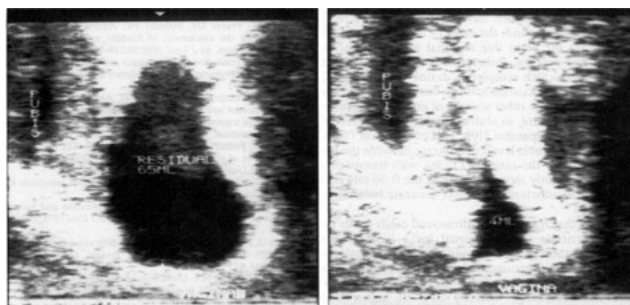


Figure 10. An image of postvoid residual of 65ml by transvaginal ultrasound, reducing to 4ml with a subsequent attempt at voiding.

(ii) Uroflowmetry¹⁻³: Measurement of urine flow rates during micturition¹⁶

- . **Flow rate:** Volume of urine expelled via the urethra per unit time. It is expressed in ml/sec.
- . **Voided volume (ml):** Total volume of urine expelled via the urethra.
- . **Maximum (urine) flow rate (MUFR - ml/sec) - Q_{max}:** Maximum measured value of the flow rate.
- . **Flow time (sec):** The time over which measurable flow actually occurs.
- . **Average (urine) flow rate (AUFR - ml/sec) - Q_{ave}:** Voided volume divided by the flow time.

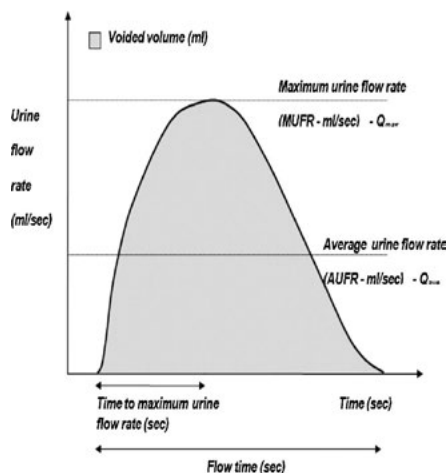


Figure 11. A schematic representation of urine flow over time.

The dependence of urine flow rates on voided volume²⁸ makes it desirable to reference raw urine flow rate data to established normative data.

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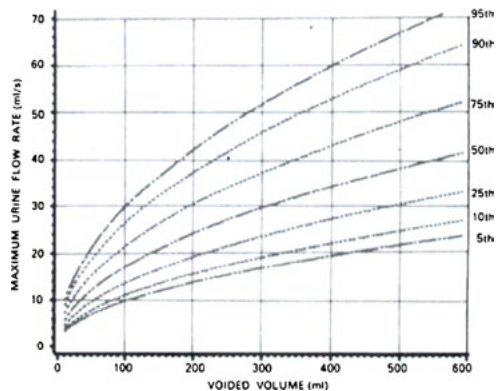


Figure 12. The Liverpool nomogram²⁹ for the maximum urine flow rate in women (under the 10th centile on repeat measurement can be regarded as abnormally slow³⁰).

(iii) Pressure- Flow studies^{1-3;31}

Cystometry: Measurement of the pressure/volume relationship of the bladder during filling and/or pressure flow study during voiding. Higher voiding detrusor pressures and slower urine flow during voiding may point an element of bladder outflow obstruction^{1-3,32}, though other patterns of pressure-flow data are possible.

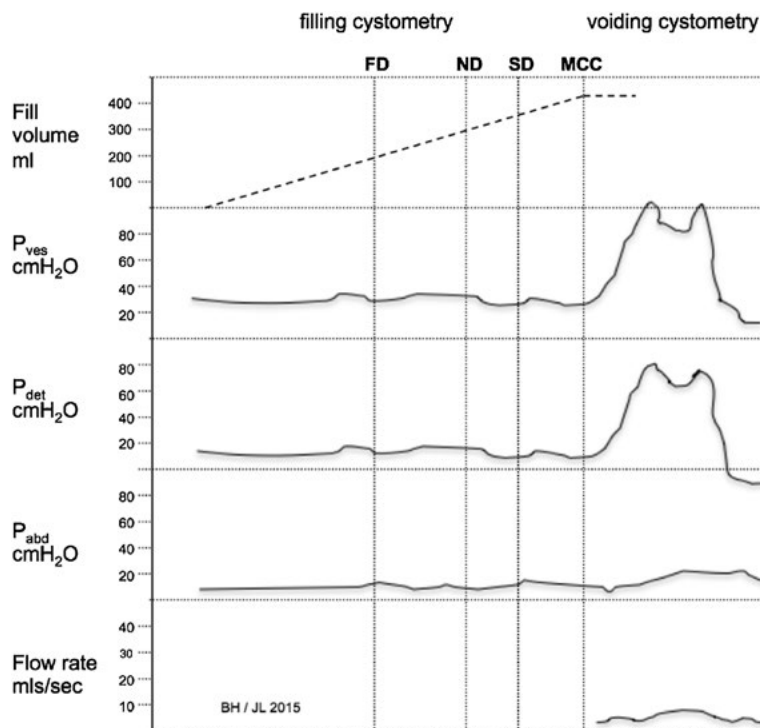


Figure 13. Filling and voiding cystometric trace, the latter part showing evidence of an element of bladder outflow obstruction. Normal bladder capacity, stable detrusor: no phasic activity seen. Voided with low urine flow rate and elevated detrusor pressure. Bladder outflow obstruction is thus demonstrated.

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B: Assessment of Impact on Prolapse on Defecatory Function

- (i) **Ultrasound Assessment:** See imaging section.
 (ii) **Radiological Assessment:** See imaging section.

C: Other urodynamic investigations for intercurrent diagnoses^{1-3,31}

(i) **Filling cystometry:** The pressure/volume relationship of the bladder during filling can evaluate the presence of intercurrent diagnoses (ii-iv).

(ii) **Urodynamic stress incontinence¹:**

Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

(iii) **Detrusor Overactivity¹:**

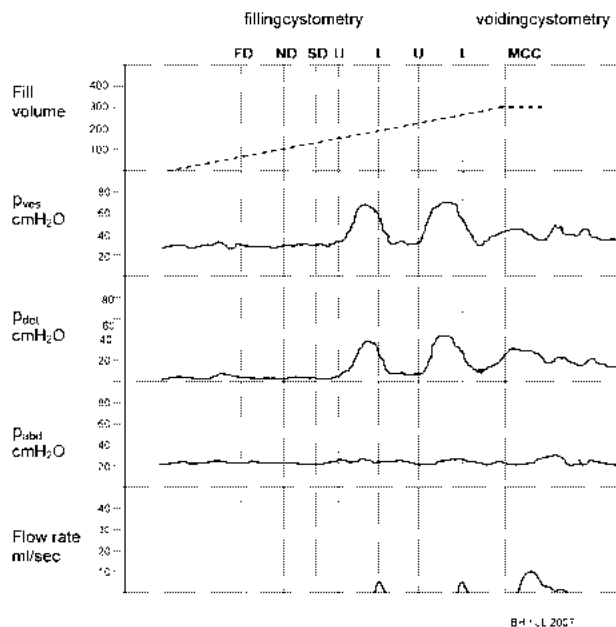
The occurrence of involuntary detrusor contractions during filling cystometry. These contractions, which may be spontaneous or provoked, produce a wave form on the cystometrogram, of variable duration and amplitude (Figure 14).

(iv) **Bladder Oversensitivity¹:**

Increased perceived bladder sensation during bladder filling with: an early first desire to void; an early strong desire to void, which occurs at a low bladder volume; a low maximum cystometric bladder capacity. No abnormal increases in detrusor pressure are noted.

(v) **Detrusor underactivity¹FN5 and Acontractile detrusor¹FN6**

Can also be diagnosed at voiding cystometry.



54 year old female with urgency and frequency. Phasic detrusor activity during filling. Leakage is associated with urgency and detrusor contractions. FD = First Desire to Void, ND = Normal desire to void, SD = Strong desire to void, U = Urgency, L = leakage, MCC = Maximum Cystometric Capacity.

Figure 14. Cystometric trace showing detrusor overactivity¹.

⁵. *Detrusor underactivity:* Detrusor contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span.

⁶. *Acontractile detrusor:* The detrusor cannot be observed to contract during urodynamic studies resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span. The term "areflexia" has been used where there is a neurological cause but should be replaced by *neurogenic acontractile detrusor*.

SECTION 5: PROLAPSE IMAGING

Imaging may assist the clinical assessment of POP or intercurrent pelvic floor diagnoses. Use of any of the different imaging modalities is, however, entirely optional.

A: Prolapse-related ultrasound imaging – 2-D**(i) Modalities**

Transabdominal, perineal, introital and transvaginal ultrasound¹.

- Transabdominal (T-A): curvilinear scanning applied to the abdomen.
- Perineal: curved array probe applied to the perineum. This term incorporates transperineal and translabial ultrasound.
- Introital: sector probe applied to the vaginal introitus.
- Transvaginal (T-V): intravaginal curvilinear, linear array, or sector scanning.

(ii) Clinical applications:

- Bladder neck descent/mobility. The position of the bladder neck at rest and on Valsalva.
- Urethral funnelling: i.e., opening of the proximal third of the urethra during coughing or on Valsalva.
- Post void residual: Several formulas have been described in the literature to measure the bladder volume by ultrasound^{33–35}. An early formula $[(h \times d \times w) \times 0.7]$ has been demonstrated to give reproducible results with a percentage error of 21%³³ (see Figure 15 for definitions of h,d,w).
- Bladder abnormalities: e.g., tumor, foreign body.
- Urethral abnormality: e.g., diverticulum.
- Intercurrent uterine and/or pelvic abnormality: dependent on probe range.
- Postoperative findings: e.g., bladder neck position and mobility, position of meshes, tapes, or implants.
- Descent of pelvic organs: visualization of descent of the bladder, uterine cervix, and rectum during coughing or on Valsalva.
- Assessment of voluntary pelvic floor muscle contractility.
- Pelvic floor/levator ani muscle defect (“avulsion”) and hiatal ballooning³⁶.
- Ultrasound measurements of bladder and detrusor wall thickness, and ultrasound estimated bladder weight (UEBW) are potential noninvasive clinical tools for assessing the lower urinary tract. UEBW is higher in women with overactive bladder and detrusor overactivity^{37,38}. FN7.

Figures 16 and 17 show examples of 2-D introital ultrasound in patients with POP symptoms.

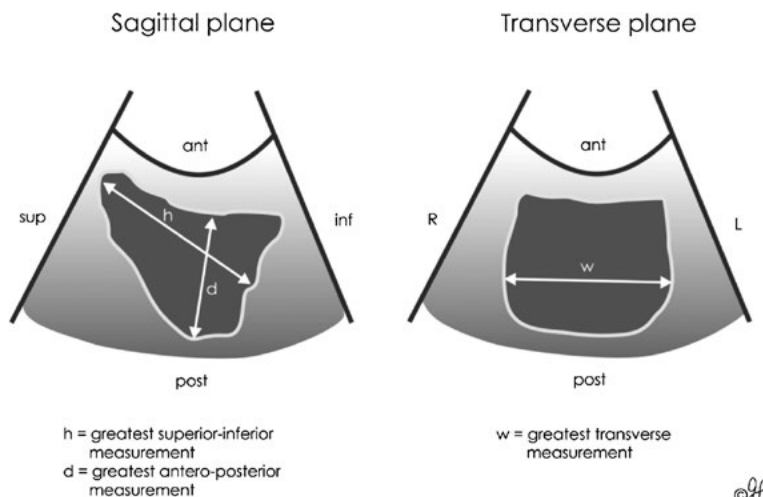


Figure 15. Ultrasound measurement of the bladder volume from Poston GJ et al. 1983³³(redrawn).

⁷: Women with detrusor overactivity have a median UEBW of 48.0 g (95% CI 46-51), with urodynamic stress incontinence a median UEBW of 30 g (95% CI 29-31) and those who have associated detrusor overactivity and urodynamic stress incontinence have a median UEBW of 37.3 g (95% CI 33-41) ($p < 0.001$)^{37,38}.

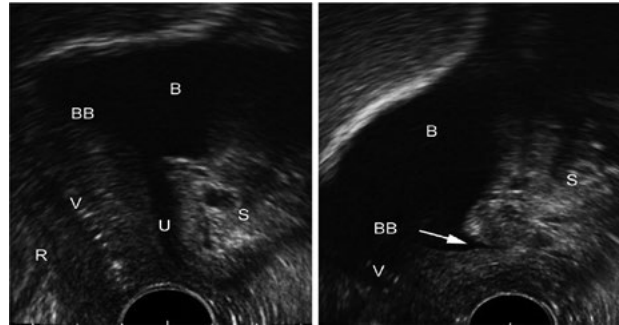


Figure 16. (above): 56 year old female with stage II cystocele and urodynamic stress incontinence. Left: at rest. Right: during Valsalva. B = Bladder, BB = bladder base, U = urethra, S = symphysis pubis, arrow = bladder neck during Valsalva, V = vagina, R = rectum. Arrow = bladder neck during Valsalva with bladder neck funneling as a sign of urethral incompetence.

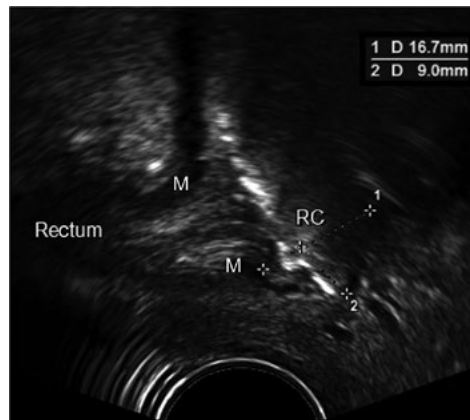


Figure 17. (above): 72 year old female with stage II rectocele. Measurement of rectocele (RC) width (1) and depth (2) during Valsalva. M = muscularis of rectum.

B: Prolapse-related ultrasound imaging – 3-D

(i) Modalities: Endovaginal, transanal, and translabial/transperineal

- Endovaginal ultrasound imaging may inadvertently compress tissues thus distorting the anatomy.
- Transanal ultrasound approach requires an expensive and dedicated transducer, and it is a more uncomfortable and embarrassing test for the woman. Its most common clinical indication is the assessment of sphincter integrity following obstetric trauma.
- Translabial/transperineal approach overcomes the limitations of endovaginal and transrectal techniques providing minimal pressure on local structures and it is least likely to alter surrounding anatomy.

(ii) Evaluations:

The following pelvic floor abnormalities/ surgical sequelae can be evaluated:

- (a) Trauma (injury/damage) of the levator ani muscle (LAM).
- (b) Excessive distensibility of the puborectalis muscle and levator hiatus (“ballooning”).
- (c) Pathologies of the anterior vaginal compartment like urethral diverticula.
- (d) Bladder tumours or foreign bodies (sling, mesh, bulking agents).
 - Polypropylene meshes: highly echogenic and thus easily identified in the coronal and axial plane, unless they are obscured by vaginal prolapse.
 - Periurethral bulking agents, used as a continence procedure, can also be depicted with 3D pelvic floor ultrasound. FN8

⁸: Synthetic implant such as macroplastique, are hyperechogenic whereas collagen injections are hypoechoic and can be seen as spherical structures surrounding the bladder neck.

Figure 18 shows 3D ultrasound imaging of the pelvic floor anatomy.

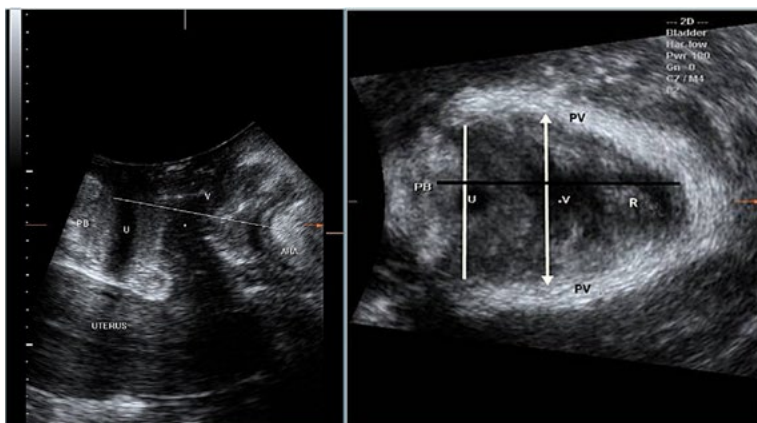


Figure 18. (above): 3D ultrasound image of levator ani muscle of an asymptomatic nulliparous woman at rest. 3D ultrasound image of the pelvic floor at rest showing the anatomy and the reference plane of measurements. Left: sagittal view; PB: pubic bone; U: urethra; V: vagina; ARA: ano-rectal angle; white line: plane of minimal hiatal dimensions (plane of all measurements). Right: axial view; PB: pubic bone; U: urethra; V: vagina; R: rectum; PV: pubovisceralis muscle; black line: antero-posterior diameter of the levator hiatus; white line: transverse diameter of the levator hiatus at the level of pubourethralis, white double-headed arrowed line: transverse diameter of the levator hiatus at the level of pubovaginalis.

(iii) 3D ultrasound imaging of the female urethra

3D ultrasound imaging of the rhabdosphincter overcomes the limits of MRI and two-dimensional (2D) ultrasound imaging that incorrectly measure the urethral sphincter volume using mathematical formulas based upon assumptions that the shape of the urethra is similar to that of an ellipse. Since the urethral shape is neither elliptical nor spherical, but rather an atypical geometric shape, equations should not be used³⁹. FN9. Figure 19 shows 3D ultrasound imaging of the urethral sphincter

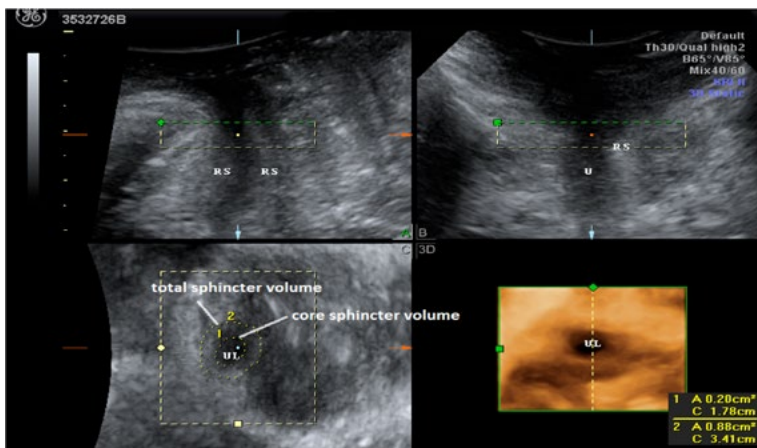


Figure 19. (above): 3D translabial image of the female urethra. The urethra lumen is shown clearly in the rendered volume image (bottom right). (U, urethra; UL, urethra lumen; RS, rhabdosphincter).

(iv) 3D ultrasound imaging of the levator ani trauma

The presence of levator ani trauma has been postulated to be associated to an increased risk of pelvic organ prolapse⁴⁰. This can be evaluated using a tomographic ultrasound imaging assessment of the levator ani muscles (Figure 20).

³⁹: The importance of precise structural assessment of the urethral sphincter using multiple axial cross-sectional areas at set distances can assist the evaluation of women with stress urinary incontinence. It has been suggested that it may predict the severity of incontinence as well as the outcome of continence surgery since a weak sphincter will have a lower volume compared to a competent/continent urethral sphincter³⁹.

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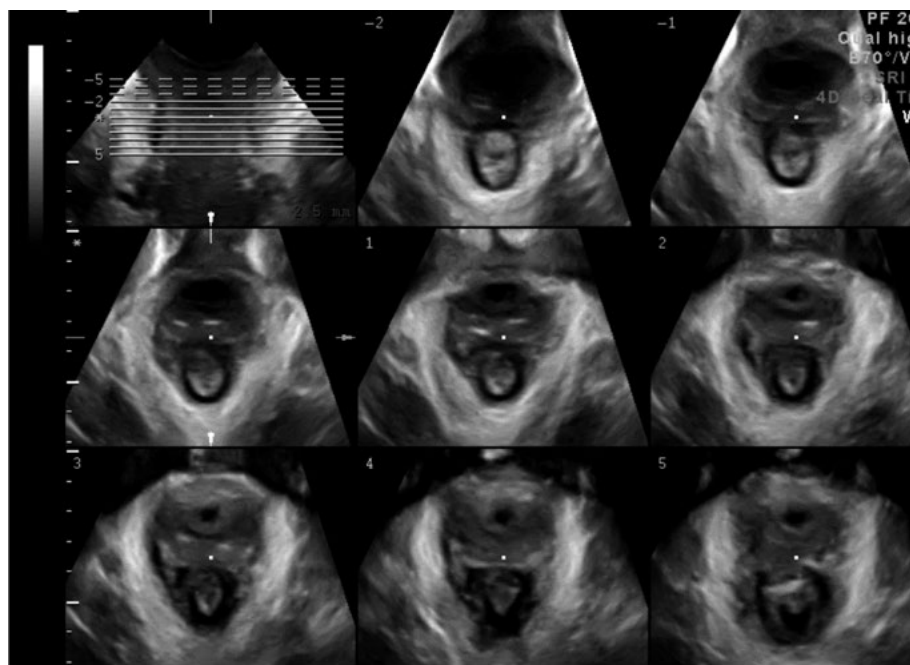


Figure 20. (above): Tomographic ultrasound imaging assessment of the levator ani muscles Intact LAM.

(v) 3D ultrasound imaging of ballooning of the genital hiatus

The presence of ballooning of the genital hiatus (= excessive distensibility of the levator hiatus) on Valsalva manoeuvre has also been associated to the severity of urogenital prolapse. An area of more than 25 cm², 30 cm², 35 cm² and 40 cm² has been defined as mild, moderate, marked and severe ballooning respectively (Figure 21)⁴¹.

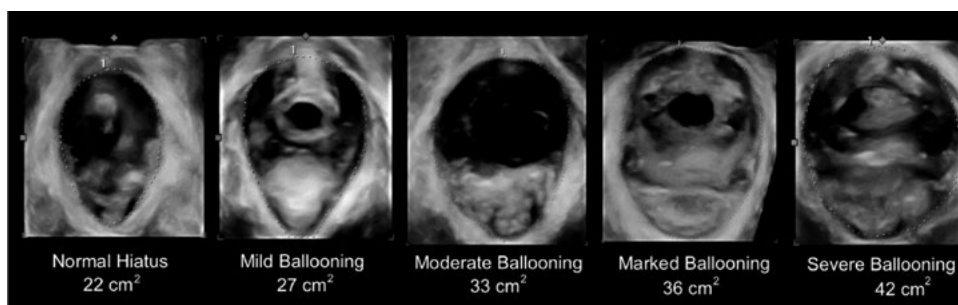


Figure 21. (above): Ballooning of the genital hiatus on Valsalva manoeuvre – levator defect.

C: Magnetic resonance imaging (MRI) of the pelvic floor

Magnetic resonance imaging (MRI) allows the detection of ligamentous and muscular pelvic floor structures in fine detail. Although it does not use ionising radiation, it is a high cost technique. Static MRI relies on static sequences and high spatial resolution images, to delineate the passive and active elements of the pelvic organ support system. Most commonly, images are acquired in axial, sagittal and coronal planes.

MRI has been proposed to be a useful method for diagnosing and staging POP. Several lines and levels of reference have been described in the literature. The most commonly used ones are either a line drawn from the inferior margin of the pubis symphysis to the last coccygeal joint (pubococcygeal line –PCL) or a line extending caudally along the longitudinal axis of the symphysis pubis in the sagittal plane, noted as midpubic line (MPL)^{42,43} (Figures 22 and 23).

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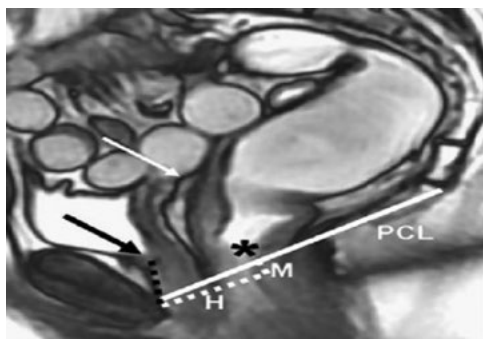


Figure 22. (above): Sagittal MRI image of the pelvic floor obtained at rest in a 50-year-old normal volunteer woman. The H line is drawn from the inferior border of the pubic symphysis to the posterior wall of the rectum at the level of the anorectal junction.

The M line is drawn perpendicularly from the PCL to the most posterior aspect of the H line. (PCL: pubococcygeal line, black arrow: bladder base, white arrow: vaginal vault, *: anorectal junction, from Colaiacomo MC⁴² et al. 2009).

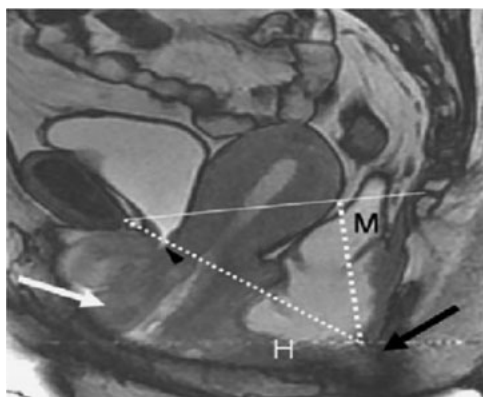


Figure 23. (above): Severe uterine prolapse in a 41-year-old woman. Sagittal function MRI image obtained during defaecation shows the uterus moving downward inside the vagina and the cervix exits the vaginal introitus (white arrow). H and M lines are abnormally elongated. Urethral funnelling without hypermobility (arrowhead) and severe posterior compartment descent (black arrow) are also noted (from Colaiacomo⁴² et al. 2009).

Other applications of MRI are the assessment of the LAM morphology (size, thickness volume) and detection of LAM injuries/defects/ ("avulsion") (figure 24)⁴⁴⁻⁴⁶.

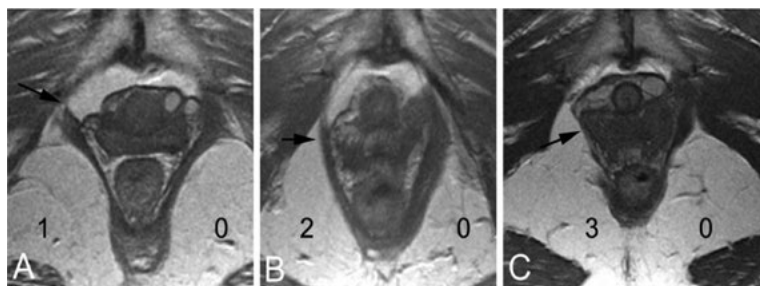


Figure 24. (above): Examples of grades of unilateral defects in the pubovisceral portion of the LAM in axial magnetic resonance images at the level of the mid urethra. The score for each side is indicated on the figure, and the black arrows indicate the location of the missing muscle (A. grade 1 defect, B. grade 2 defect, and C. grade 3 defect, from Delancey. *Levator Ani Impairment in Prolapse. Obstet Gynecol* 2007).

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D: Current possible measurements using MRI in urogynecology

(i) Bladder neck and cervical descent / mobility:

- Position of bladder neck and cervix at rest and on Valsalva
- Pubo-coccygeal line: A line extending from the inferior border of the pubic symphysis to last coccygeal joint (pubococcygeal line—PCL) Bladder neck or cervical descent > 2 cm below this line with straining indicates weakness of the pelvic floor. If alternative landmarks are used in scientific papers they should be clearly described.

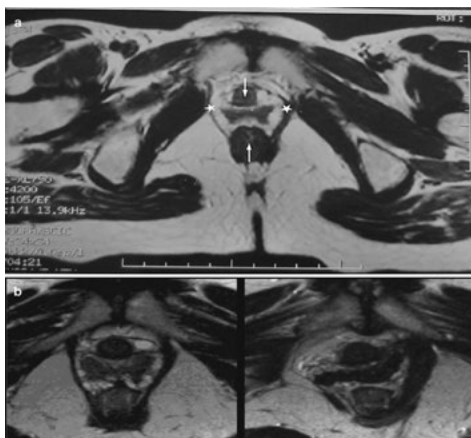


Figure 25. (above): shows a number of possible measurements using MRI imaging. (a) Axial T2-weighted image of the pelvic floor of a healthy nulliparous Caucasian woman showing measurement of the anteroposterior diameter of the genital hiatus between the arrows from midurethra to mid-anus at the level of the lower border of the pubic symphysis. Transverse diameter (width) of the levator hiatus was measured between the stars at the point of maximum extension of the levator muscles at the level of the urinary bladder and proximal urethra. Reproduced from Am J Obstet Gynecol with permission from the Publisher. (b) An example of a unilateral levator defect of the pubococcygeus muscle (right image) seen on MRI imaging. Reproduced with kind permission from Mr. Olubenga Adekanmi; image reviewed by Professor John DeLancey.

E: Computed tomography (CT) of the pelvic floor

Computed tomography (CT) is not routinely recommended for imaging the pelvic floor mainly due to irradiation and poor soft tissue contrast. However multiplanar spiral CT may offer an accurate visualization of the pelvic floor soft and bony structures by reconstruction of axial images using 1 mm thick slices without gaps thus increasing the diagnostic accuracy of pelvic floor anatomical disorders (ie. LAM trauma) (Figures 26 and 27).



Figure 26. (above): Computed tomography (CT) of the LAM. Axial view of CT multiplanar 3-dimensional data volume, with 1 mm slice thickness without gaps, showing an intact pubovisceral muscle arising from the body of the pubic bone and forming a sling around the rectum (U: urethra, V: vagina, R: rectum, PM: pubovisceral muscle, PR: puborectalis muscle).

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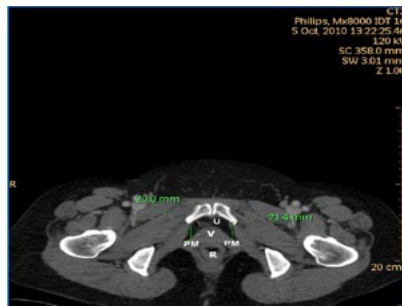


Figure 27. (above): Computed tomography (CT) of the LAM. Axial view of CT scan of a woman with bilateral injury of the pubovisceral muscle. Measurement of levator symphysis gap (LSG) is denoted bilaterally (U: urethra, V: vagina, R: rectum, PM: pubovisceral muscle).

F: Associated POP-related Radiology⁸

Defecography demonstrates normal anatomy of the anorectum as well as disorders of rectal evacuation. With barium paste inserted rectally prior to defecation, measurement of the anorectal angle is allowed with evidence of the presence, size or emptying of any rectocele.

Enteroceles, rectal intussusception and mucosal prolapse might be diagnosed as well as a spastic pelvic floor (anismus).

6: DIAGNOSES

This Report highlights the need to base diagnoses for female pelvic organ prolapse on the **correlation between a woman's symptoms, signs and any relevant diagnostic investigations.**

A: Pelvic Organ Prolapse

Diagnosis by **symptoms and clinical examination, assisted at times by any relevant imaging (i.e. clinically evident):**

- (i) **Uterine/ cervical prolapse:** Clinically evident descent of the uterus or uterine cervix.
- (ii) **Anterior vaginal wall (compartment) prolapse:** Clinically evident descent of the anterior vaginal wall (compartment).
- (iii) **Posterior vaginal wall (compartment) prolapse:** Clinically evident descent of the posterior vaginal wall (compartment).
- (iv) **Vaginal vault (cuff scar) prolapse:** Clinically evident descent of the vaginal vault (cuff scar after hysterectomy).

Clinical staging (see Figures 6 and 28-30) assists in description.

Figures 28–30: Different types and stages of pelvic organ prolapse.



Figure 28. (above): Stage II Anterior vaginal wall (compartment) prolapse.

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Figure 29. (above): Stage III Uterine prolapse.



Figure 30. (above): Stage IV Vaginal prolapse (complete eversion).

B: Possible prolapse-related diagnoses:

(i) Voiding dysfunction: A diagnosis by **symptoms and urodynamic investigations** is defined as abnormally slow and/or incomplete micturition, based on abnormal slow urine flow rates and/or abnormally high post void residuals, ideally on repeated measurement to confirm abnormality. (Voiding cystometry can be required to determine the cause of the voiding dysfunction). *FN10*

(ii) Recurrent urinary tract infections (UTI): A diagnosis by **clinical history** assisted by **the results of diagnostic tests** involves the determination of the occurrence of at least three symptomatic and medically diagnosed urinary tract infections (UTI) over the previous 12 months. One possible POP-related cause is a chronically elevated postvoid residual.

(iii) Defecatory dysfunction: A diagnosis by **clinical history** assisted, at times, by **the results of diagnostic tests** involving the confirmation of abnormal or difficult function in the initiation, passage or completion of defecation.

(iv) Sexual dysfunction: A diagnosis by **clinical history** (including specific questionnaires) involving the confirmation of abnormal function and/or difficulty with sexual intercourse.

¹⁰: It is acknowledged this definition may not encompass cases of (i) symptoms of voiding dysfunction without abnormality of voiding parameters; (ii) abnormality of voiding parameters without symptoms of voiding dysfunction.

C: Intercurrent diagnoses:

(i) **Urodynamic stress incontinence:** Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction. In the circumstances where this diagnosis is only made when the POP is reduced, the additional term **“occult”** is appropriate.

(ii) **Detrusor overactivity:** The occurrence of involuntary detrusor contractions during filling cystometry.

(iii) **Bladder oversensitivity:** Increased perceived bladder sensation during bladder filling with: an early first desire to void; an early strong desire to void, which occurs at a low bladder volume; a low maximum cystometric bladder capacity. No abnormal increases in detrusor pressure are noted.

(iv) **Detrusor underactivity¹FN5 and Acontractile detrusor¹FN6**

7: CONSERVATIVE TREATMENTS

Conservative: restricted to non-surgical and non-pharmacological treatments.

A: Lifestyle interventions: Interventions that intentionally change the way a person lives in order to improve health status (e.g. weight loss and avoiding heavy lifting or coughing, e.g. by ceasing tobacco smoking), to avoid exacerbation of POP by decreasing intra-abdominal pressure.

B: Devices

Device: An object or instrument that has been invented/created for a particular purpose.

(i) **Pessary:** A device that is inserted into the vagina to provide structural support to one or more of descending vaginal compartments, i.e.; the uterus, anterior vaginal wall (and bladder), posterior vaginal wall (and rectum) and/or vaginal apex (with or without small intestine after a prior hysterectomy)⁴⁷.

Types of pessary: Vaginal pessaries can be broadly divided into two types: support pessaries (ring, ring with support, Gehrung, Hodge) and space filling pessaries (doughnut, gellhorn, cube, inflatable pessaries).



Figure 31. Pessaries (clockwise from top left) donut, cube, ring with central support, gellhorn.



Figure 32. Shelf pessary.

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The most frequently used pessaries are listed below, as shown in figure 31⁴⁷.

- a. Ring pessary with or without central support
- b. Gellhorn pessary; round solid pessary with a central stem
- c. Donut pessary FN11
- d. Cuboid pessary FN12
- e. Shelf pessary: Similar to a Gellhorn but asymmetric

C: Physical Therapies⁹

Pelvic physiotherapy: Assessment, prevention and/or treatment of pelvic floor dysfunction, performed by a pelvic physiotherapist. The therapy aims at reducing POP symptoms and related bother as well as improvement of pelvic floor function. Pelvic physiotherapy covers many specialized therapies that can be used to train the pelvic floor: physical activity, cognitive behavioural therapy, bladder training, bowel habit training, muscle training (endurance, power), coordination training, biofeedback, and electrical muscle stimulation⁹. The role of continence nurses amongst other health professionals in performing some of these specialized therapies is acknowledged.

Other therapies: Refer to the terminology document of Bo et al⁹.

8: SURGICAL TREATMENTS

A: General POP Surgical Terminology

- (i) **Prosthesis**⁵: A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure.
- (ii) **Mesh**⁵: A (prosthetic) network fabric or structure; open spaces or interstices between the strands of the net. The use of this term would be for POP surgery with synthetic materials.
- (iii) **Mesh kit**⁵: A set of articles or equipment utilized for POP surgery containing mesh with a system of trocars designed to achieve mesh fixation or allow mesh passage to or through specific areas within the pelvis.
- (iv) **Implant**⁵: A surgically inserted or embedded prosthesis or graft. (*Explant*: a surgically excised prosthesis or graft).
- (v) **Tape (Sling)**⁵: A flat strip of synthetic material. The use of this term would be for incontinence surgery with synthetic materials.
- (vi) **Graft**⁵: Any tissue or organ for transplantation. This term will be used to refer to biological materials inserted.

Autologous grafts: From patient's own tissues e.g. rectus sheath or fascia lata. Allografts: From post-mortem tissue banks. Xenografts: From other species e.g. modified porcine dermis, porcine small intestine and bovine pericardium.

Terminology for grafts has not been separated into the different applications for POP and continence surgery.

- (vii) **Trocar**⁵: A surgical instrument with either a pyramidal, conical or needle-type cutting or dissecting point.
- (viii) **Tissue**⁶: A collection of similar cells and the intercellular substances surrounding them.
- (ix) **Native**⁶: Pertaining to birth - "in situ autologous".

B: Specific Surgeries

The following classification of surgical procedure subtypes is proposed when describing specific surgeries. It is acknowledged that more complex cases may require two or more procedures in addition to other non-POP related surgical interventions. Each surgical procedure should be described with respect to site specificity and either as primary surgery or further surgery⁷. All surgical procedures are primarily divided by surgical approach as follows:

I. Vaginal repairs:

- (i) Anterior vaginal wall repair with native tissue.
- (ii) Anterior vaginal wall repair with mesh or graft reinforcement.
- (iii) Posterior vaginal wall repair with native tissue.
- (iv) Posterior vaginal wall repair with mesh or graft reinforcement.
- (v) Vaginal vault repair involving uterus.
- (vi) Vaginal vault repair (post-hysterectomy).

II. Abdominal repairs:

- (i) Abdominal Repair with Mesh or Graft.
- (ii) Abdominal Repair without Mesh or Graft.

¹¹: A more space occupying pessary.

¹²: A cuboid pessary does deliver 'support' by suction of the vaginal walls.

III. Obliterative Procedures:

- (i) Colpocleisis.
- (ii) Total colectomy.

I: Vaginal Repairs (colporrhaphy): (Greek: *kolpō* vagina + *raphē* suture)

(i) Anterior vaginal wall repair with native tissue: Repair the vagina by excision and suturing of the edges of any defect. Native tissue repair may be further sub-classified depending on the type of associated fascial repair:

- (a): Midline fascial plication: This represents perhaps the most common procedure currently performed for anterior wall prolapse [Fig 33 below]. FN13
- (b) Site specific repair: Paravaginal – bilateral vaginal reattachment of the lateral edge of damaged fascia to the Arcus Tendineus Fasciae Pelvis (Alt: White line).
- (c) Other site specific repair: Transverse, distal, combined.
- (d) Anterior enterocele repair.

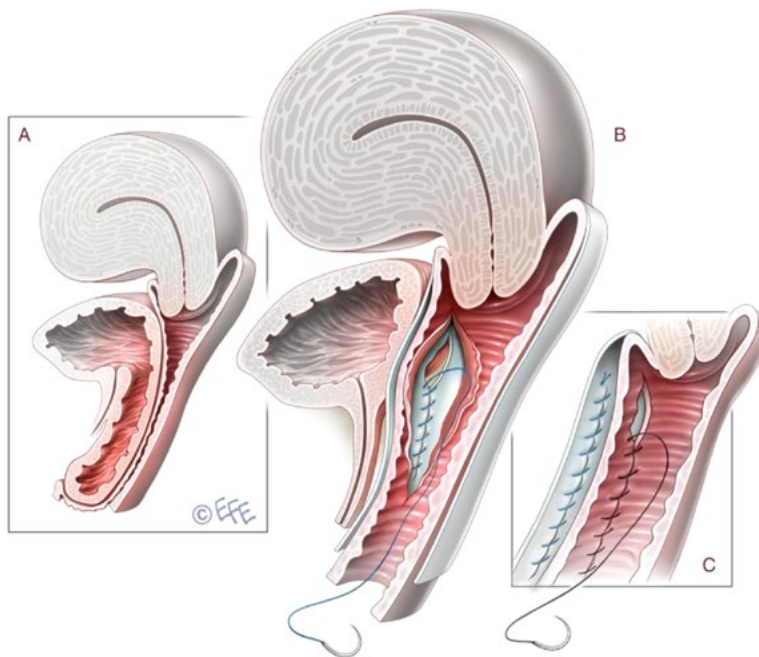


Figure 33. (above): Midline native tissue anterior vaginal repair.

(ii) Anterior Vaginal Wall Repair with mesh or graft reinforcement (a structural addition or inclusion used to give additional strength in function). It should be noted whether the graft is biologic, absorbable synthetic or permanent synthetic.

This may be further sub-classified into:

- (a) Mesh or graft placement **without** additional vault/uterine support with or without concurrent fascial plication.
- (b) Mesh or graft placement **with** additional vault/uterine support. This may be sub-divided into:
 - **Transobturator mesh kit:** Normally involves two needle passes through the obturator membrane bilaterally to retrieve and secure mesh arms through the area of the Arcus Tendineus Fasciae Pelvis (ATFP) and thus stabilize a central mesh support to the anterior vaginal wall.

¹³: It was first described by Kelly in 1913 and involves dissection under the full thickness of the vaginal epithelium followed by central plication of the pubocervical fascia over the bulging bladder with excision of the 'excess' vaginal wall skin. The Kelly-Kennedy plication suture (Alt: bladder neck buttress) is an extrapolation of midline fascial plication involving placement of sutures under the proximal urethra and bladder neck to try and treat or prevent stress incontinence.

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- **Mesh kit with bilateral fixation to Sacrospinous Ligament [SSL]:** Anterior vaginal wall mesh or graft with concurrent vault/uterine suspension employing either bilateral iliococcygeal fixation or fixation to the SSL.

(iii) Posterior vaginal wall repair with native tissue: Repair the vagina by excision and suturing of the edges of any defect. Native tissue repair may be further sub-classified depending on the type of associated fascial repair:

- Midline fascial plication - This represents perhaps the commonest procedure currently performed for posterior wall prolapse and involves dissection under the full thickness of the vaginal epithelium followed by central plication of the pre-rectal fascia over the bulging rectum with excision of the 'excess' vaginal wall skin. [Fig 34 below]
- Site specific repair: Lateral (Uni- or Bilateral), Transverse (upper and/or lower), Combined
- Closure and/or excision of enterocele vaginally with or without concurrent posterior wall repair.

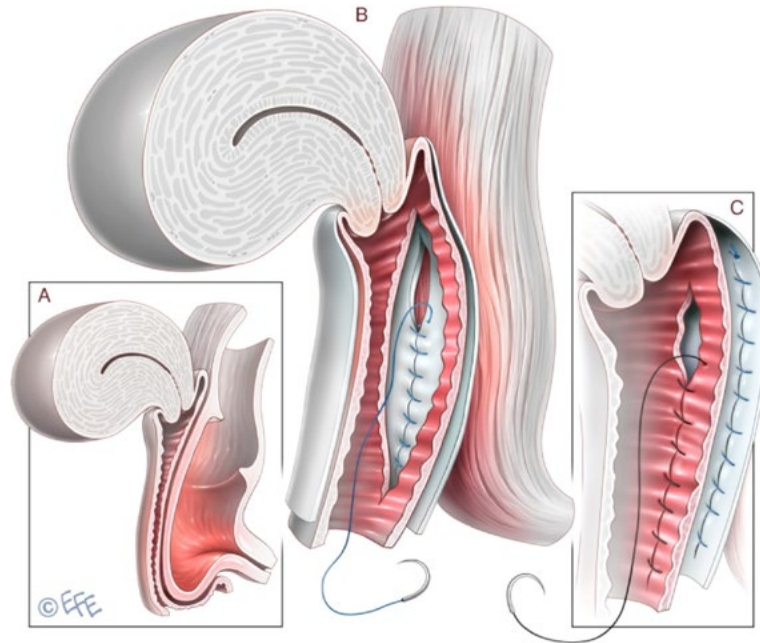


Figure 34. (above): Midline native tissue posterior vaginal repair.

(iv) Posterior Vaginal Wall Repair with mesh or graft reinforcement (a structural addition or inclusion used to give additional strength in function. It should be noted whether the graft is biologic, absorbable synthetic or permanent synthetic.

This may be further sub-classified into:

- Mesh or graft placement **without** additional vault/uterine support with or without concurrent fascial plication.
- Mesh or graft placement **with** additional vault/uterine support. This may be sub-divided into:
 - Mesh kit with bilateral mesh fixation to the SSL.
 - Mesh suspension kit with ischio-anal needle pass.
 - Posterior vaginal wall mesh/graft with concurrent vault/uterine suspension employing either bilateral iliococcygeal fixation or fixation to the SSL.
 - Transperineal mesh/graft insertion.

Concurrent surgery performed in addition to vaginal posterior wall repairs:

- Perineal Repair (alternatives; Perineorrhaphy, Perineoplasty).
- Levator ani muscle plication.
- Repair/closure of enterocele.
- Anal sphincter repair.

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(v): Vaginal Vault Repairs (involving uterus)

(a) Vaginal hysterectomy – removal of the uterus and cervix vaginally.

(b) Vaginal hysterectomy with adjunctive McCall Culdoplasty – Culdoplasty sutures incorporate the uterosacral ligaments into the posterior vaginal vault to obliterate the cul-de-sac and support and suspend the vaginal apex after vaginal hysterectomy.

(c) (Modified) Manchester Repair (Fothergill operation) – This procedure combines anterior vaginal wall repair with amputation of the cervix and uterosacral ligament suspension with or without concurrent vaginal posterior wall repair. FN14

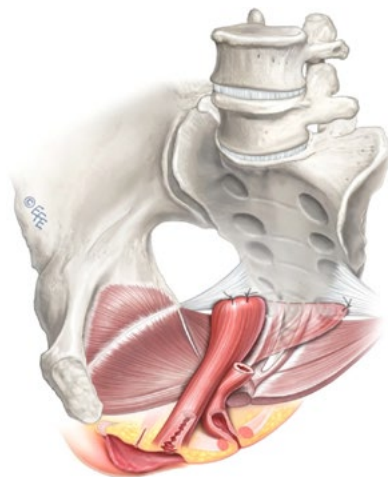
(d) Sacrospinous hysteropexy - fixation of the uterus to the SSL. Variations of this technique to include:

- (a) Unilateral or bilateral procedure.
- (b) Anterior or posterior approach.
- (c) Permanent or absorbable suture and number of 'bites' taken.
- (d) Type of suture placement device employed.
- (e) Direct vision or with the use of a specific instrument (tactile feedback).

(e) Laparoscopic assisted vaginal hysterectomy with or without concurrent laparoscopic uterosacral ligament plication.

(vi) Vaginal Vault Repairs (Post-hysterectomy)

(a) Sacrospinous colpopexy – Fixation of the vaginal vault to the SSL. Variations of this technique (as above a-e for sacrospinous hysteropexy).



Figures 35. Sacrospinous colpopexy.

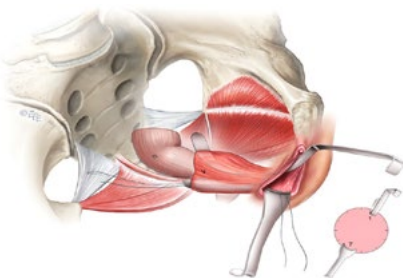


Figure 36. Suture placement around junction of medial third and lateral two-thirds of ligament assisted by retraction (Miya speculum 7 o'clock; narrow Deaver 1 o'clock; Yankauer sucker not shown).

¹⁴: Its essential feature is suturing the cut cardinal/uterosacral ligament complex in front of the stump of the cervix hence pulling the cervix upwards and backwards, maintaining anteversion and creating anterior vaginal wall length. This procedure can be performed intra- or extra-peritoneally. Concurrent McCall culdoplasty or vaginal vault suspension techniques may be employed dependant on the extent of prolapse⁴⁷.

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(b) Intraperitoneal uterosacral ligament (USL) vaginal vault fixation: This is usually associated with posterior wall fascial wall reconstruction and possible concurrent excision and closure of enterocele.

(c) Extraperitoneal USL vaginal vault fixation: This is usually combined with posterior wall fascial reconstruction with or without enterocele closure and/or excision.

(d) Mesh suspension kit with ischio-anal needle pass. The graft is fixed to the vault and elevation achieved when the upper graft arms are retrieved back through the levator ani muscle bilaterally.

(e) Vaginal Trachelectomy for Cervical Stump Prolapse (previous subtotal hysterectomy) The cervical stump is removed in an identical fashion to the initial steps of a vaginal hysterectomy.

II Abdominal Procedures

(i) Abdominal Procedures with Mesh or Graft ^{FN15}

(a) Open / Laparoscopic / Robotic Sacrocolpopexy – Suspension of the vagina utilizing mesh or graft to the anterior longitudinal ligament usually at the level of the sacral promontory. (Fig 37 below)

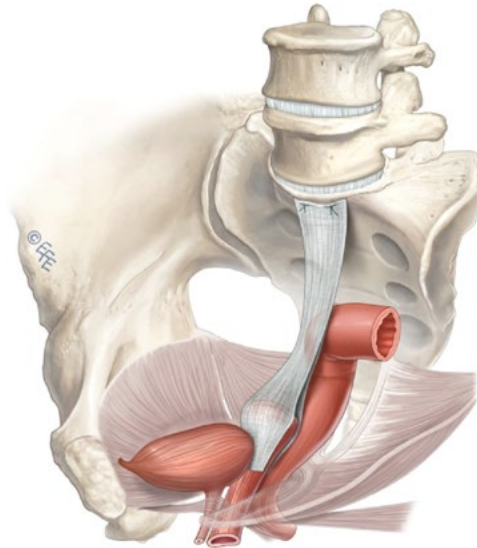


Figure 37. Sacrocolpopexy.

(b) Open / Laparoscopic / Robotic Sacrocervicocolpopexy – Suspension of the cervix (and usually vagina) utilizing mesh or graft to the anterior longitudinal ligament usually at the level of the sacral promontory. This procedure is commonly performed as an adjunct following subtotal hysterectomy for advanced utero-cervical prolapse.

(c) Open / Laparoscopic / Open Sacrohysteropexy- suspension of the cervix (with or without additional vaginal attachment) utilizing mesh or graft to the anterior longitudinal ligament usually at the level of the sacral promontory. Sacrohysteropexy is performed for women who are keen to preserve their uterus.

(ii) Abdominal Procedures without Mesh or Graft

(a) Open / Laparoscopic / Robotic paravaginal repair – Extraperitoneal bilateral reattachment of the lateral edge of damaged fascia to the Arcus Tendineus Fasciae Pelvis (Alt: White line).

(b) Laparoscopic / Robotic suture hysteropexy – The plicated uterosacral ligaments are resutured to the cervix.

(c) Open / Laparoscopic / Robotic closure of enterocele sac:

- (a) Moschowitz procedure- Concentric purse string suture(s) are placed around the cul-de-sac to include the posterior vaginal wall, pelvic side-walls and serosa of the sigmoid.
- (b) Halban procedure- Obliteration of the cul-de-sac by using successive sutures placed sagittally between the uterosacral ligaments.
- (c) Uterosacral ligament plication (Fig 38 below) – transverse plication of the uterosacral ligaments to obliterate the cul-de-sac. Successive sutures are placed into the medial portion of one ligament, into the back wall of the vagina and into the medial border of the opposing ligament.

¹⁵ : Variations in technique for all abdominal mesh/graft procedures: (i) Type of mesh or graft used; (ii) Shape of mesh /graft- single piece, 'DIY' two piece 'Y' mesh, Y mesh kit product; (iii) Points and length of attachment to vagina. (iv) Suture material employed / Metal stapling devices; (v) Peritoneal closure over mesh/graft.

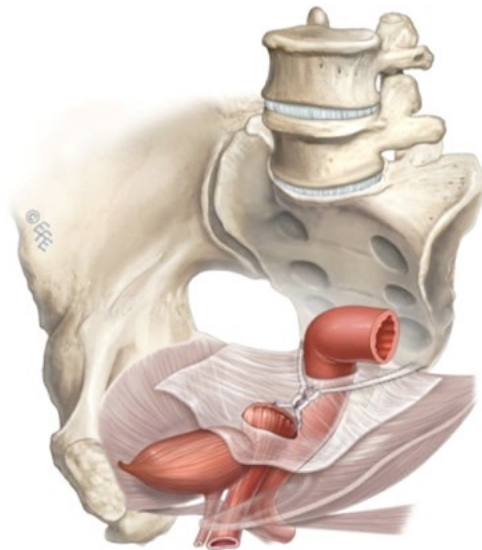


Figure 38. Uterosacral ligament plication.

(d) Open / Laparoscopic / Robotic Burch Colposuspension – Elevation or attachment of the upper paraurethral tissue adjacent to the bladder neck region to the iliopectineal ligament bilaterally. Although a recognized treatment for stress incontinence, this procedure will often correct associated anterior wall prolapse symptoms.

III: Obliterative Procedures

(i) Colpocleisis: (Greek: kolpō + kleisis closure) – Operation for obliterating the lumen of the vagina. FN16

(ii) Total colpectomy: (Greek: kolpō + ektomē excision): Total excision of the vagina in a woman with no uterus and vaginal eversion. FN17

C: Measuring Outcome in POP surgeries⁷

As per IUGA-ICS Report on outcome measures for POP surgery⁷, every study evaluating POP surgery should report.

(i) Perioperative data: i.e. blood loss, operating time, length of hospital stay, return to normal activities and complications.

(ii) Subjective (patient-reported) outcomes: At its simplest level this can be reported as the presence or absence of vaginal bulge. Patient satisfaction and quality of life can be measured by validated instruments that cover prolapse, urinary, bowel and sexual function.

(iii) Objective outcomes: POP-Q measurement generally and should be tabulated with absolute values and percentages to allow other studies to compare results.

(iv) Secondary outcomes (e.g. lower urinary tract symptoms, stress urinary incontinence or bowel and sexual dysfunction) in their studies whenever possible.

(v) Surgery type and operated compartment:

(a) **Primary surgery:** indicates the first procedure required for treating POP in any compartment.

(b) **Further surgery:** provides a term for any subsequent procedure relating to primary surgery. Further surgery is subdivided into:

- Primary surgery in a different (new) site/compartment.
- Repeat surgery in the same site/compartment for POP symptom recurrence.
- Surgery for complications e.g. mesh exposure, pain, infection or hemorrhage.
- Surgery for non-POP-related conditions usually urinary or fecal incontinence.

¹⁶: This is usually performed in a woman with a uterus who is no longer sexually active. It can be performed in the absence of a uterus in a woman with vaginal eversion instead of total colpectomy. The Le Fort's procedure involves denuding the vagina of skin both anteriorly and posteriorly, typically in a rectangular shape, avoiding the bladder neck and cervix. The cut edges are sewn together to achieve vaginal closure whilst leaving a bilateral epithelium-lined tunnel behind. The Labhardt procedure involves the removal of a 1 cm horse shoe shape of vaginal epithelium is removed over the posterior fourchette up to just under the urethra. By closing the incision and building up the perineum, an extremely high posterior repair almost closing the vagina is created.

¹⁷: The vagina is totally denuded of skin, typically in sections, whilst avoiding the bladder neck region. The prolapse is then reduced by a series of successive purse-string sutures and the epithelium at the entrance closed.

D: Complications of POP surgeries^{5,6}

Complications related to POP native tissue repair and surgeries using prostheses/graft/mesh have been classified separately according to joint IUGA/ICS recommendation^{5,6}. The sorting system used in both documents utilizes specific category, time and site taxonomy together referred as *CTS classification system*. Classification is aided by on line calculators at either <http://www.ics.org/complication> or <http://www.ics.org/ntcomplication>.



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APPENDIX - Concepts and available measurements awaiting further validation.

A: Subdivision of Stage II POP-Q:

An optional subdivision of Stage II into IIA (-1 to hymen) and IIB (hymen to +1) was considered at length. Stage IIA would then be defined as -1 to 0 (so the hymen, that is 0, is included in stage IIA) and stage IIB (>0 to +1), meaning the dependent part of prolapse beyond the hymen but no further than +1. It was felt that this might reflect a clinical difference between the two subdivisions in terms of symptoms. That change was not made at this time in part to maintain the current strictly anatomical definition of the “sign of POP”.

B: Vaginal Anatomical Levels and Lengths:

- (i) **Level I:** Uterine cervix (if present) and/or upper 2.5cm of vagina. Footnote FN18
- (ii) **Level II:** Mid-vagina from distal end of Level I to hymen. FN19
- (iii) **Level III (vaginal vestibule):** Vaginal entrance (Latin: “vestibulum” = “a space at the entrance of a canal”) from hymenal ring to just below the clitoris anteriorly (anterior vestibule), labia minora laterally and anterior perineum posteriorly (posterior margin of vestibule) FN20

¹⁸: Refinement of previous classification⁴⁹ reflecting the average length of non-gravid uterine cervix⁵⁰ and the average length of the supportive influence of the distal segment of the uterosacral ligaments on the posterolateral vaginal wall bilaterally⁵¹.

¹⁹: Mean length of Level II in women at posterior colporrhaphy found to be 5.0cm⁵²

²⁰: The outer edge of the vestibule is known as Hart's line (see white line in Figure 39 with blue line demarcating anterior and posterior vestibule).



Figure 39. Anterior and posterior vestibule.

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- (iv) **Posterior vestibule:** Posterior hymenal ring to anterior perineum (posterior margin of vestibule). FN21
- (v) **Total vaginal length²¹:** Posterior vaginal vault to hymen (cm), i.e. Levels I and II posteriorly.
- (vi) **Total posterior vaginal length⁵²⁻⁵⁴:** Posterior vaginal vault to posterior margin of vestibule (anterior perineum - cm), i.e. Levels I, II and III posteriorly.
- (vii) **Anterior vaginal length⁵⁵:** Anterior hymenal ring to the anterior vaginal vault (anterior cervicovaginal junction or anterior cuff post-hysterectomy)⁵⁵.

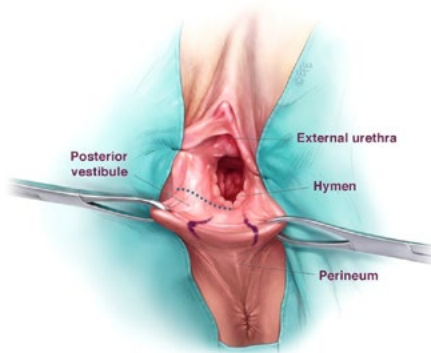


Figure 40. *Posterior vestibule.*

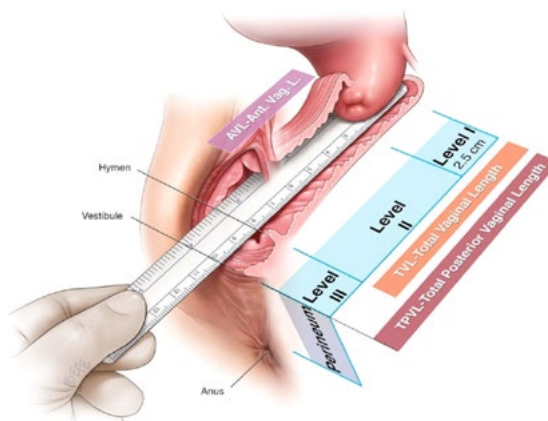


Figure 41. Vaginal Levels (I to III) and Vaginal lengths (Anterior, Total, Total Posterior).

C: Additional available intraoperative measurements.

(i) Perineal measurements:

(a,b) Perineorrhaphy Width (PW) and Depth (PD)⁵⁴: Width and depth of the excised perineum

²¹: Mean length in women at posterior colporrhaphy was found to be 1.8cm⁵².

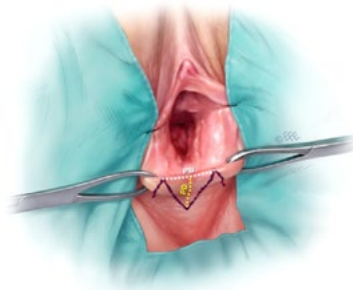


Figure 42. Perineorrhaphy width (PW) and perineorrhaphy depth (PD).

(c) Perineal length (PL)⁵⁴: Distance from posterior margin of vestibule to anterior anal verge.

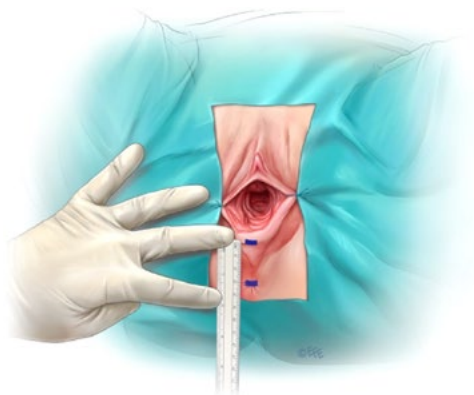


Figure 43. Perineal length.

(d) Mid-perineal thickness (MPT)⁵⁴: Thickness (cm) of the mid-perineum in the midline.

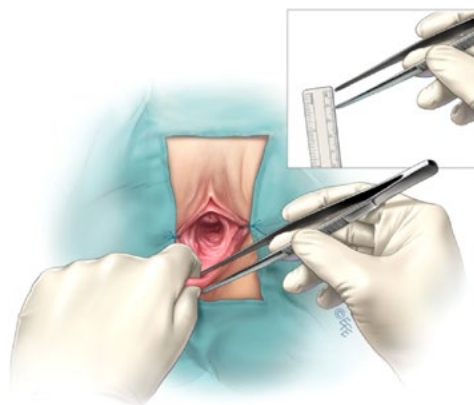


Figure 44. Mid-perineal thickness.

(e) Perineal Gap (PG)⁵²⁻⁵⁴: Thinned out medial area (cm) between Moynihan forceps placed bilaterally where the labia minora meet the perineum.

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Figure 45. Perineal Gap.

(f) Perineorrhaphy Commencement Position (PCP): NEW Where in Level III, the perineorrhaphy is commenced, e.g. hymen, mid-vestibule, posterior margin of vestibule.

(ii) Posterior vaginal measurements⁵³:

(a) Posterior Vaginal Vault Descent (PVVD)^{52,53}: Descent of the posterior vaginal vault towards the perineal gap obtained by subtracting the inferiorly displaced vaginal vault and the anterior perineum (second figure) from the total posterior vaginal length (TPVL - first figure – posterior vaginal vault to anterior perineum).

(b) Mid-Vaginal Laxity (MVL) (Undisplaced)^{52,53}: Laxity of the vaginal mucosa (anterior traction) midpoint in the vagina super-posteriorly and in the midline with the vaginal vault held in an undisplaced position (similar to that after vault fixation)

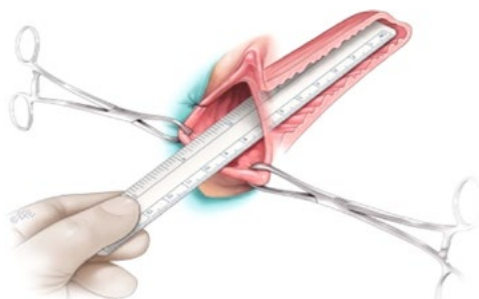


Figure 46. (left): Total posterior vaginal length (TPVL).

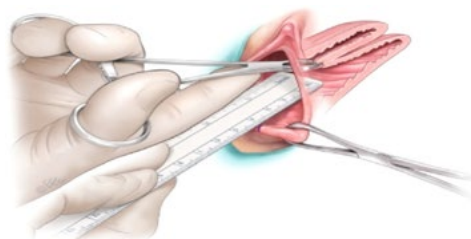


Figure 47. (right): Distance from vaginal vault (on traction) to anterior perineum. Posterior vaginal vault descent is the subtraction of this measurement from the TPVL.

(c) Recto-vaginal Fascial Laxity (RVFL)^{52,53}: Laxity of the rectovaginal fascia (anterior traction) midpoint in the vagina super-posteriorly (mucosa opened) and in the midline with the vaginal vault held in an undisplaced position

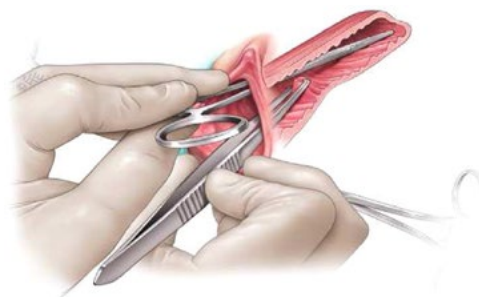


Figure 48. (left): Mid-vaginal laxity (vault undisplaced).



Figure 49. (right): Recto-vaginal fascial laxity.

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An International Urogynecological Association (IUGA)/ International Continence Society (ICS) Joint Report on the Terminology for Female Anorectal Dysfunction

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Introduction: The terminology for anorectal dysfunction in women has long been in need of a specific clinically-based Consensus Report. **Methods:** This Report combines the input of members of the Standardization and Terminology Committees of two International Organizations, the International Urogynecological Association (IUGA) and the International Continence Society (ICS), assisted on Committee by experts in their fields to form a Joint IUGA/ICS Working Group on Female Anorectal Terminology. Appropriate core clinical categories and sub classifications were developed to give an alphanumeric coding to each definition. An extensive process of twenty rounds of internal and external review was developed to exhaustively examine each definition, with decision-making by collective opinion (consensus). **Results:** A Terminology Report for anorectal dysfunction, encompassing over 130 separate definitions, has been developed. It is clinically based with the most common diagnoses defined. Clarity and user-friendliness have been key aims to make it interpretable by practitioners and trainees in all the different specialty groups involved in female pelvic floor dysfunction. Female-specific anorectal investigations and imaging (ultrasound, radiology and MRI) has been included whilst appropriate figures have been included to supplement and help clarify the text. Interval review (5–10 years) is anticipated to keep the document updated and as widely acceptable as possible. **Conclusion:** A consensus-based Terminology Report for female anorectal dysfunction terminology has been produced aimed at being a significant aid to clinical practice and a stimulus for research. *NeuroUrol. Urodynam.*

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Key words: anorectal; fecal incontinence; female sexual dysfunction; female pelvic floor; imaging; terminology

INTRODUCTION

The anatomical configuration of the anorectum is complex. The mechanisms that control continence and allow defecation are multifactorial and dependent on many factors such as the consistency of stool, bowel transit, rectal compliance and sensitivity, intact neurological function and integrity of the pelvic floor, and anal sphincters.

This document is being published simultaneously in *Neurourology and Urodynamics* (NAU) (DOI 10.1002/nau.23055) and the *International Urogynecology Journal* (IJU) (DOI 10.1007/s00192-016-3140-3), the respective journals of the sponsoring organizations, the International Continence Society (ICS) and the International Urogynecological Association (IUGA).

*Standardization and Terminology Committees IUGA.

^bICS.

^cJoint IUGA/ICS Working Group on Female Anorectal Terminology.

Dr. Mickey Karram led the peer-review process as the Associate Editor responsible for the paper.

Potential conflicts of interest: Dr. Sultan has patent on anal sphincter blocks with royalties paid to the Mayday Childbirth Charity fund. He described the Sultan Classification of third degree tears and runs hands-on workshops on Perineal and Anal Sphincter Trauma (www.perineum.net). A Monga: reports being Consultant for Gynecare and AMS and Speaker for Astellas and Pfizer and advisor for Allergan.; Dr. Lee reports personal fees from AMS, personal fees from BSCI, during the conduct of the study; Dr. Emmanuel served on advisory boards for Coloplast, Shire, Pfizer. Honoraria for talks from these companies as well as Ferring and Astra-Zeneca; Dr. Norton reported Consultancy for SCA, Coloplast, Shire, Dr Falk, Clinimed; Dr. Santoro has nothing to disclose; Dr. Hull has nothing to disclose; Dr. Berghmans has nothing to disclose; Dr. Brody has nothing to disclose; Dr. Haylen has nothing to disclose.

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Historically, anorectal physiological investigations have quite often produced inconsistent results. Until the advent of imaging techniques such as endoanal ultrasound, the etiology of fecal incontinence was largely attributed to pudendal neuropathy.¹ We now better understand the contribution of vaginal delivery to anal sphincter trauma.² Imaging has taught us that training in clinical digital assessment can improve detection and repair of obstetric anal sphincter injuries and thereby minimize the risk of developing fecal incontinence.³ Obstructive defecation is another common embarrassing problem and imaging techniques that attempt to capture the defecation process are often inconclusive.⁴ Artificial contrast material replicating normal fecal consistency for defecating proctography is not available and magnetic resonance imaging requires an upright scanner.

When multiple conditions such as fecal incontinence, obstructive defecation, urinary incontinence, neurological diseases, medical conditions etc. co-exist, management becomes increasingly difficult and multidisciplinary assessment becomes important.⁵ As the pelvic organs (bowel, bladder, and vagina) are in close proximity to each other, clinicians need to be aware of the impact of dysfunction and surgery of one organ may have on the neighboring structures. It is therefore important for clinicians and pelvic surgeons to have more global knowledge and adopt a holistic approach to pelvic floor dysfunction.

There is a need for standardized terminology in female anorectal dysfunction to accumulate accurate prevalence data, perform the appropriate investigations, institute management, and conduct audit and research. Lack of a unified definition of anal incontinence has resulted in variations in prevalence data from epidemiological data. "Pseudo incontinence" with mucoid leakage (usually caused by organic colonic disease, dietary sensitivity or fecal impaction) is often mistaken as fecal incontinence as questionnaires do not quite differentiate them.⁶ There is indeed the need for a general terminology, forming a "backbone" or "core" terminology to which more specific terminologies can be attached.⁷

This Terminology Report is inherently and appropriately a definitional document, collating the definitions of those terms, that is, words used to express a defined concept, in a particular branch of study. Emphasis has been on comprehensively including those terms in current use in the relevant peer-reviewed literature. The aim is to assist clinical practice and research. Some new and revised terms have been included. Explanatory notes on definitions have been referred, where possible, to the "Footnotes section."

Similar to a previous report⁷ the female-specific terminology report should be as follows:

(1) User-friendly: It should be able to be understood by all clinical and research users.

(2) Clinically-based: Symptoms, signs, and validated investigations should be presented for use in forming workable diagnoses. The first three sections will address symptoms, signs, and assessment tools. The next two sections will describe anorectal physiological investigations and currently used pelvic imaging modalities routinely used in the office or anorectal laboratory to make those diagnoses. A number of related radiological investigations as well as magnetic resonance imaging (MRI) have also been included. The value of electromyography and related nerve conduction, reflex latency, and sensory investigations will be outlined.

(3) Origin: Where a term's existing definition (from one of multiple sources used) is deemed appropriate, that definition will be included and duly referenced. A number of terms in female anorectal function and dysfunction, because of their long-term use, have now become generic, as apparent by their listing in medical dictionaries.

(4) Able to provide explanations: Where a specific explanation is deemed appropriate to explain a change from earlier definitions or to qualify the current definition, this will be included as an addendum to this paper (*Footnote [FN] 1,2,3 ...*). Wherever possible, evidence-based medical principles will be followed.

It is suggested that acknowledgement of these standards in written publications related to female anorectal dysfunction, be indicated by a footnote to the section "Methods and Materials" or its equivalent, to read as follows: "Methods, definitions and units conform to the standards jointly recommended by the International Urogynecological Association and the International Continence Society, except where specifically noted." It should be noted that the Working Group for this document was formed and started generation of this document prior to the Rosier statement.⁸

SECTION 1: SYMPTOMS

Symptom: Any morbid phenomenon or departure from the normal in structure, function, or sensation, experienced by the woman and indicative of disease⁹ or a health problem. Symptoms are either volunteered by, or elicited from the individual, or may be described by the individual's caregiver.^{7,10,11}

1.1: Anorectal Incontinence Symptoms

Anal incontinence (symptom⁷). Complaint of involuntary loss of feces or flatus.

(i) **Fecal incontinence⁷:** Complaint of involuntary loss of feces.

(a) Solid

(b) Liquid

(ii) **Flatus incontinence⁷:** Complaint of involuntary loss of flatus (gas).

(iii) **Double incontinence (NEW):** Complaint of both anal incontinence and urinary incontinence [^{FN1}].

(iv) **Coital fecal (flatal) incontinence (NEW):** Fecal (flatal) incontinence occurring with vaginal intercourse (see related definition "Coital fecal urgency") [^{FN2}].

^{FN1} In regards to definition of various types of urinary incontinence, the interested reader can refer to (Haylen 2010).⁷

^{FN2} A history of receptive anal intercourse has been shown to increase the risk of anal incontinence.¹²

- (v) **Passive fecal leakage (NEW)**: Involuntary soiling of liquid or solid stool without sensation or warning or difficulty wiping clean ^[FN3].
- (vi) **Overflow fecal incontinence (NEW)**: Seepage of stool due to fecal impaction.

1.2: Anorectal Storage Symptoms

- (i) **Increased daytime defecation (NEW)**: Complaint that defecation occurs more frequently during waking hours than previously deemed normal by the woman.
- (ii) **Nocturnal defecation (NEW)**: Complaint of interruption of sleep one or more times because of the need to defecate.
- (iii) **Fecal (rectal) urgency⁷**: Complaint of a sudden compelling desire to defecate that is difficult to defer.
- (a) Fecal urgency warning time: time from first sensation of urgency to voluntary defecation or fecal incontinence.
- (iv) **Fecal (flatal) urgency incontinence⁷**: Complaint of involuntary loss of feces (gas) associated with (fecal) urgency.
- (v) **Tenesmus (NEW)**: A desire to evacuate the bowel, often accompanied by pain, cramping, and straining, in the absence of feces in the rectum.
- (vi) **Coital fecal urgency (NEW)**: Feeling of impending bowel action during vaginal intercourse.

1.3: Anorectal Sensory Symptoms

- (i) **Diminished rectal sensation⁷**: Complaint of diminished or absent sensation in the rectum.
- (ii) **Increased rectal sensation (NEW)**: Complaint of a desire to defecate (during rectal filling) that occurs earlier or more persistent to that previously experienced.

1.4: Defecatory and Post-Defecatory Symptoms

- (i) **Constipation⁷ (Updated)**: Complaint that bowel movements are infrequent and/or incomplete and/or there is a need for frequent straining or manual assistance to defecate ^[FN4].
- (a) Slow transit: infrequent bowel motions due to delay in transit of bowel contents to reach rectum.
- (b) Obstructed defecation: Complaint of difficulty in evacuation ^[FN5].
- (ii) **Feeling of incomplete bowel evacuation⁷**: Complaint that the rectum does not feel empty after defecation and may be accompanied by a desire to defecate again.
- (iii) **Straining to defecate⁷**: Complaint of the need to make an intensive effort (by abdominal straining or Valsalva) to either initiate, maintain, or improve defecation.
- (iv) **Sensation of blockage (NEW)**: Complaint suggestive of anorectal obstruction.
- (v) **Digitation (NEW)**: Use of fingers in rectum or vagina to manually assist in evacuation of stool contents.
- (a) Rectal digitation: Use of fingers in rectum to physically extract stool contents to assist in evacuation.
- (b) Vaginal digitation: Use of thumb or fingers in the vaginal to assist in evacuation of stool.
- (vi) **Splinting (NEW)**: Support perineum or buttocks manually (usually with thumb or fingers) to assist in evacuation of stool content.
- (vii) **Post defecatory soiling (NEW)**: Soiling occurring after defecation.

^{FN3} Soiling is a bothersome disorder characterized by continuous or intermittent liquid anal discharge. It should be differentiated from discharge due to fistulae, proctitis, hemorrhoids, and prolapse. Patients complain about staining of underwear and often wear protection.

- The discharge may cause inflammation of the perineal skin with excoriation, perianal discomfort, burning sensation, and itching.
- It often indicates the presence of an impaired internal sphincter function or a solid fecal mass in the rectum but could also be due to the inability to maintain hygiene due to hemorrhoids.

^{FN4} Rome III criteria for functional constipation:

1. Must include two or more of the following:
 - a. Straining during at least 25% of defecations.
 - b. Lumpy or hard stools in at least 25% of defecations.
 - c. Sensation of incomplete evacuation for at least 25% of defecations.
 - d. Sensation of anorectal obstruction/ blockage for at least 25% of defecations.
 - e. Manual maneuvers to facilitate at least 25% of defecations (e.g., digitalevacuation, support of the pelvic floor).
 - f. Fewer than three defecations per week.
2. Loose stools are rarely present without the use of laxatives.
3. Insufficient criteria for irritable bowel syndrome.

*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.

^{FN5} Difficulty evacuating stool, requiring straining efforts at defecation often associated with lumpy or hard stools, sensation of incomplete evacuation, feeling of anorectal blockage/obstruction or manual assistance to defecate (or inability to relax EAS/dyssynergic defecation).

1.5: Anorectal Prolapse Symptoms

(i) **Anorectal prolapse (updated)**: Complaint of a “bulge” or “something coming down” towards or through the anus/rectum. The woman may state she can either feel the bulge by direct palpation or see it aided with a mirror [FN6].

1.6: Anorectal Pain Symptoms (NEW)^[FN7]

- (i) **Pain during straining/defecation**: Complaint of pain during defecation or straining to defecate.
- (ii) **Inflammatory anorectal pain**: Complaint of pain characterized by burning or stinging [FN8] (fissure, inflammation, sepsis).
- (iii) **Non-inflammatory anorectal pain**: Complaint of blunted anorectal pain, as opposed to sharp stinging or burning type of pain (proctalgia fugax, Levator ani syndrome, pudendal neuralgia¹³) See Section Pain Syndromes.

1.7: Anorectal Sexual Dysfunction Symptoms^[FN9]

Symptoms of sexual dysfunction⁷. A departure from normal sensation and/or function experienced by a woman during sexual activity.

Female sexual dysfunction²². Complaint of dyspareunia or impairment of sexual desire, arousal, or orgasm.

- (i) **Receptive anal intercourse (NEW)**: Having a penis penetrating one’s anus [FN10].
- (ii) **Other anal sexual practices with body parts**: Stimulation of the anus and/or rectum with bodily parts other than the penis (e.g., finger, fist) for sexual purposes by the recipient and/or a partner.
- (iii) **Other anal sexual practices with non-living objects**: Stimulation of the anus and/or rectum with non-living objects (e.g., dildo) for sexual purposes by the recipient and/or a partner.
- (iv) **Anodyspareunia (NEW)**: Complaint of pain or discomfort associated with attempted or complete anal penetration¹²[FN11].
- (v) **Anal laxity (NEW)**: Complaint of the feeling of a reduction in anal tone [FN12].

1.8: Miscellaneous Anorectal Symptoms

- (i) **Rectal bleeding/mucus**⁷: Complaint of the loss of blood/mucus per rectum [FN11].
- (ii) **Perianal itching/pruritus ani (NEW)**: Complaint of itchy anus [FN13].
- (iii) **Flaturia (NEW)**: Complaint of passage of gas per urethra.
- (iv) **Fecaluria (NEW)**: Complaint of passage of fecal material per urethra.
- (v) **Vaginal flatus/feces (NEW)**: Complaint of passage of flatus or feces per vagina.

SECTION 2: SIGNS

Sign: Any abnormality indicative of disease or health problem, discoverable on examination of the patient: an objective indication of disease or health problem.⁷

2.1: Vaginal and Anorectal Inspection²³

- (i) **Excoriation**: Perianal excoriation, skin rashes.
- (ii) **Soiling**: Perianal fecal soiling or vaginal fecal soiling.
- (iii) **Discharge**: Perianal or vaginal bloody or mucus discharge.
- (iv) **Gaping anus**: Non-coaptation of anal mucosa at rest.

^{FN6} Anorectal prolapse can be due to hemorrhoidal, mucosal, rectal prolapse, or rectal intussusception. These definitions are further explained under “Signs.”

^{FN7} This refers to pain localized to the anorectal region, and may include pain, pressure, or discomfort in the region of the rectum, sacrum, and coccyx that may be associated with pain in the gluteal region and thighs.

^{FN8} Fissure pain during, and particularly after, defecation is commonly described as passing razor blades or glass shards See FN10.

^{FN9} Receptive anal intercourse is associated with increased risk of both any female sexual dysfunction,¹⁴ as well as with specifically female sexual arousal disorder with distress¹⁵ (“a persistent or recurrent inability to attain [or to maintain until completion of the sexual activity] an adequate wetness and vaginal swelling response of sexual excitement”). The association of receptive anal intercourse with sexual dysfunction might be due to physiological and/or psychological processes. The psychological factors including emotional development problems,¹⁶ poorer mood,¹⁷ poorer intimate attachment¹⁸ as well as general dissatisfaction are associated with women’s receptive anal intercourse.¹⁹ Physiologic factors could include that: (1) mechanical stimulation of the anus and rectum during anal intercourse increases hemorrhoid risk; (2) women with hemorrhoidectomy have impaired sexual function; and (3) persons with hemorrhoids who have not yet had hemorrhoidectomy “are more likely to have abnormal perineal descent with pudendal neuropathy.”^{20,21} Thus, pudendal nerve dysfunction could be one mechanism leading to sexual dysfunction, and this might be the case even in the absence of diagnosed haemorrhoids.¹³

^{FN10} A history of receptive anal intercourse has been shown to increase the risk of anal incontinence, rectal bleeding, and anal fissure.¹²

^{FN11} Unlike dyspareunia (from coitus), it might be normal to experience pain or discomfort during receptive anal intercourse.

^{FN12} This may be accompanied by a finding of decreased anal resting tone (in some cases, the result of anal intercourse)—see under Signs. Damage to the internal anal sphincter is the likely basis for the laxity. Unlike stool passage, receptive anal intercourse is not likely to elicit reflex relaxation of the internal sphincter.

^{FN13} Pruritus ani has been classified into primary and secondary. The primary form is the classic syndrome of idiopathic pruritus ani. The secondary form implies an identifiable cause or a specific diagnosis.

(v) **Scars, sinuses, deformities, condylomata, papillomata, hematoma:**^[FN14].

(vi) **Deficient perineum/cloacal-like defect:** A spectrum of tissue loss from the perineal body and rectovaginal septum with variable appearance. There can be a common cavity made up of the anterior vagina and posterior rectal walls or just an extremely thin septum between the anorectum and vagina.

(vii) **Anal fissures:** Longitudinal split in the skin of the anal canal, exposing the internal anal sphincter muscle. The majority of fissures are found in the mid-line posteriorly and there may be a skin tag associated with them.

(viii) **Hemorrhoids:** Abnormality of the normal cushion of specialized, highly vascular tissue in the anal canal in the submucosal space. Hemorrhoids can be divided into those originating above the dentate line which are termed internal and those originating below the dentate line which are termed external. Internal hemorrhoids are graded as follows:

Grade I - bleeding without prolapse.

Grade II - prolapse with spontaneous reduction.

Grade III - prolapse with manual reduction.

Grade IV - incarcerated, irreducible prolapse.

Grade II and Grade III hemorrhoids will become evident on asking the patient to bear down and grade IV hemorrhoids are obvious at the time of the examination. A proctoscopy is essential in examining for hemorrhoids unless they are completely prolapsed.

(ix) **Anorectal prolapse:** Full thickness eversion of the lower part of the rectum and anal canal. The exposed mucosa is red with circumferential folds around the central pit, which is the lumen of the rectum. Look for associated utero-vaginal prolapse, fistulas, sepsis, and ulcers.

(x) **Fistula in ano:** An anal fistula is an abnormal connection between the anal canal epithelium (or rarely rectal epithelium) and the skin epithelium. Patients may complain of pain, swelling, intermittent discharge of blood or pus from the fistula, and recurrent abscesses formation.

(xi) **Rectovaginal fistula:** Is a communication from the rectum to the vagina.

(xii) **Ano-rectal/vaginal/perineal fistula:** Is an abnormal communication from the anal canal to the vagina or perineal area.

2.2: Vaginal Examination

All examinations for pelvic organ prolapse should be performed with the woman's bladder empty (and if possible an empty rectum),⁷ straining to maximally reveal the prolapse. All compartments should be examined for prolapse but of particular relevance to ano-rectal dysfunction is posterior vaginal wall prolapse.

(i) **Posterior vaginal wall prolapse⁷:** Observation of descent of the posterior vaginal wall. Commonly, this would represent rectal protrusion into the vagina (rectocele). Higher stage posterior vaginal wall prolapse after prior hysterectomy

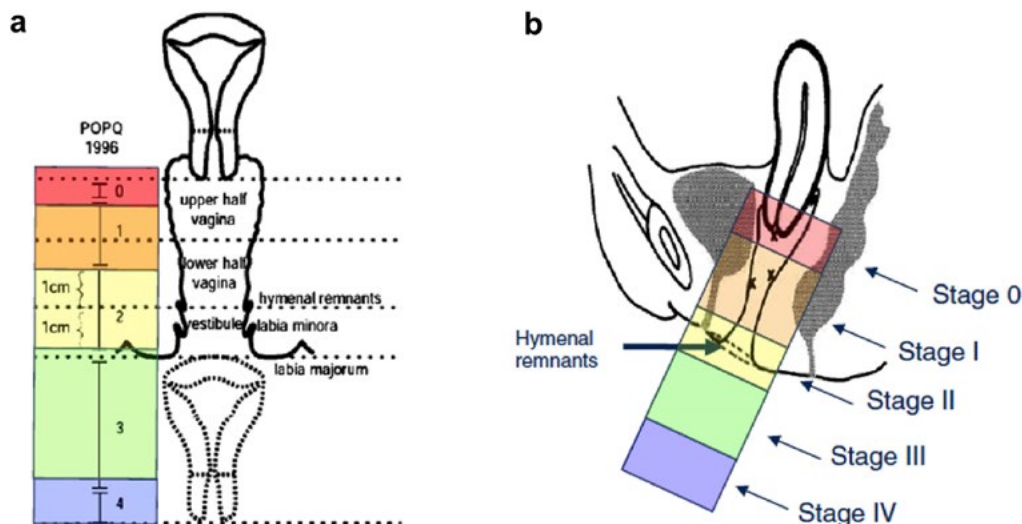


Fig. 1. Figure a and b shows prolapse staging—0, I, II, III, and IV (uterine by the position of the leading edge of the cervix).

^{FN14}With perianal hematomas, the lump may be anywhere around the anal margin and may be multiple. Pilonidal sinuses are usually a small mid-line pit with epithelialized edges.

^{FN15}Figure used from Pelvic floor dysfunction document⁷ (Fig. 1a and b).

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would generally involve some vaginal vault (cuff scar) descent and possible enterocele formation. Posterior vaginal wall prolapse can be a rectocele, enterocele, or a perineocele. Enterocele formation can also occur in the presence of an intact uterus.

(ii) **Rectocele:** Bulge in posterior vaginal wall associated with herniation of anterior wall of the rectum.

(iii) **Enterocele:** Bulge of upper wall of the vagina associated with herniation of the peritoneal sac and loops of small bowel.

(iv) **Perineocele:** Bulge in the perineum associated with herniation of the anterior wall of the rectum.

2.3: Anorectal Examination

The patient lies in the left lateral position with hips flexed and ankles away from the examiner. Dorsal lithotomy position could also be used.

(i) **Perianal sensation/reflex:** In patients with possible neurogenic pelvic floor dysfunction there should be particular note of those neurological signs related to S2-4 but these should be complimented by a more general neurological examination as indicated. Specific to ano-rectal dysfunction, assessment of anal reflex, and perianal sensation should be performed.

(ii) **Digital rectal examination:** The gloved finger should be placed in the center of the anus with the finger parallel to the skin of the perineum in the midline. The finger should then be pressed gently into the anal canal but at the same time pressed backwards against the skin of the posterior wall of the anal canal and underlying sling of the puborectalis muscle. This overcomes most of the tone of anal sphincter and allows the finger to straighten and slip into the rectum. This will allow assessment of:

- (a) Resting anal tone, voluntary squeeze of the anal sphincter as well as the levator muscles, sustained squeeze over 5 sec and involuntary contraction elicited during a cough.
- (b) Obvious hemorrhoids can be palpated but grade II and grade III. Hemorrhoids are better assessed by proctoscopy. Painful examination may be associated with fistula in ano, fissure in ano, infection or pilonidal abscess.
- (c) Palpable anal sphincter gap. An assessment can be made of a palpable anal sphincter gap to assess if there has been previous obstetric or surgical damage. The perineal body can be assessed for deficiency.
- (d) Rectal contents. The contents of the rectum can be assessed. The feces may be hard or soft, the rectum may be empty or collapsed and sometimes ballooned out. This allows assessment of fecal impaction.
- (e) Confirmation of presence of rectocele, enterocele, or perineocele. Use of POP-Q for staging of prolapse [See ^{FN15}].
- (f) Bidigital examination may be carried out with the patient supine in a gynecological examining position. By inserting the index finger in the vagina and the middle finger in the rectum, the rectovaginal septum and any intervening small bowel loops can be palpated to differentiate a rectocele from an enterocele, during a Valsalva maneuver.
- (g) Rectal lesions such as carcinoma, intussusception or recto-vaginal fistula. If a mass is felt on a fingertip, the patient should be asked to strain, and this will often move the mass down to bring it within reach.
- (h) An assessment can be made of the rectovesico/recto uterine pouch to look for extra rectal masses.

2.4: Examination of Pelvic Floor Muscle Function⁷

Pelvic floor muscle function can be qualitatively defined by the tone at rest and the strength of a voluntary or reflex contraction as strong, normal, weak, or absent or by a validated grading symptom. Voluntary pelvic floor muscle contraction and relaxation may be assessed by visual inspection, by digital palpation (vaginal or anorectal) (circumferentially), electromyography, dynamometry, manometry, or ultrasound. Factors to be assessed include muscle strength (static and dynamic) (graded as strong, normal, weak or absent), voluntary muscle relaxation (graded as absent, partial, complete, delayed), muscular endurance (ability to sustain maximal or near maximal force), repeatability (the number of times a contraction to maximal or near maximal force can be performed), duration, co-ordination, and displacement.²⁴ Assessment can be made of each side of the pelvic floor separately to allow for any unilateral defects and asymmetry.²³ Assessment of displacement (perineal elevation or descent) of the pelvic floor can be made during cough or Valsalva. Normally, there is some downward movement of the pelvic floor muscles or there is a ventral movement (perineal elevation, inward (cephalad) and upward movement of vulva, perineum, and anus). Rectal examination observations can include:

(a) Anal sphincter tone and strength: given the absence of a formal quantitative assessment via the rectal route, assessment of anal tone and strength on digital examination, can be graded using the same convention used when grading transvaginally—as strong, normal, weak, or absent or by a validated grading symptom.

(b) Anal sphincter tear: may be recognized as a clear “gap” in the anal sphincter on digital examination.

2.5: Squeeze Pressure

Measurement of squeeze pressure involves the exertion of pressure, compressing the assessor’s finger during digital palpation or using a mechanical device. The patient is asked to squeeze the PFM as hard as possible (maximum strength), to sustain the squeeze contraction (endurance), or to repeat squeeze contractions (repetitions). The measurement can be done in the anorectum using manual muscle testing with digital rectal palpation or pressure manometry in the vagina using manual

muscle testing with digital vaginal palpation or pressure manometry, or dynamometry. So far, not all quantitative assessments and scales of pelvic floor squeeze pressure have the same methodological qualities, like validity, reproducibility, and responsiveness.^{24–28}

Pelvic floor muscle **spasm** was defined as persistent contraction of striated pelvic floor muscle that cannot be released voluntarily. If the contraction is painful, this is usually described as a cramp.²⁹ Spasm over days or weeks may lead to a contracture.

Pelvic floor muscle **tenderness**: sensation of discomfort with or without pain; discomfort of pelvic floor muscle elicited through palpation. Tenderness can be scored³⁰ during a digital rectal (or vaginal) examination of levator ani, piriformis and internal obturator muscles bilaterally, according to each subject's reactions: 0, no pain; 1, painful discomfort; 2, intense pain; with a maximum total score of 12.

Although not universally accepted, pelvic floor muscle **traction** is the use of a pulling force to examine or treat pelvic floor muscles, postulated to end pelvic muscle spasm or relieve pain.³¹

2.6: General Examination

Anorectal dysfunction may be associated with systemic disease and intestinal malignancy and a thorough medical examination should observe for signs relating to conditions such as anaemia, jaundice, lymphadenopathy, etc.

2.7: Neurological Examination

In patients with possible neurogenic pelvic floor dysfunction there should be particular note of those neurological signs related to S2-4 but these should be complimented by a more general neurological examination as indicated. Specific to ano-rectal dysfunction, assessment of anal reflex, and perianal sensation should be performed.

2.8: Abdominal Examination

A thorough abdominal examination should evaluate for the following:

- (i) Abdominal masses or distension.
- (ii) Scars indicating previous relevant surgery or trauma.
- (iii) Tenderness.

SECTION 3: ASSESSMENT TOOLS AND QUESTIONNAIRES (NON INVASIVE)

3.1: Pictorial Stool Chart

It is a pictorial chart of stool consistencies. First described (but not published as a pictorial instrument) by Heaton et al.,^{32,33} the "Bristol stool chart" seems to have widespread face validity and recognition and is useful in conversations with patients about their stool consistency, despite little validation work. It has not been validated as an outcome measure and a reported change in category may not represent sufficient degree of precision for use as a trial end point.

3.2: Bowel Diary

It is a recording of bowel actions. Bowel diaries have been widely used in diagnostic and intervention studies. Patient recall is less accurate than a diary.^{34,35} Patients tend to underestimate symptom frequency, in one study by over 50%.³⁶ However, there are few published examples and no consensus on what should be included. Elements that might be included:

- Urgency,
- Fecal incontinence (amount, consistency),
- Flatus incontinence,
- Passive staining/soiling (tends not be discrete episodes),
- Pads (changes, degree of soiling),
- Straining/difficulty/time in the toilet,
- Unsuccessful attempts to defecate,
- Assistive measures (e.g., digital stimulation, manual evacuation, irrigation),
- Laxative or rectal evacuant use,
- Diet and fluids (type and/or timing).

Patients often need careful and detailed instructions on how to complete a diary, and still many are poorly completed. An incomplete diary is difficult to interpret and is liable to misinterpretation as a low bowel/event frequency.

3.3: Symptom Scores and Questionnaires

(i) Fecal incontinence (FI)

The International Consultation on Incontinence (ICI) chapter 5B³⁷ has reviewed FI questionnaires and found none with a grade A recommendation (validity, reliability, and responsiveness established with rigor). The ICI grades B (validity and reliability established with rigor, or validity, reliability, and responsiveness indicated) and C (early development—further work required) are noted where available in the text below.

The Cleveland Clinic Score,³⁸ often termed the “Wexner” score, was the first attempt to have a score based on both the frequency and consistency of FI and effect on lifestyle. In the original version it was physician-completed, although in subsequent literature it has also been completed by patients (grade C). The St Mark’s score³⁹ was an adaptation of the original Wexner score, adding scores for urgency and use of anti-diarrheals (grade C). This has been found to correlate reasonably well to patients’ global assessment of their bowel function.⁴⁰

The Fecal Incontinence Quality of Life Scale⁴¹ (grade B) and Fecal Incontinence Severity Index⁴² (FISI) (grade B) were developed using items suggested by experts and then proposed to patients for ranking.

The international consultation on incontinence questionnaire—bowels (ICIQ-B)⁴³ has 23 items developed by literature review, expert opinion and in-depth qualitative interviews with patients, to include items of greatest importance to both clinicians and people with symptoms.⁴⁴ It has been validated up to the point of responsiveness to change, but further work is needed.

(ii) Constipation

There has been no exercise similar to the ICI Chapter 5B³⁷ which has graded constipation questionnaires.

The Patient Assessment of Constipation Quality of Life questionnaire⁴⁵ (PAC-QOL) and the PAC-SYM⁴⁶ are the best validated and most widely used tools for idiopathic constipation.⁴⁷ The PAC-SYM items were developed from the literature and patient focus group interviews. The validation process was robust and the instrument has 12 items grouped into three subscales (stool symptoms, rectal symptoms, and abdominal symptoms), each scored 0–4. It has also been validated for use with constipated older people in a care home environment⁴⁷ and opioid-induced constipation.⁴⁸

The Cleveland Clinic constipation score gives a simple numerical total score⁴⁹ based on symptoms and physiological findings. Values allocated to symptoms and findings appear to be arbitrary. Validation has been limited.

Altomare has developed a scoring system specifically for the Obstructed Defecation Syndrome,⁵⁰ but this has not been formally validated. Table I shows utility of patient reported outcomes questionnaires for female anorectal dysfunction in clinical or research settings.

TABLE I. Patient Reported Outcome Questionnaires for Female Anorectal Dysfunction

Conditions	Tools	Clinical	Research
Bowel dysfunction	Bristol stool chart	R	R
Bowel dysfunction	Bowel diary	R	R
Fecal incontinence	Cleveland clinic score/	R	R
	Wexner	R	R
	St Marks score	R	R
	FI QoL	O	R
	FISI	O	R
	ICIQ-B	O	R
	PAC-QoL	R	R
Constipation	PAC-SYM	R	R
	Altomare	O	R

O, optional; R, recommended.

SECTION 4: ANORECTAL PHYSIOLOGICAL INVESTIGATIONS

Anorectal physiological assessment is a key part of the assessment of some patients with pelvic floor symptoms^{51,52} providing a clinically meaningful, quantitative measure of a specific anorectal function. It is only in the context of the patient’s symptoms, thorough examination and radiological investigations that physiological measurements can be correctly interpreted.

4.1: Investigations to Exclude Organic Disease

(i) Anoscopy or proctoscopy is the inspection of the anal canal to identify anal fissure, fistula, or hemorrhoids as a cause of anal symptoms.

(ii) Rigid sigmoidoscopy is a bedside test to inspect the rectal mucosa, with no bowel preparation.

(iii) Flexible sigmoidoscopy refers to the inspection of the distal colonic mucosa, typically up to the splenic flexure, with a 60 cm flexible endoscope following enema preparation. Colonoscopy examines the entire colon following a full oral preparation to clear the bowel to allow this.

4.2: Anorectal Physiology Tests

Functional assessment tests of fecal incontinence and evacuatory disorders aim to qualify and quantify function, determine the etiology, guide management, and monitor progress.

4.2.1 Manometry

Anal manometry is a test to assess the mechanical strength of the anal sphincters.^{53,54} A range of methods is available, including water perfused, solid state, and micro-balloon systems. The length of the canal is measured either by station pull-through or continuous pull-through. Station pull-through involves inserting the catheter to 6 cm from the anal verge, withdrawing the catheter at 5–10mm intervals and measuring for 1–5 min at each “station” (see Fig. 2). Continuous pull-through involves withdrawing the catheter at a set speed by hand or by a mechanical puller. As normal values can differ substantially between laboratories according to the style of catheter used, each unit is encouraged to generate its own normal data.^{51,52}

In patients with fecal incontinence the value of manometry is:

- (a) To define functional weakness of one or both sphincter muscles (as a compliment to anal endosonography).
- (b) To support findings of other tests and to monitor outcome and predict response to biofeedback training.
- (c) In cases where anal endosonography is not available, vector manometry may help identify anatomic defects of the anal sphincter complex.

In constipated patients the value of manometry is:

- (a) To exclude Hirschsprung’s disease.
- (b) To identify and predict responses to biofeedback training (pelvic floor dyssynergia = failure to expel a water-filled balloon).

4.2.1.1: Functional anal length

Functional anal canal length is defined as the length of the anal canal over which resting pressure exceeds that of the rectum by greater than 5 mmHg or, alternatively, as the length of the anal canal over which pressures are greater than half of the maximal pressure at rest.

4.2.1.2: Maximum resting pressure

The maximum resting pressure is the maximum resting pressure generated in the anal canal at rest. Strictly speaking, it is defined as the difference between the intrarectal pressure and the highest recorded rectal pressure at rest. However, rectal contents may affect the accuracy of rectal pressure measurements. The internal anal sphincter (IAS) exhibits continuous tonic activity and is responsible for 55–85% of the resting anal canal pressure (see Fig. 2). Its contribution to resting tone is variable along the length of the anal canal with the proximal two thirds being more reliant on IAS tone to maintain adequate resting pressures.^{55,56} The range of maximal resting pressure is typically between 60 and 120 cmH₂O. The EAS has constant tonic activity contributing to the resting anal canal pressure.

4.2.1.3: The maximum squeeze pressure

The maximum squeeze pressure is the maximum pressure generated in the anal canal during a voluntary contraction. Although the EAS contributes to the resting pressure the specific function of the EAS can be assessed during the *squeeze* and *cough* maneuvers. The pressure increment above resting pressures during these maneuvers is a direct representation of EAS function. The normal range, as stated above, varies according to measurement modality in each laboratory, but is approximately above 60 cmH₂O.^{57,58} Typically, higher values are obtained by automated pull-through rather than station withdrawal methodologies.⁵¹

4.2.1.4: Involuntary maximum squeeze pressure

A common maneuver is a maximal cough to measure this involuntary increment, usually reported as a present or absent response, rather than numerically.

4.2.1.5: Endurance squeeze pressure

The endurance squeeze pressure is the length of time the individual is able to maintain the pressure during a voluntary contraction. To assess the endurance squeeze pressure, measurements are taken during a 5–10 sec squeeze (normal ≥ 5 sec). Incontinent patients typically have fatigue rate of greater than two-thirds of initial pressure at the end of the sustained squeeze. By calculating fatigability, the fatigue rate (using linear regression on the mean pressure over one second periods throughout the endurance squeeze) can be derived.

4.2.1.6: Rectoanal inhibitory reflex

The recto-anal inhibitory reflex (RAIR) a relaxation response in the IAS following rectal distension. A drop of at least 25% of resting pressure has to occur with subsequent restoration to at least two thirds of resting pressure for it to be deemed present. It is elicited by rapid insufflation and disinflation of 50 mls of air into a balloon positioned in the distal rectum during anal manometry at the level of the proximal high pressure zone.⁵² This reflex is absent in Hirschsprung’s disease: of greater physiological meaning, this reflex is thought to underlie the sampling response that allows rectal content to be sensed by the anal mucosa, thus ensuring continence of flatus and stool.⁵⁹

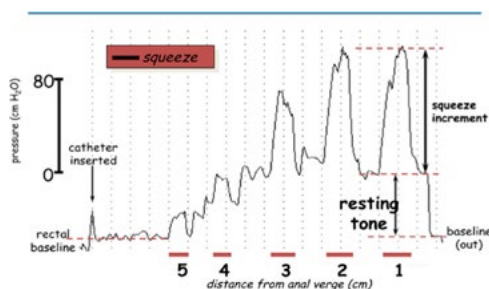


Fig. 2. Typical station pull through manometry trace on a patient, with explanations.

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4.2.1.7: Balloon expulsion pressure

The balloon expulsion pressure is the anal canal pressure during straining with a filled balloon in the rectum. Balloon expulsion can be performed on patients with evacuatory difficulty. An inappropriate increase in sphincter pressure on attempted voiding evacuation is usually reported as a present or absent response, rather than numerically. Such increased pressure is referred to as “anismus” or “paradoxical sphincter contraction.”

4.2.1.8: Advanced manometric techniques

4.2.1.8.1: Vector manometry

Vector manometry is a quantitative measure of radial symmetry and volume of the anal sphincter. It involves withdrawing (commonly using a mechanical puller) a radially arranged multi-channel anorectal manometry catheter through the length of the anal canal.^{60,61} The following parameters are identified:

- Radial asymmetry index (RAI) is a quantitative measure of the radial symmetry and can be calculated at any level in the anal canal but most commonly refers to the level at which the highest resting pressure is generated. The principle is that an asymmetrical sphincter is more likely to have a sphincter defect.
- The vector volume is the volume of the 3D shape generated and provides a value which reflects the overall length and symmetry of the sphincter (Fig. 3).

4.2.1.8.2: High resolution manometry

In this technique, a catheter with a large number of pressure sensors spaced less than 0.5 mm apart along the length of the catheter. This allows complete definition of the intra-anal pressure environment. The resulting data is displayed on a topographical three dimensional plot to allow easier pattern recognition. It is a measurement with the variables of pressure (displayed as the color), distance into the anal canal (y-axis) and time (x-axis). Normal ranges are slightly higher than measured with standard manometry, but the readings agree well with each other.⁶²

4.2.1.8.3: Ambulatory anorectal manometry

Using solid-state catheters, prolonged ano-rectal motor events have been recorded, including in ambulant subjects. The clinical applicability of these techniques has not been established.^{63–65}

4.2.2: Sensory measurements

4.2.2.1: Assessment of rectal sensation to distension

Rectal sensation to distension is most commonly assessed by manually inflating an intrarectal domestic balloon at a rate of approximately 5 ml/second.^{56,66} The following are elicited:

- Volume which elicits the first sensation of balloon expansion (threshold) [typical normal range 12–25 ml],
- Volume to get an urge to defecate (typical normal range 35–65 ml),
- Maximal tolerated volume (typical normal range 120–300 ml).

[normal ranges for the latter two sensations are highly variable due to lack of consensus on measurement technique especially of the nature and speed of inflation of the balloon]

The pressure required to elicit these sensations can also be measured using an electro-mechanical barostat and may be more reproducible. The barostat measures the volume and the pressure required to elicit these volumes sensations.^{67,68} Typically distension thresholds with a barostat are higher, with larger volumes being required to elicit the same sensation. However, again, the published ranges vary widely between units: typically distension volumes 1.5 to 3 times are published for thresholds with a barostat compared to manual balloon inflation.

Distension sensitivity testing is of proven value in:

(a) Patients with fecal incontinence to help with biofeedback training by normalization of the initial sensation sensory thresholds.

(b) Identifying visceral hypersensitivity, poor rectal compliance, or rectal irritability if maximal tolerated volumes are low.^{51,52}

There is no evidence to support use of the sensory thresholds for diagnosis and biofeedback training of patients with constipation. Compliance testing has also not proven valuable in identifying candidates for specific therapies.

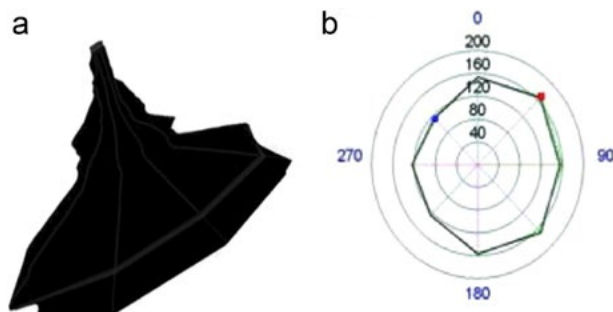


Fig. 3. Vector volume anal manometry trace. The left hand panel illustrates the shape of the contour curve at a fixed point, and the right hand figure shows the integrated whole across the length of the sphincter (from proximal to distal). It is evident that the greatest pressure is exerted in the distal canal.

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4.2.2.2: Mucosal electrosensitivity

This is test to measure anal and rectal sensory thresholds. Mucosal electrical stimulation is performed using a probe with two ring electrodes between which a small electrical potential is applied generating an alternating square wave with a variable frequency. Normal ranges have been established as anal electrosensation <10 mA, and rectal as <30 mA.⁶⁹ In general, prolonged anal electrosensation is suggestive of damage to the sensory fibers of pudendal nerve, and prolonged rectal electrosensation is suggestive of autonomic neuropathy.

4.2.3: Rectal dynamics**4.2.3.1: Rectal compliance**

Rectal compliance is the term that describes the relationship between pressure and volume, reflecting the ability of the rectum to act as a reservoir and is assessed using a barostat, inflating the bag within the rectum prior to the recording inflation protocol, known as conditioning, has been shown to improve the precision of compliance testing.⁵⁹ Typically, compliance figures between 4 and 11 mmHg/ml are quoted as the normal range.

4.2.3.2: Rectal impedance planimetry

These studies are the preserve of research institutions rather than clinical practice. The rationale is to calculate the diameter or cross sectional area of an intra rectal bag during a distension sequence. Impedance planimetry measures the cross sectional area which enables the circumferential wall tension to be calculated.⁷⁰

4.2.4: Attempted defecation and balloon expulsion

Patients with symptoms of prolapse and elderly patients with a history of constipation who present with passive incontinence should be thoroughly examined for the presence of a full thickness rectal prolapse. Patients are asked to strain as they would to pass stools whilst on a toilet or commode and given enough time to reproduce the prolapsing lump before examination.

Expulsion of a water-filled balloon can be used in the assessment of constipated patients. The ability to expel the balloon within 1 min may be a useful tool in demonstrating the absence of pelvic floor dyssynergia.

4.2.5: Neurophysiology**4.2.5.1: Single fiber EMG**

A single fiber needle EMG technique is used to measure the muscle fiber density in the external sphincter and puborectalis. A raised fiber density indicates re-innervation in the muscles, which may occur following partial denervation. Calculating EAS fiber density is another method of assessing denervation and re-innervation of the EAS. It is used almost exclusively as a research tool. Conventional EMG can be used to quantify the re-innervation of the EAS by detecting prolongation in the duration of the motor unit potential.

4.2.5.2: Concentric fiber EMG

Concentric needle EMG can be used to record activity in the external sphincter and puborectalis. The responses of these muscles to voluntary contraction, coughing, and straining can be displayed. The data are qualitative and compared to appearances in these muscles at rest. The muscles can also be studied at several sites to define areas of functioning muscle and identify sites of muscle injury (sphincter mapping) although this is has now been superseded by anal endosonography.

4.2.5.3: Surface EMG

Electrodes placed on the skin of the perineum or inside the vagina or rectum. Surface recordings from the sphincter show increased activity with body actions and decreased activity in sleep. Needle EMG however is regarded as superior.⁷¹ Some centers use surface EMG as an indicator of anal sphincter activity to provide feedback for patients undergoing behavioral biofeedback training for fecal incontinence or constipation.

4.2.5.4: Pudendal nerve terminal motor latencies (PNTMLs)

The PNTML is a measurement of the delay between the electrical stimulation of the pudendal nerve and the EMG activity of the EAS. The pudendal nerve is stimulated as it passes over the ischial spine using a specially designed electrode attached to the index finger of the assessor in the rectum.⁷¹ The surface EMG recording electrode which sits on the base of the assessor's index finger and measures external sphincter activity. The test does not reliably reflect the pudendal nerve damage. This may be because PNTMLs measure the speed of nerve conduction, which involves the fastest nerve fibers that are least susceptible to damage. The latencies are reported as normal if below 2.2 msec, but are also very operator dependent, with poor reproducibility and hence not recommended for general clinical use.⁷²

4.3: Clinical Role of Anorectal Physiological Measurements

As can be seen from the above, the reliability, reproducibility, and clinical validity of these tests are unproven, owing to the variety of methodologies of measurement undertaken. Standardization in each individual laboratory, with normal ranges from each laboratory, is therefore the required standard. Table II shows the utility of anorectal physiology tests within clinical or research settings.

TABLE II. Anorectal Physiology Tests for Female Anorectal Dysfunction

Anorectal physiological tests	Conditions	Clinical	Research/optional
Anorectal manometry	Anal sphincter function	R	R
Defecography	Extent of rectal intussusception/rectocele	O	R
Neurophysiological testing	Preoperative before sphincteroplasty or SNM; or in	O	R
PTNML ⁷³	Patients with possible pudendal neuralgia		
CN-EMG	When USS or MRI equivocal		

O, optional; R, recommended.

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SECTION 5: IMAGING

5.1: Ultrasonography (2D/3D/4D) of the Posterior Compartment Including Anal Sphincters, Pelvic Floor Muscles, and Prolapse (Endoanal, Transperineal, Transvaginal)

Ultrasound is increasingly being incorporated as an investigation of posterior compartment disorders^{7,74} (Table III). An integrated multi-compartmental pelvic floor ultrasonography with a combination of different modalities has been described to assess pelvic floor dysfunction for a global and multi-compartmental perspective.^{75,76}

Modalities in current routine clinical use:

(a) **Endoanal:** intra-anal 360° sector scanning using rotational mechanical probe or radial electronic probe.
 (b) **Transperineal:** curved array probe applied in the perineum between the mons pubis and the anal margin. This term incorporates trans-labial ultrasound. Introital ultrasound is usually assumed to imply the placement of transducer with smaller footprints (such as end-firing endo-vaginal probe) within the introitus.

(c) **Transvaginal:** intra-vaginal curvilinear, linear array, or 360° sector scanning.

5.1.1: Endoanal ultrasonography (EAUS)

The majority of current systems provide **2D & 3D Imaging** which give a 360° axial view of the anal canal and of the rectal wall.^{4,77,78} Endoanal ultrasound can be performed with the patient placed in the dorsal lithotomy, left lateral or prone position. Irrespective of the position, the probe should be rotated so that the anterior aspect of the anal canal is superior (12 o'clock) and left lateral is right (3 o'clock) on the screen. The anal canal is divided into three levels of assessment in the axial plane referring to the following anatomical structures:

- **Upper level:** the hyperechoic sling of the puborectals muscle (PR) and the complete ring of the internal anal sphincter (IAS) are visualized (Fig. 4a),
- **Middle level:** corresponds to the superficial part of the EAS (concentric band of mixed echogenicity), the conjoined longitudinal layer, the IAS (concentric hypoechoic ring), and the transverse superficial perinei muscles (Fig. 4b),
- **Lower level:** corresponds to the subcutaneous part of the EAS where the IAS is absent (Fig. 4c).

The acquisition of a three-dimensional data volume (**3D ultrasound**) and the underlying techniques vary. Acquisition may be “free-hand” (low resolution 3D) or “automatic computer-controlled” (high resolution 3D).^{79,80}

5.1.2: Transperineal Ultrasonography (TPUS)

Conventional convex transducers (frequencies between 3 and 6 MHz and field of view at least 70°) provide 2D imaging of the pelvic floor.^{81,82} Transperineal ultrasound is performed with the patient placed in the dorsal lithotomy position, with the hips flexed and abducted. If necessary, the patient can be examined standing, to maximise descent of pelvic organs, especially if the patient finds it difficult to produce an effective Valsalva maneuver. No rectal or vaginal contrast is used. Perineal ultrasound provides sagittal, coronal and oblique sectional imaging, with the mid-sagittal plane being the most commonly used as this gives an overall assessment of all anatomical structures (bladder, urethra, vaginal walls, anal canal, and rectum) between the posterior surface of the symphysis pubis (SP) and the posterior part of the levator ani (LA) (Fig. 5a and b). The imaging is usually performed at rest, on maximal Valsalva maneuver and on pelvic floor muscle contraction (PFMC). The access to the mid-sagittal plane allows the following evaluations⁸³:

- Integrity of the perineal body: appearing as a triangular shaped, slightly hyperechoic structure anterior to the anal sphincter,
- Measurement of the anorectal angle (ARA): formed by the longitudinal axis of the anal canal and the posterior rectal wall,
- Dynamic assessment of the posterior compartment. During Valsalva it is possible to visualize descent of an enterocele, to assess the movement of the anterior rectal wall to detect a rectocele, and to evaluate movement of the PR and ARA to diagnose pelvic floor dyssynergy (Fig. 5c).

3D TPUS may be performed with volumetric probes (electronic curved array of 4–8 MHz). An advantage of this technique is the opportunity to obtain tomographic or multi-slice imaging, for example, in the axial plane, in order to assess the entire PR and its attachment to the pubic rami⁸⁴ (Fig. 6). It is also possible to measure the diameter and area of the levator hiatus (LH) and determine the degree of hiatal distension on Valsalva. Four dimensional (4D) imaging indicates real-time acquisition of volume ultrasound data.

TABLE III. Imaging Modalities for Female Anorectal Dysfunction

Conditions	Imaging techniques	Levels of evidence	Grade of recommendation
Fecal incontinence	Endoanal US	Level II	Grade B
	Static MRI	Level II	Grade B
	Defecating proctography	Level III	Grade C
Pelvic organ prolapse	Dynamic MRI	Level II	Grade B
	Transperineal US	Level II	Grade B
	Defecating proctography	Level II	Grade B
Obstructed defecation	Dynamic MRI	Level II	Grade B
	Defecating proctography	Level II	Grade B
	Transperineal US	Level III	Grade C
Perianal sepsis	Static MRI	Level II	Grade B
	Endoanal US	Level II	Grade B
Chronic pelvic pain	Fistulography	Level III	Grade C
	Static MRI	Level III	Grade C

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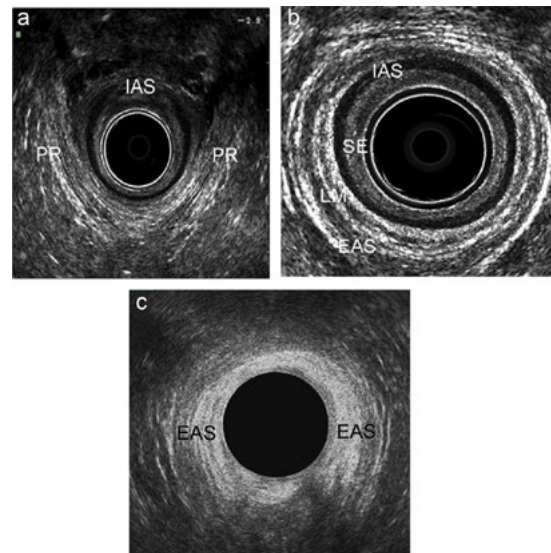


Fig. 4. Endoanal ultrasonography. (a) Upper level of the anal canal; (b) Middle level of the anal canal; (c) Lower level of the anal canal. PR, puborectalis; IAS, internal anal sphincter; EAS, external anal sphincter; LM, longitudinal muscle; SE, sub epithelium.

5.1.3: Transvaginal Ultrasonography (TVUS)

Transvaginal ultrasound is performed with the patient placed in the dorsal lithotomy position. Currently, the transducers used for pelvic floor 3D TVUS are high multi-frequency (9–16 MHz), 360° rotational mechanical probe or radial electronic probe (Fig. 7a). The pelvic floor is divided into four levels of assessment in the axial plane referring to the following anatomical structures⁸⁵: (not to be confused with Delancey's description of vaginal Levels of supports).

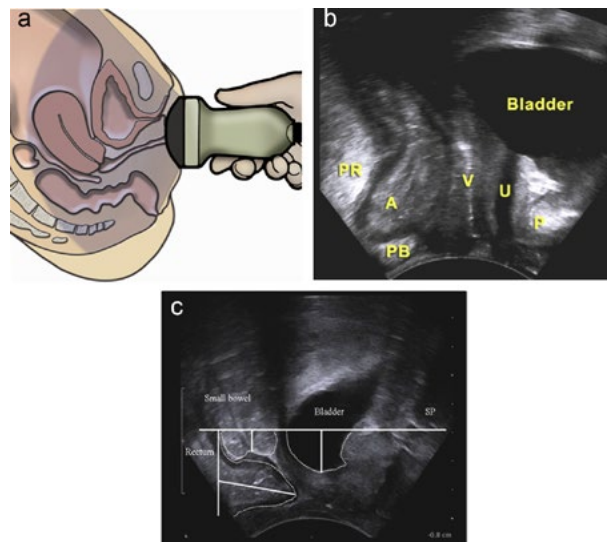


Fig. 5. 2D-Transperineal ultrasound. (a) Schematic drawing; (b) Pelvic organs at rest; (c) Pelvic organs descend below the symphysis pubis line after Valsalva maneuver (cystocele, enterocele, rectocele). PR, puborectalis muscle; A, anal canal; PB, perineal body; V, vagina; U, urethra; P/SP, symphysis pubis.

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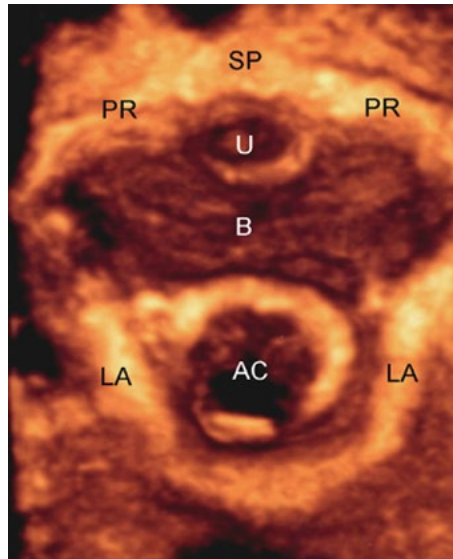


Fig. 6. 3D-Transperineal ultrasound. Axial image of the pelvic floor at rest showing the LA attachment to the pubic rami (PR). AC, anal canal; LA, levator ani; B, bladder; U, urethra; SP, symphysis pubis.

- **Level I:** at the highest level the bladder base is visualized on the screen at 12 o'clock position and the inferior third of the rectum at 6 o'clock position,
 - **Level II:** corresponds to the bladder neck, the intramural region of the urethra and to the anorectal junction. At this level the subdivisions of the LA (pubovaginalis, puboperinealis, puboanalis, puborectalis, and iliococcygeus) may be identified,
 - **Level III:** corresponds to the midurethra and to the upper third of the anal canal. At this level the LA is visualized as a multilayer hyperechoic sling coursing lateral to the vagina and posteriorly to the anal canal and attaching to the inferior pubic ramus (Fig. 7b). In the axial plane of minimal hiatal dimensions, identified as the minimal distance between the inferior edge of the SP and the anterior border of the LA at the ARA, the biometric indices (anteroposterior and transverse diameters, area) of the LH can be determined (Fig. 7c),⁸⁶
 - **Level IV:** at the outer level, the perineal muscles (bulbospongiosus, ischioavernosus, and superficial transverse perineii muscles), the perineal body, the distal urethra and the middle and inferior third of the anal canal are visualized. The anterior-posterior diameter of the urogenital hiatus (UGH), corresponding to the SP-perineal body distance, can be determined.⁸⁷
- Transvaginal ultrasound may be also performed with electronic probes with linear array, which provide mid-sagittal image of the posterior compartment.⁷⁶ The main advantage of this technique is the dynamic assessment of the anorectal region, during Valsalva and pelvic floor muscle contraction (PFMC).

5.1.4: Clinical applications of ultrasonography of the posterior compartment

5.1.4.1: Fecal incontinence

Anal inspection and digital rectal examination can give information about internal and external anal sphincter function but are inaccurate for determining external anal sphincter defects <90 degrees and internal sphincter defects. Therefore, a sufficient diagnostic work-up should comprise at least rectal examination, anal inspection and endoanal ultrasonography.⁸⁸ EAUS has become the gold standard for morphological assessment of the anal canal.⁷⁵ The International Consultation on Incontinence (ICI)⁸⁹ has recommended EAUS as the first line imaging investigation for fecal incontinence to differentiate between those with intact anal sphincters and those with sphincter lesions (defects, scarring, thinning, thickening, and atrophy). Routine use of transperineal, transvaginal and translabial ultrasonography to image the anal sphincter complex are not recommended,⁸⁹ although research is ongoing. The operator should identify if there is a combined or isolated lesion of the IAS and EAS and report the number of defects, as well as the extent of the defect circumferentially (radial angle in degrees or in hours of the clock) and longitudinally (proximal, distal or full length).⁸⁹⁻⁹¹ Using 3D EAUS, two scoring systems have been proposed to define the severity of anal sphincter damage.^{92,93}

EAUS has an important role in detecting undiagnosed anal sphincter injuries following vaginal delivery² and can be useful in the management of subsequent pregnancies following OASIS (119). It is also useful to evaluate the results of treatment (anterior sphincter repair, bulking agent injections).^{75,89}

5.1.4.2: Levator ani injuries

Levator avulsion is the disconnection of the muscle from its insertion on the inferior pubic ramus and the pelvic sidewall, whereas tears may occur in any part of the muscle. Avulsion is a common consequence of overstretching of the levator ani during the second stage of labor and it is detectable by 3D TVUS and 3D TPUS imaging as the lateral attachments of the levator ani to the

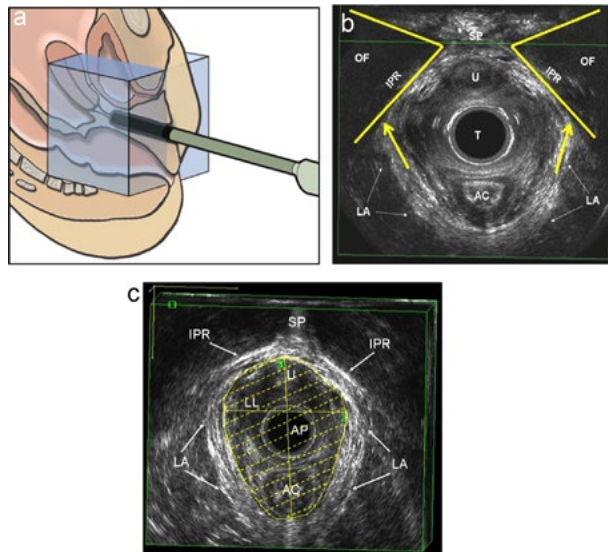


Fig. 7. 3D-Endovaginal ultrasound. (a) Schematic drawing; (b) Axial image of the pelvic floor at Level III, showing the LA attachment to the inferior pubic rami (IPR); and (c) the levator hiatus. AC, anal canal; LA, levator ani; B, bladder; U, urethra; SP, symphysis pubis; OF, obturator foramen; T, transducer; AP, anteroposterior diameter of the levator hiatus; LL, laterolateral diameter of the levator hiatus.

pubic bone are clearly visualized.⁹⁴ Defects are usually visualized most clearly on maximal PFMC. Tomographic ultrasound imaging is particularly useful. Levator ani injuries affect the size of the levator hiatus, with a hiatal enlargement to over 25 cm² on Valsalva maneuver defined as “ballooning,” and are related to symptoms and signs of prolapse.

5.1.4.3: Obstructed defecation syndrome (ODS)

The term obstructed defecation syndrome (synonym: “outlet obstruction”) encompasses all pelvic floor dysfunctions, which are responsible for an incomplete evacuation of fecal contents from the rectum, straining at stool and vaginal digitations. During maximal Valsalva maneuver, dynamic TPUS and TVUS may be used to demonstrate.^{82,95}

- **Rectocele:** herniation of a depth of over 10 mm of the anterior rectal wall,
- **Rectal intussusception:** invagination of the rectal wall into the rectal lumen, into the anal canal or exteriorized beyond the anal canal (rectal prolapse),
- **Enterocoele:** herniation of bowel loops into the vagina. It can be graded as small, when the most distal part descends into the upper third of the vagina, moderate, when it descends into the middle third of the vagina, or large, when it descends into the lower third of the vagina,
- **Dyssynergic defecation:** the ARA becomes narrower, the LH is shortened in the anteroposterior dimension, and the PR muscle thickens as a result of contraction.

5.1.4.4: Perianal abscesses and fistulas

5.2: MRI for Anal Sphincters and Pelvic Floor (Static, Dynamic, Endocoil) Upright, Supine, Left Lateral Position

5.2.1: Static MRI

Static MRI provides detailed information of the pelvic floor anatomy.⁹⁶ Current state-of-the-art MR imaging of the pelvic floor includes imaging at a magnetic field strength of 1.5 Tesla (T), using pelvic or phased-array coils and T2-weighted fast-spin echo (FSE) sequences. The spatial resolution can be enhanced by using endoluminal (endorectal, endovaginal) coils. In combination with T2-weighted FSE sequences, endoluminal coils provide improved signal-to-noise ratio (SNR) and high resolution images.⁹⁷ Based on T2-weighted turbo spin-echo sequences, muscles are relative hypointense, ligaments and fascia hypointense while fat and smooth muscle are hyperintense. The prominent pelvic floor structures of the posterior compartment visualized at MRI are (Fig. 8):

- Perineal body and superficial perineal muscles,
- Anal sphincters: the IAS is easily recognized as a circular hyperintense structure. It is approximately 2.9 mm thick on endoluminal MRI. The inter-sphincteric space is seen as a bright line on T2-weighted MRI. The EAS has a thickness of 4.1 mm on endoluminal imaging,
- Puborectalis muscle and levator ani,
- Superficial perineal muscles,
- Rectum and rectal support.

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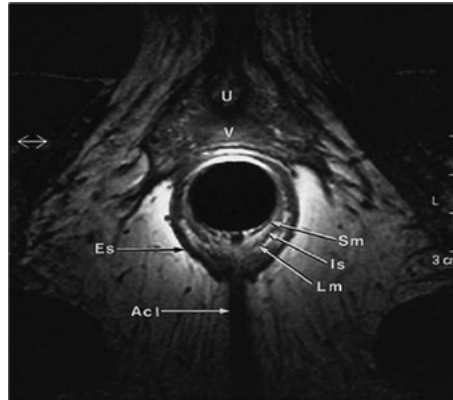


Fig. 8. Static MRI. Axial image of the anal canal. U: urethra; V: vagina; SM: submucosa; IS: internal sphincter; LM: longitudinal muscle; ES: external sphincter; ACL: anococcygeal ligament.

5.2.2: Dynamic MRI

With the development of fast multi-slice sequences MR imaging has gained increasing acceptance for dynamic imaging of pelvic floor. Because the posterior compartment is traditionally in the focus of interest, dynamic MR imaging of the pelvic floor is often called "MR defecography."⁹⁸

Dynamic pelvic imaging may be performed in an open-configuration MR system in the sitting position, or in a closed-configuration MR-system in the supine position. Both techniques are equally effective in identifying most of the clinically relevant abnormalities of the pelvic floor.⁹⁸ For evaluation of the posterior compartment of the pelvic floor, the rectum should be filled with a contrast agent (ultrasound gel or mashed potatoes, gadolinium-based MR contrast agent) to study the actual act of defecation.

The use of reference lines for image evaluation is helpful.^{99,100} The most used reference line is the pubococcygeal line (PCL), which is defined on mid-sagittal images as the line joining the inferior border of the symphysis pubis to the last or second last coccygeal joint (Fig. 9a). The anorectal junction (ARJ) is defined as the cross point between a line along the posterior wall of the distal part of the rectum and a line along the central axis of the anal canal. To determine pathologic pelvic floor descent, the measurements are made on the images, which show maximal organ descent, usually during maximal straining or during evacuation (Fig. 9b). The anorectal angle (ARA) is defined as the angle between the posterior wall of the distal part of the rectum and the central axis of the anal canal and can be measured at rest, squeezing and straining. The extent of rectoceles and enteroceles are measured.

The degree of pelvic floor relaxation is measured with two reference lines (Fig. 9a): the H line which represents hiatal widening and extends from the inferior aspect of the symphysis pubis to the posterior wall of the rectum at the level of the ARJ and the M line which represents hiatal descent and extends perpendicularly from the PCL to the posterior end of the H line. Lesions of the pelvic musculofascial support result in widening of the hiatus and descent of the levator plate. Thus, the H and M lines tend to elongate

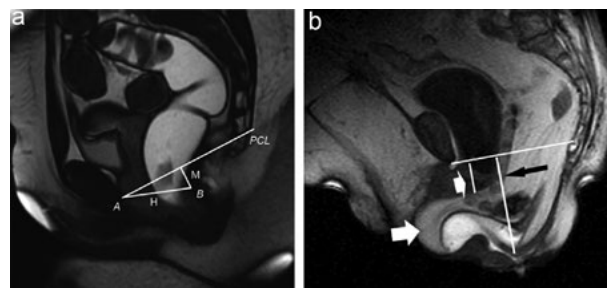


Fig. 9. Dynamic MRI. (a) Mid-sagittal steady state free precession T2-weighted image obtained at straining shows landmarks used in the HMO-system. The landmarks are the inferior aspect of the symphysis pubis (A) and the posterior wall of the rectum at the level of the anorectal junction (B). The H line (H) represents the anteroposterior hiatal width and extends from A to B. The M line (M) represents hiatal descent and extends perpendicularly from the pubococcygeal line (PCL) to the posterior end of the H line. (b) During Valsalva maneuver, there is a bladder descent below the PCL (small white arrow), with a perineal descent (black arrow) and a rectocele developing with a posterior vaginal wall prolapse (long white arrow).

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with pelvic floor relaxation, widening the levator plate descent. Abnormal pelvic floor relaxation is present, when the H line exceeds 6 cm, and when the M line exceeds 2 cm in length.

5.2.3: Clinical applications of MRI of the posterior compartment

5.2.3.1: Fecal incontinence

Endoanal ultrasound and endoanal magnetic resonance imaging (MRI) have been demonstrated to be comparable in the detection of external sphincter defects.¹⁰¹ External phased array coil MRI can replace endoluminal MRI with comparable results.¹⁰²

5.2.3.2: Levator ani injuries

Abnormalities of the LA are identified on MRI as present or absent.¹⁰³ Defect severity is further scored in each muscle from 0 (no defect) to 3 (complete loss). A summed score for the two sides (0–6) is assigned and grouped as minor (0–3) or major (4–6).

5.2.3.3: Obstructed defecation

During maximal Valsalva maneuver, dynamic MRI may be used to demonstrate:

- **Rectocele:** measured as the depth of wall protrusion beyond the expected margin of the normal anorectal wall. Based on sagittal MR-sections through mid of pelvis, rectoceles are graded as small (<2 cm), moderate (from 2 to 4 cm), and large (>4 cm),
- **Rectal intussusception:** the infolding of the rectal mucosa occurring during defecation. Depending on the location, an intrarectal intussusception, limited to the rectum, is distinguished from an intra-anal intussusception extending into the anal canal. The location of the intussusception may be anteriorly, posteriorly, or circumferentially. The intussusception either involves only the mucosa or the full thickness of the rectal wall,
- **Enterocoele:** defined as a herniation of the peritoneal sac, which contains omental fat (peritoneocoele), small bowel (enterocoele) or sigmoid (sigmoidocoele), into the rectovaginal or rectovesical space below the PCL. The largest distance between the PCL and the most inferior point of the enterocoele is measured with a perpendicular line. Depending on this distance, small (<3 cm), moderate (3–6 cm), and large (>6 cm) enterocoeles are distinguished,
- **Dyssynergic defecation:** different structural imaging findings can be seen on dynamic pelvic MRI, including prominent impression of the puborectal sling, narrow anal canal, prolonged evacuation, a lack of descent of the pelvic floor and thus a failure to increase the ARA.

In comparison with clinical examination (POP-Q), dynamic MRI has no additional value in the prediction of symptoms with increasing degree of POP.¹⁰⁴

5.2.3.4: Perianal abscesses and fistulas

5.3: Defecating Proctography

Evaluates in real time the morphology of rectum and anal canal in correlation with pelvic bony components both statically and dynamically by injection of a thick barium paste into the rectum and its subsequent evacuation.¹⁰⁵ Contrast administration into the bladder and vagina provides a more comprehensive assessment of the pelvic organs and has been labelled "**dynamic cystoproctography**".¹⁰⁴

At rest, the anal canal is closed and rectum assumes its normal upright configuration. The position of the pelvic floor is inferred by reference to the PCL (inferior margin of pubic symphysis to the sacro-coccygeal junction) (Fig. 10a). Perineal descent is measured from to this line to the ARJ, and may be up to 1.8 cm at rest. Some pelvic floor descent during evacuation is considered normal, and a descent of up to 3 cm from the rest position to anal canal opening is acceptable. The ARA is defined as the angle between the anal canal axis and the posterior rectal wall, and on average is around 90° (Fig. 10b). The puborectalis length (PRL) can be estimated by measuring the distance between the ARA and symphysis pubis.

A normal emptying phase at the proctogram is described by five elements:

- Increase in the ARA by around 20–30 degrees,
- Obliteration of the puborectalis impression and the PRL should increase by around 3–4 cm,
- Wide opening of the anal canal within a couple of seconds,
- Evacuation of rectal contents proceeding promptly and to completion,
- Lack of significant pelvic floor descent.

After evacuation is complete, the anal canal should close, the ARA recover and the pelvic floor return to its normal baseline position. Post toilet imaging may be required, particularly in those suspected of retained barium within rectoceles (Fig. 10c).

5.3.1: Clinical applications of defecating proctography

Assuming that posterior wall prolapse and rectocele can be considered the same anatomic entity, clinical examination is not accurate in diagnosing anatomical defects of posterior vaginal wall and enterocoeles compared to defecography as reference standard. Clinical examination overestimates the presence of the posterior wall defects (large false positive rates) but misses enterocoele in patients with primary POP (large false negative rates).^{106,107} The major function of proctography is not merely to document evacuatory abnormalities, but also to classify those abnormalities into those potentially surgically relevant, those likely to benefit from behavioral biofeedback therapy alone, or indeed those which are incidental.¹⁰⁸

5.3.1.1: Pelvic floor descent

Pelvic floor descent, defined as the distance moved by the ARJ or ARA at rest to the point of anal canal opening, is considered abnormal if it exceeds 3 cm.¹⁰⁵

5.3.1.2: Intussusception and prolapse

Intussusception refers to infolding of the rectal wall into the rectal lumen. It may be described as intra-rectal, intra-anal or external to form a complete rectal prolapse.

5.3.1.3: Rectocele

Rectocele diagnosis on evacuation proctography is defined as any anterior rectal bulge (Fig. 10c). The depth of a rectocele is measured from the anterior border of the anal canal to the anterior border of the rectocele. A distance of <2 cm is classified as small, 2–4 cm as moderate and >4 cm as large. Of more relevance however is barium trapping at the end of evacuation (defined as retention of >10% of the area, and this itself is related the size of the rectocele).

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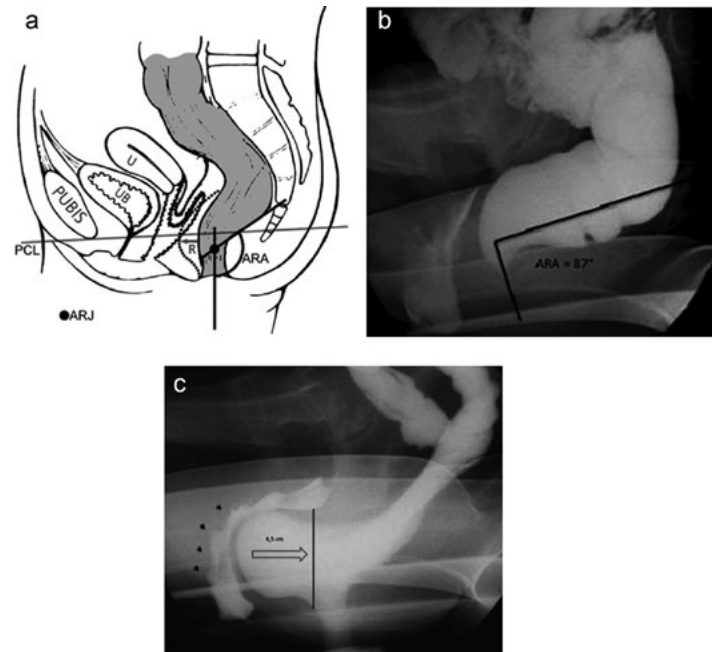


Fig. 10. Defecating proctography. (a) Schematic drawing; (b) Measurement of the anorectal angle at rest (ARA); (c) Image during Valsalva maneuver, showing the displacement of the anterior rectal wall (rectocele) with posterior vaginal wall prolapse (black arrows). PCL, pubococcygeal line; UB, urinary bladder; U, uterus; ARJ, anorectal junction; R, rectocele.

5.3.1.4: Enterocoele

An enterocoele is diagnosed when small bowel loops enter the peritoneal space between the rectum and vagina. Diagnosis of an enterocoele on proctography is only really possible if oral contrast has been administered before the examination.¹⁰⁵ Herniation of the sigmoid into the rectogenital space (sigmoidocoele) is significantly less common than an enterocoele.

5.3.1.5: Dyssynergic defecation

Various proctographic abnormalities have been described including prominent puborectal impression, a narrow anal canal, and acute anorectal angulation. However these observations may be found in normal controls and are in themselves unreliable distinguishing features.

5.4: Contrast Enema

Contrast enema is used to identify colon pathology (benign and malignant lesions, diverticular disease, inflammatory conditions, congenital anomalies, intrinsic and extrinsic abnormalities).

5.4.1: Single-contrast barium enema

Using an appropriate catheter, a barium-water mixture or a water-soluble solution of diatrizoate sodium (Gastrografin) is inserted into the colon with the patient in the prone position until the column of barium reaches the splenic flexure.

5.4.2: Double-contrast or air-contrast barium enema

This procedure has become the routine study for evaluation of the bowel.¹⁰⁸ With the double-contrast examination, the colon is coated with a thin layer of contrast material and the bowel is distended with air so that the entire mucosal circumference is visualized.

5.5: Colonic Transit Studies (Radio-Opaque Oral Markers, Pill Transit, Nuclear Medicine Scintigraphy)

Slow transit constipation can be distinguished by colonic transit studies.^{109,110}

5.5.1: Radiological transit (shapes) study

Segmental and total colonic transit time is assessed with the use of radio-opaque markers and sequential abdominal X-rays. There are different protocols. Most frequently used, utilizes a capsule containing 24 markers of 1×4.5 mm. Patient takes one capsule on day 0 by mouth and X-ray is performed on day 5 (Fig. 11). Patients who expel at least 80% markers on day 5 have normal colonic transit. Patients who retain 6 or more markers may have follow-up abdominal X-rays within several days. If remaining markers are scattered about the colon, the condition is slow transit or colonic inertia. If the remaining markers are accumulated in the rectum or rectosigmoid, this suggests functional outlet obstruction.

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Fig. 11. Radiologic transit study. On day 5, the remaining markers are more than 80%, suggesting functional outlet obstruction.

5.5.2: Nuclear transit study

Colon scintigraphy is performed at 6, 24, and 48 hr in ventral and dorsal projection after oral administration of methacrylate-coated capsule of non-resorbable ^{111}In -labeled polystyrene (^{111}In -DTPA) micropellets.¹⁰⁹ The geometric center, as the sum of products of colon segment activity and colon segment number (1 = ascending colon, 2 = transverse colon, 3 = descending colon, 4 = rectosigmoid, and 5 = evacuated feces) dividing by the total counts is used to determine the velocity of colonic transit. Meals normally reach the cecum at 6 hr and are evacuated in 30 to 58 hr. Retention of radioactivity in the proximal colon at 48 hr, indicates slow colonic transit while retention in the rectum indicates anorectal dysfunction. Table III shows utility of various imaging modalities for female anorectal dysfunction.

6: DIAGNOSIS

6: **DIAGNOSIS** (most common) [defined as prevalence >10%]

Diagnosis is based on symptoms, signs, examination, and any relevant diagnostic investigations

6.1: Local (Fissures, Hemorrhoids)

Fissure: Is a break in the lining of the anal canal

Hemorrhoids: Abnormality of the normal cushion of specialized, highly vascular tissue in the anal canal in the submucosal space.

6.2: Fecal Incontinence

Fecal incontinence: involuntary loss of solid or liquid stool and could be due to:

6.2.1: Anal sphincter disruption is due to discontinuity of the external anal sphincter, internal anal sphincter or both.

6.2.2: Hypocontractile/acontractile sphincter is due to neuropathy or atrophy.

6.2.3: Combined anal sphincter disruption and hypocontractile/acontractile sphincter.

6.2.4: Rectal overactivity due to exaggerated smooth muscle contraction of the rectum could also be associated with hypersensitivity.^{110,111}

6.2.5: Overflow incontinence seepage of stool due to fecal impaction.

6.3 Obstructed Defecation Syndrome

Obstructed defecation: incomplete evacuation of fecal contents from rectum due to physical blockage of the fecal stream during defecation attempts. It includes symptoms such as straining to defecate, sensation of blockage, digitation, and splinting. Constipation due to slow transit, irritable bowel syndrome, Hirschsprung's disease, megarectum, anismus are not within the remit of this standardization document. Associated features of obstructed defecation are:

6.3.1: Rectocele: Bulge in posterior vaginal wall associated with herniation of anterior wall of the rectum (See ^{FN16}).

6.3.2: Enterocele/sigmoidocele: Bulge of upper wall of vagina associated with herniation of peritoneal sac and small bowel (enterocele) or sigmoid colon (sigmoidocele).

6.3.3: Intussusception: Full thickness invagination of the upper rectum without extrusion through the anus leading to interruption of flow of the fecal stream.

^{FN16} A transverse defect rectocele occurs simply by a detachment of the perineal body from the rectovaginal fascia. The hammock of rectovaginal fascia supporting the rectum remains intact but separates from the perineal body. A midline vertical defect is created by a midline separation of the rectovaginal fascia, and a separation of the rectovaginal fascia can occur from its lateral attachments. Rectoceles are more commonly situated in the mid to distal aspect of the posterior vaginal wall.

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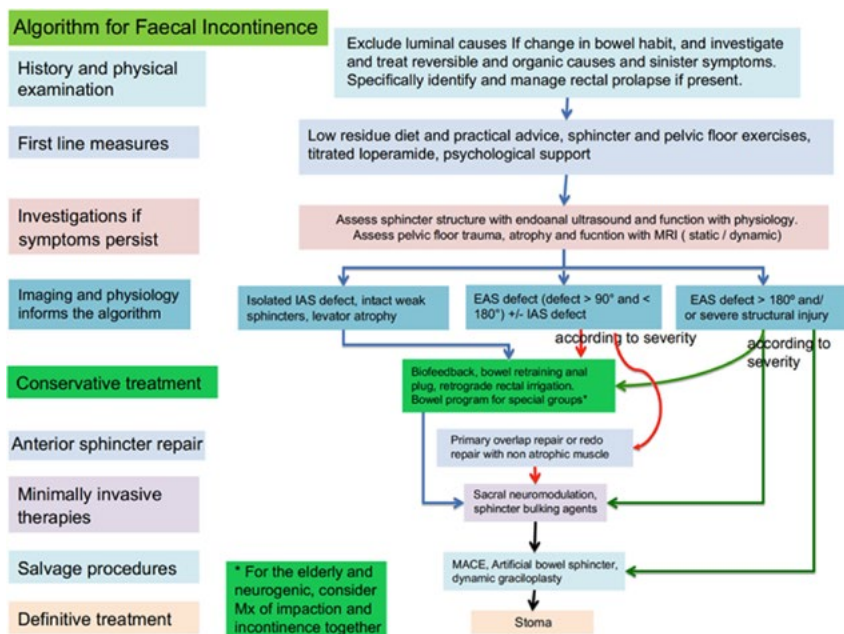


Fig. 12. (adapted from ref. [125]). Algorithm: fecal incontinence. IAS, internal anal sphincter; EAS, external anal sphincter; SNM, sacral neuromodulation; MACE, malone antegrade continence enema.

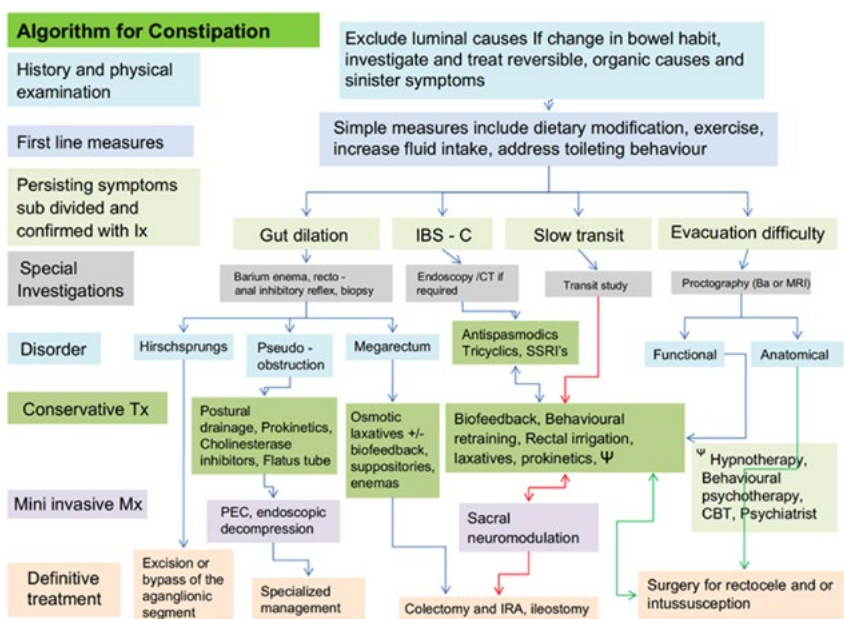


Fig. 13. (adapted from ref. [125]). Algorithm: constipation. IBS-C, irritable bowel constipation predominant; IRA, ileorectal anastomosis; J, hypnotherapy; behavioural psychotherapy; CBT, psychiatrist management; CBT, cognitive behavioural therapy; Ix, investigations; Mx, management; Tx, treatment.

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6.3.4: Internal mucosal prolapse: Mucosal prolapse of the anterior, posterior, or circumferential mucosal layer.

6.3.5: External rectal prolapse: Full thickness rectal prolapse outside the anal canal

6.4: Sepsis

6.4.1: Abscess

Infection in a (non Crohn's) anal gland, located at the base of the dentate line, that initially forms an abscess, which can be located in one of the potential spaces surrounding the anus and rectum.

6.4.2: Ano-rectal/vaginal/perineal fistula

Rectovaginal fistula is a communication from the rectum to the vagina and rarely the perineal area. An anovaginal/perineal fistula is an abnormal communication from the anal canal to the vagina or perineal area.

6.5: Pain Syndromes

6.5.1: Levator ani syndrome

Episodic rectal pain caused by spasm of the levator ani muscle. Proctalgia fugax (fleeting pain in the rectum) and coccydynia (pain in the coccygeal region) are variants of levator ani syndrome (See ^{FN17}).

6.5.2: Proctalgia fugax

Definition: Proctalgia fugax (or Levator syndrome) is a severe, episodic, rectal and sacrococcygeal pain.¹¹² It can be caused by cramp of the pubococcygeus or levator ani muscles (See ^{FN18}).

6.5.3: Pudendal neuralgia

Pudendal Neuralgia (PN) is a painful condition that is caused by inflammation of the pudendal nerve involving its dermatome.¹¹⁵ It can affect both men and women (See ^{FN19}).

^{FN17} Symptoms of levator ani syndrome are painful rectal spasm, typically unrelated to defecation, usually lasting >20 min. The pain may be brief and intense or a vague ache high in the rectum. It may occur spontaneously or with sitting and can waken the patient from sleep and occurs more often on the left. The pain may feel as if it would be relieved by the passage of gas or a bowel movement. In severe cases, the pain can persist for many hours and recur frequently. During clinical evaluation: a dull ache to the left 5 cm above the anus or higher in the rectum and a feeling of constant rectal pressure or burning. Physical examination can exclude other painful rectal conditions (e.g., thrombosed hemorrhoids, fissures, abscesses, scarring from previous surgery). Physical examination is often normal, although tenderness or tightness of the levator muscle, usually on the left, may be present. Occasionally the cause can be low back disorders. Coccydynia (coccygodynia) is complaint of pain and point tenderness of the coccyx (this is NOT anorectal pain).

^{FN18} Proctalgia fugax most often occurs in the middle of the night and lasts for seconds to 20 min. During an episode, which sometimes occurs after orgasm, the patient feels spasm-like, sometimes excruciating pain in the anus, often misinterpreted as a need to defecate. Because of the high incidence of internal anal sphincter thickening with the disorder, it is thought to be a disorder of the internal sphincter or that it is a neuralgia of pudendal nerves. It tends to occur infrequently (once a month or less). Like all ordinary muscle cramps, it is a severe, deep rooted pain. Defecation can worsen the spasm, but may relieve it,¹¹³ or provide a measure of comfort. The pain might subside by itself as the spasm disappears on its own, or may persist or recur during the same night. Patients with proctalgia fugax are usually asymptomatic during the anorectal examination, leaving no signs or findings to support the condition, which is based on symptoms by history taking, diagnostic criteria, described above, and the exclusion of underlying organic disease (anorectal or endopelvic) with proctalgia.¹¹⁴

^{FN19} The condition is also known as pudendal neuropathy, pudendal nerve entrapment, cyclist's syndrome, pudendal canal syndrome, or Alcock's syndrome. The Nantes criteria¹³ includes:

1. Pain in the anatomical region of pudendal nerve innervation.
2. Pain that is worse with sitting.
3. No waking at night with pain.
4. No sensory deficit on examination.
5. Relief of symptoms with a pudendal block.

Primary symptoms of PN include:

- a) Pelvic pain with sitting that may be less intense in the morning and increase throughout the day. Symptoms may decrease when standing or lying down. The pain can be perineal, rectal or in the clitoral/penile area; it can be unilateral or bilateral.
- b) Sexual dysfunction. In women, dysfunction manifests as pain or decreased sensation in the genitals, perineum or rectum. Pain may occur with or without touch. It may be difficult or impossible for the woman to achieve orgasm.
- c) Difficulty with urination/defecation. Patients may experience urinary hesitancy, urgency and/or frequency. Post-void discomfort is not uncommon. Patients may feel that they have to "strain" to have a bowel movement and the movement may be painful and/or result in pelvic pain after. Constipation is also common among patients with PN. In severe cases, complete or partial urinary and/or fecal incontinence may result.
- d) Sensation of a foreign object being within the body. Some patients will feel as though there is a foreign object sitting inside the vagina or the rectum.

It is important to note PN is largely a "rule out" condition. In other words, because its symptoms can be indicative of another problem, extensive testing by physical examination, assessment by touch, pinprick, bimanual pelvic palpation with attention to the pelvic floor muscles, in particular the levator and obturator muscles, tenderness of the bladder and sacrospinous ligaments are required to ensure that symptoms are not related to another condition. Maximum tenderness, or a trigger point can be produced by applying pressure to the ischial spine. Palpation of this area can reproduce pain and symptoms as a positive Tinel's sign.¹¹⁵

As PN is a diagnosis of exclusion, other conditions that should be excluded include coccygodynia, piriformis syndrome, interstitial cystitis, vulvodynia, vestibulitis, chronic pelvic pain syndrome, proctalgia, anorectal neuralgia, pelvic contracture syndrome/pelvic congestion, proctalgia fugax, or levator ani syndrome.

In addition to eliminating other diagnoses, it is important to determine if the PN is caused by a true entrapment or other compression/tension dysfunctions. In almost all cases, pelvic floor dysfunction accompanies PN. Electrodiagnostic studies will help the practitioner determine if the symptoms are caused by a true nerve entrapment or by muscular problems and neural irritation.

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First degree: laceration of the vaginal epithelium or perineal skin only.

Second degree: involvement of the perineal muscles but not the anal sphincter.

Third degree: disruption of the anal sphincter muscles that should be further subdivided into:

3a: <50% thickness of external sphincter torn.

3b: >50% thickness of external sphincter torn.

3c: internal sphincter also torn.

Fourth degree: a third degree tear with disruption of the anal epithelium as well.

Button hole tear of rectum: isolated tear of rectum without involvement of the anal sphincter

Fig. 14. Classification of perineal trauma.¹¹⁹

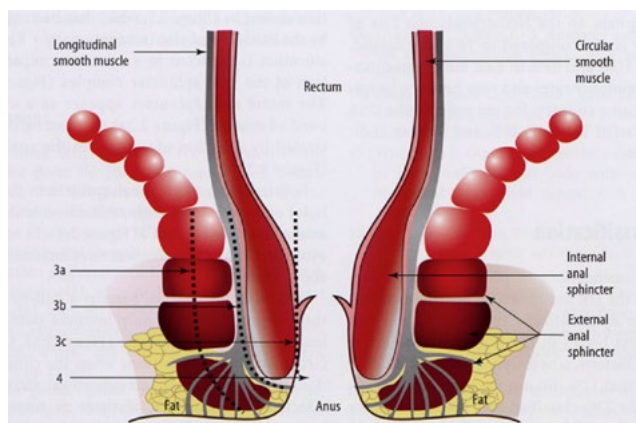


Fig. 15. Classification of 3rd and 4th degree tears (with permission from Springer¹¹⁶).

6.6: Obstetric Anal Sphincter Injuries (OASIS)

OASIS are reported to occur in 0.5–14% of vaginal deliveries (2.9–19% of primiparous vaginal deliveries).¹¹⁶ It has previously been shown in a prospective study that about one third of OASIS can be diagnosed 8 weeks after delivery by endoanal ultrasound alone. As these were not identified clinically, the injuries were believed to be “occult.”² However, it has subsequently been proven that such injuries are not necessarily occult but in fact undiagnosed due to lack of expertise of midwives and doctors.³

Training in diagnosis and management of perineal trauma has been shown to be suboptimal¹¹⁷ and dedicated hands-on courses have shown significant improvements in diagnosis and classification of OASIS.¹¹⁸ Sultan therefore proposed a more descriptive classification of OASIS (Figs. 12 and 13)¹¹⁹ that has now been accepted internationally to support consistency in reporting.^{120–122} To avoid underestimation of the injury, if there is uncertainty regarding the full extent of the injury it should be classified as the greater degree, for example, if one is unsure as to whether an injury is a Grade 3a or 3b it should be classified as 3b (Figs. 14 and 15). This classification also has clinical relevance as it ensures increased vigilance for internal sphincter injuries that are best repaired soon after delivery¹²³ as persistent internal sphincter defects are associated with fecal incontinence.¹²⁴ Examination techniques to improve detection of these injuries and avoiding pitfalls in diagnosis have been described in detail.¹¹⁶

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International Continence Society Good Urodynamic Practices and Terms 2016: Urodynamics, uroflowmetry, cystometry, and pressure-flow study

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AIMS: The working group initiated by the ICS Standardisation Steering Committee has updated the International Continence Society Standard “Good Urodynamic Practice” published in 2002.

METHODS: On the basis of the manuscript: “ICS standard to develop evidence-based standards,” a new ICS Standard was developed in the period from December 2013 to December 2015. In July, a draft was posted on the ICS website for membership comments and discussed at the ICS 2015 annual meeting. The input of ICS membership was included in the final draft before ICS approval and subsequent peer review (for this journal).

RESULTS: This evidence-based ICS-GUP2016 has newly or more precisely defined more than 30 terms and provides standards for the practice, quality control, interpretation, and reporting of urodynamics; cystometry and pressure-flow analysis. Furthermore, the working group has included recommendations for pre-testing information and for patient information and preparation. On the basis of earlier ICS standardisations and updating according to available evidence, the practice of uroflowmetry, cystometry, and pressure-flow studies are further detailed.

CONCLUSION: ICS-GUP2016 updates and adds on to ICS-GUP2002 to improve urodynamic testing and reporting both for individual care and scientific purposes.

KEYWORDS

clinical practice standard and quality, cystometry, incontinence, lower urinary tract dysfunction, pressure-flow study, urodynamic, uroflowmetry

1 | INTRODUCTION

The ICS Standardisation Steering Committee has initiated a working group (WG) to update the International Continence Society's Good Urodynamic Practice 2002¹ (GUP2002) with the aim of including new evidence and information on

urodynamic practice and urodynamic quality control and the revised ICS standard on urodynamic equipment.² Following the traditional ICS Standardisation style, while including the new method and structure,³ changes of current standards are recommended and arguments provided for making these changes.

This report provides evidence-based specific recommendations for routine clinical urodynamic testing, and includes expert consensus where evidence is lacking.

Dr. Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper

Conclusions and recommendations are highlighted in the text and can be used for summary and express reading. We define “ICS standard” as: “Best practice, based on evidence, with the use of standard terms and standard techniques, evaluated and reported clinically or scientifically, in a complete and validated manner.” In individual cases and/or in research settings, the decision may be made not to adhere to this standard, but any deviation from the standard should be specified.

The ICS standard is particularly intended for evaluation of the function of the lower urinary tract (LUT) of adult persons without relevant neurological abnormalities and with intact “normal” anatomy of the LUT. Many of the recommendations in this document may, however, also be considered relevant, generalizable, or applicable for patients with neurological abnormalities, for Video-urodynamics or for urodynamics in research settings and/or also for patients with neobladders, augmented bladders, or diversions. The recommendations may also be helpful for performing urodynamics in children.⁴

2 | DEFINITIONS OF TERMS FOR URODYNAMIC TESTS

2.1 | Introduction and evidence base

Over the years, a variety of terms have been developed for the group of diagnostic tests that evaluate LUT function. The WG has constructed a table with terms and has provided their frequencies of use, both in PubMed (searching in title and abstract) and in Google (Table S1). Uroflowmetry, Post Void Residual (PVR), Cystometry, Pressure-flow study, Electromyography (EMG), Urethral Pressure Profile, and Video urodynamics are the terms most frequently used in the scientific literature. The ICS Standardisation of Terminology of LUT Function (ST2002)⁵ (re-) introduced or used many of these terms, and the AUA-SUFU has also provided definitions of some terms.⁶

2.2 | Conclusions

Many terms have been introduced in earlier standardizations, without providing a precise definition.

A significant variety of synonyms are used for urodynamic tests and studies in the scientific literature as well as in lay texts and we conclude that the use of currently existing terms is not yet without variation in scientific literature.

2.3 | Discussion

Variations in the application of terms may bias communication, in science and also in communication with patients. The following terms are not really new and many were introduced earlier, sometimes long ago.

2.4 | Recommendation

For the purpose of uniformity, particularly in research we recommend and define the following as ICS standard terms:

Urodynamics: The general term to describe all the measurements that assess the function and dysfunction of the LUT by any appropriate method. Urodynamics allows direct assessment of LUT function by the measurement of relevant physiological parameters. (GUP2002 not changed).

Invasive urodynamics: Any test that is invasive, as it involves insertion of one or more catheters or any other transducers into the bladder and/or other body cavities, or insertion of probes or needles, for example for EMG measurement.

Non-invasive urodynamics: All urodynamics done without the insertion of catheters: for example, uroflowmetry, PVR, penile compression-release test, penile cuff, urethral connector, condom catheter, or sonography.

Ambulatory urodynamics: See the applicable ICS Standard.⁷ (Not further discussed in this standard.)

ICS standard urodynamics protocol (NEW): a patient undergoing collection of a clinical history (should include (a) valid symptom and bother score(s) and medication list), relevant clinical examination, (3 days) bladder diary, representative uroflowmetry with post-void residual (PVR) and a complete ICS standard urodynamic test (see below), is referred to as having had the “ICS standard urodynamics protocol (ICS-SUP).”

ICS standard urodynamic test (NEW): Uroflowmetry and PVR plus transurethral cystometry and pressure-flow study (see below): all tests are performed in the patient's preferred or most usual position: comfortably seated and/or standing, if physically possible. The patient(s) is reported as having had an ICS standard urodynamic test (ICS-SUT).

ICS supplementary urodynamic tests: ICS-SUT may be supplemented with EMG, with imaging, with continuous urethral pressure(s) and/or with urethral pressure profile measurement. Cystometry may be done via a suprapubic catheter (specify supplements).

Recommendation: The WG suggests all ICS-SUT-data as a minimum, and preferably complete ICS-SUP data should be specifically reported or summarized for the total cohort of patients in all research reports that contain (invasive) urodynamic results.

Furthermore, the WG suggests referring to the current manuscript when research is reported as “. . . according to ICS Standard Good Urodynamic Practices (ICS-GUP2016),” when complete ICS-SUT or SUP data are reported.

Uroflowmetry: A test that produces the [Citation from GUP2002]: “. . . flow rate of the external urinary stream as

volume per unit time in millilitres per second (mL/s).” ICS uroflowmetry minimally reports the maximum flow rate and the volume voided and PVR. (GUP2002, not changed.) Other characteristics such as flow pattern (specify) and other parameters may be added but should be specified.

Post-void residual volume (PVR): (GUP 2002) The remaining intravesical fluid volume determined directly after completion of the voiding. The technique (eg, ultrasound or catheter) used to measure the volume should be specified.

Voided percentage (Void%): The numerical description of the voiding efficacy or efficiency which is the proportion of bladder content emptied. Calculation: $[(\text{volume voided}/\text{volume voided} + \text{PVR}) \times 100]$. The WG suggests—solely for the purpose of standardization—that the term voided percentage with the abbreviation Void% is preferred. The relevance of the parameter is not discussed here.

Cystometry: Continuous fluid filling of the bladder via a transurethral (or other route, eg, suprapubic or mitrofanoff) catheter, at least with intravesical and abdominal pressure measurement and display of detrusor pressure, including cough (stress) testing. Cystometry ends with “permission to void” or with incontinence of the total bladder content. The fluid type and temperature, filling method and rate, catheter sizes, pressure recording technique, and patient position should all be specified.

Cysto-urethrometry: A cystometry is done with continuous urethral pressure measurement (specify technique).

Pressure-flow study: The intravesical and abdominal pressures are measured, from the moment of “permission to void,” while uroflowmetry is performed with a transurethral (or suprapubic) catheter in place. The position of the patient, the catheter sizes, and the pressure and flow recording technique should be specified.

Pelvic muscle electromyography (EMG): Pelvic muscle activity is judged with surface electrodes. ICS Standard: two skin electrodes on the perineal surface with an appropriate reference (=Pelvic muscle EMG). Other type, for example, vaginal probe: “vaginal EMG,” “anal EMG” or “needle EMG,” etc. and/or number and position of electrodes should be specified.

Urethral pressure profile: See ICS Standardisation of urethral pressure measurement.⁸

Urodynamics may be combined with imaging (specify). Invasive urodynamics performed with contrast fluid as the filling medium is Video urodynamics: X-ray (image amplifier) pictures or cine-loops are made at relevant moments. The contrast medium and report patient radiation dose should be specified. Video urodynamics is not further discussed in this document.

3 | PATIENT INFORMATION AND PREPARATION OF THE PATIENT FOR INVASIVE URODYNAMICS

3.1 | Introduction and evidence base

Although evidence indicates that urodynamics is generally well tolerated, studies have examined pain and embarrassment, using a variety of questionnaire methods. Younger patients have been identified as a group that may experience more pain and apprehension⁹ associated with depression, anxiety and/or bladder pain syndrome.¹⁰ Effectiveness of patient information leaflets requires comprehensibility and communicative effectiveness.^{11–13} However, reports analysing existing information conclude that this is of poor quality. Studies to develop a detailed explanatory leaflet, which were used in a double-blind randomized controlled trial to conclude that “leaflet” or “no leaflet” intervention had a disappointing satisfaction outcome.^{14,15} Poor understanding of the test has been associated with lack of satisfaction with care and with, for example, the perception that the investigation in itself is therapeutic.¹⁶

3.2 | Conclusions

Some evidence exists that information leaflets about urodynamic investigations are too difficult for patients to understand.

Young adults and patients with a bladder pain syndrome may have a relatively negative experience with urodynamic investigation.

Conflicting evidence exists about which precise information is helpful to give to patients before urodynamic testing to reduce distress.

3.3 | Discussion

Effective communication is an expectation in modern healthcare, so that patients become actively engaged in the test and their care delivery. The WG has discussed that a leaflet with a minimum set of items would facilitate informed decision making. The WG is convinced that good information before and during the test increases a patient's acceptance and confidence, and will reduce confusion.

3.4 | Recommendation

The WG suggests, although in the absence of good evidence, that an explanatory leaflet about urodynamic investigation with sufficient information, which uses clear, unambiguous wording will be appreciated by the majority of patients.

The WG suggests that a leaflet should include the items listed here below. The WG recommends that a leaflet that includes these items in an understandable manner for the

patient is referred to as the (NEW) ICS Standard Information Leaflet for Urodynamics.

Overview of the content of an ICS Standard Information Leaflet for Urodynamics.	
•	What is a urodynamic investigation
•	That the tests involves insertion of catheters into the bladder and rectum, and relevant technical issues
•	What is the usefulness of urodynamics, Why is the testing done
•	What are the different steps of urodynamic investigation and how they are performed (e.g. uroflowmetry, cystometry, urethral pressure measurement and pressure-flow)
•	How dignity, communication and comfort during the investigation are maximized (What you do or offer in this regard)
•	The symptoms that may occur following the investigation, what they indicate and how can they be handled or prevented, e.g. the fact that mild discomfort, frequency, dysuria and haematuria may be experienced, and a urinary tract infection may occasionally develop*
•	Additional information including length of the investigation, sterility of relevant parts of equipment, lack of 'injections'
•	That the test is done interactively and that communication with the patient is a necessary part of the test.
•	What the patient should do before the test (e.g. arrive if possible with a full bladder for uroflow, and also with an empty bowel if possible).
•	Whether the patient should continue medication before the test, or whether there are specific medications that the patient should not take in (a defined period) before the test. Note: This should be individualized, e.g. with a tick box or a written instruction of the requester.
•	What the patient should do after the test <ul style="list-style-type: none"> ○ e.g.: Immediately drink one portion of ½ - 1L extra fluid to ensure prompt voiding again, in order to relieve urethral irritation rapidly. ○ All usual activities are permitted after the test. ○ Symptoms and signs of urinary tract infection and what steps to take if these arise.

* Consider (also depending on local situation and regulations) to list adverse events (and incidence) that a reasonable patient might be expected to be informed as a standard.

4 | URODYNAMIC PRACTICE PROTOCOLS

4.1 | Introduction and evidence base

In an area where a minimum standard for urodynamic testing workload exists,¹⁷ it was concluded on the basis of a postal survey that training had insufficient effect, and that practice significantly varied.¹⁸ When 100 consecutive graphs from all men who underwent cystometry in one center were reviewed, “significant defects [in the pressures] were not uncommon”; furthermore, $\pm 10\%$ of the transurethral catheters was reported to have been “falling out during voiding.”¹⁹ Disappointingly, although willingness to change practice was observed, actual changes did not occur despite the distribution of a standard protocol for some of the elements of urodynamic testing.²⁰

4.2 | Conclusions

Published evidence to support implementation of practice standards is scarce and the conclusion on the basis of simple implementation strategies toward the achievability of practice improvement is not very encouraging.

4.3 | Discussion

Implementation of standardized practice is a complex process that requires changing routine habits and beliefs while keeping an eye on context, for example, acceptability, adoption, appropriateness, feasibility, fidelity, and costs.²¹ Furthermore, the quality of the practice guidelines or

standards for implementation is of importance.²² Simple dissemination is not usually very effective and, as an example, for example, “blended” or “continuous quality improvement,” strategies may be required.²³

4.4 | Recommendations

The WG recommends that departments develop urodynamic practice protocols on the basis of the ICS-GUP standards and facilitate specific training in, and evaluation of, urodynamic practice.

We recommend that centers should—ideally coordinated and together on a nationwide level—decide on individual accreditation and recertification (eg, required minimum number of tests) as well as the level of authority and autonomy to perform urodynamic tests.

5 | CLINICAL PRACTICE PRE-TESTING INFORMATION

5.1 | Introduction and evidence base

All guidelines on urinary incontinence recommend a clinical history, and validated symptom and/or bother scores are recommended in the majority of these.^{24–28} Urinalysis and physical examination as the first step in the evaluation of a patient with urinary incontinence are considered routine. The GUP2002 has in this regard mentioned non-invasive urodynamics, frequency/voiding chart (FVC), or bladder diary (BD) uroflowmetry and PVR) for all patients with LUT symptoms (LUTS). FVC and BD are mentioned in ST2002 and defined after that publication.²⁹ The test should be requested with the goal of answering a specific question (GUP2002). In order to formulate this question prior to urodynamics, as mentioned here above, a complete history, a list of medications taken must available as well as the results of the physical exam. Observation of the patient's gait, evaluation of sacral sensation and reflexes and identification of other neuro-urological findings are important. An abdominal exam and evaluation of the extremities for oedema are also helpful. In women, a systematic pelvic exam should include evaluation for prolapse,²⁹ vaginal wall masses, atrophy, pelvic muscle quality, and the ability to voluntarily contract them (as is standardized³⁰), urinary leakage with strain, and any other details. In men, genital exam and a digital rectal prostate examination with an estimation of size is necessary. Prostate pain or abnormalities and degree of anal tone should be noted.

A (3-day) FVC or BD provides information that may obviate cystometry (eg, when excessive fluid intake is recognized) or may help to ensure and evaluate whether the cystometry, especially cystometric capacity, is representative of the patient's typical situation (“typical voided volumes”;

from GUP2002). Non-invasive urodynamic testing, that is, uroflowmetry plus PVR in men and women, should precede invasive urodynamics. This information gathering process serves as the foundation for determining treatment as well as formulating questions that can be answered with (invasive) urodynamics. A urinalysis to screen for infection or haematuria should be available.

When planning urodynamic tests, the physician should specifically instruct the patient whether or not to change any conservative measures or change or take medication before or after the test according to ((local) standards and/or guidelines and) the individual situation of the patient.

5.2 | Conclusion

We conclude that clinical practice guidelines and expert “first principles” agree that prior to invasive urodynamics, history, physical examination, and urinalysis should be completed.

The usefulness of a FVC-BD to help anticipate cystometric capacity and appropriate fill rate has never been formally investigated. It is, however, the WG's conclusion that the FVC-BD voided volumes should be considered relevant to evaluate the representativeness of the cystometry, as was recommended in GUP2002.

5.3 | Recommendation

The WG advises that apart from the clinical information (history, medication, and clinical examination), the information from the (3-day) FVC or BD, and the uroflowmetry and PVR are utilized while performing invasive urodynamics.

The WG advises specific instructions to the patient with regard to the continuation of usual LUT management (eg, medication) if the patient is on treatment, and—persisting or new onset—symptoms require urodynamic analysis.

6 | PRACTICE OF UROFLOWMETRY

6.1 | Introduction and evidence base

GUP2002 presents uroflowmetry as a first line screening for most patients with LUTS and has provided practice recommendations. ICI consultations and clinical practice guidelines have reconfirmed uroflowmetry as the first line test.^{5,7,28} Data quality control is relevant and important³¹ and ICS has updated equipment performance requirements.² Apart from technical quality, the clinical situation is relevant. Some papers concerning position during voiding of men^{32–39} or women^{40–46} have been published since GUP2002, with a

variety of primary outcomes related to different voiding positions (see Table S2). The results do not allow a very strong recommendation to be made, partly because test-retest variation inherently plays a role.⁴⁷ On the basis of these results and also on the basis of expert experience and plausibility, the WG concludes as follows.

6.2 | Conclusions

The WG concludes that it is useful, considering the representativeness of the test-result, for patients to be allowed to undergo uroflowmetry in their own preferred position.

6.3 | Discussion

Uroflowmetry and therefore flow rate, voided volume, and PVR are inherently sensitive to patient cooperation and emotion, and should only be clinically interpreted if the voiding has been representative with regard to both voided volume and the patient's opinion (eg, uroflowmetry may be abnormal if voiding was postponed for too long before the test). Furthermore, the interpretation can only be relevant if the test was done in a technically reliable manner, based on the examiner's opinion.

6.4 | Recommendations

The WG recommends permitting patients to undergo uroflowmetry in their preferred position and to strive for minimum physical discomfort and anxiety for the patient, as well as ensuring personal dignity.

The WG recommends checking if the voiding is representative, based on the patient's report and also on the association with the patient's FVC or BD volumes.

The position of the patient during voiding studies should be reported.

The WG recommends considering repetition of the uroflowmetry if the result has not been representative for the patient or if the result indicates abnormality. Particularly, if the voided volume and/or flow rate are unexpectedly low or the PVR is (much) larger than expected or explainable in both women and in men.

7 | PRACTICE OF CYSTOMETRY

7.1 | Introduction and evidence base

GUP2002 has specified catheters, pressures, pressures reference and quality checks for cystometry (and also for pressure-flow study). The WG has not found evidence that supports changes in these specifications. The WG has however studied and further specified six items in relation to the practice of filling cystometry. For each item we report

conclusions on the basis of the evidence and provide recommendations below.

7.2 | What determines filling rate?

The rate at which the bladder is filled during cystometry affects the results of the cystometry.^{48,49} ST2002 has defined two different ranges of filling rate: maximum physiological filling rate as estimated by body weight in kilogram divided by four, thus typically in the range of 20–30 mL/min. The commonly applied filling rate in practice is often higher and, and this is (ST2002-) referred to as non-physiological filling rate. Neither ST2002 nor GUP2002 are however specific in the rate to select however GUP2002 has stated that the [citation] “typical voided volumes should be used for the control of subsequent invasive studies.”

The actual volumes in the bladder during cystometry may differ from the recorded filling volumes due to diuresis, which can add significantly volume, for example, up to 25% to the cystometry volume.^{50,51} Cystometric capacity is most reliably determined by calculation of voided volume (mL) plus PVR (mL) immediately after pressure-flow study (ST2002). The WG has been unable to find evidence that stopping or slowing down the filling rate, for example, when urgency is perceived and/or when detrusor overactivity (DO) is observed, is of any relevance. GUP2002 has suggested that the investigator should stop filling and observe the pressure, when reduced compliance is thought to be a consequence of filling rate above physiological filling rate.

7.2.1 | Conclusions

Current ST2002 cystometry (pump-) non-physiological filling rate is frequently applied, but a recommended more specific value or range is lacking.

Filling rate, especially when very fast or to volumes that are very much larger than the person's usual (maximum) volumes, may influence the results or the representativeness of the cystometry. Evidence that filling rate should be changed during the cystometry is lacking.

Diuresis, occurring during cystometry, adds volume that is not recorded by the urodynamics system with automated filling volume recording, but that is relevant for interpretation of the results.

Correction of filled volume for diuresis in retrospect should be considered with regard to reporting of filling sensation parameters, compliance and cystometric capacity (=pressure-flow voided volume plus PVR; and assuming the diuresis to be constant).

7.2.2 | Discussion

A balance between a filling rate that is slow enough to mimic a representative bladder filling and fast enough to complete the cystometry in an efficient fashion is a pragmatic approach to achieving a representative result. The WG considered,

without specific evidence, but similar to practice in children's cystometry, that a filling rate in mL/min of roughly 10% of the largest voided volume (reported on a FVC or –BD; and PVR should be taken into account here) at a constant rate is a practical means to implement the above cited GUP2002 recommendation to use the person's typical voided volumes. This would, in a sensible manner, narrow the currently existing non-physiological fill rate-range and may also prevent too fast filling or filling to very unusual volumes. The WG suggests standardizing the filling in a fixed rate for the purpose of comparability in clinical cohort (management) research protocols where cystometric capacity, sensation, or compliance are outcome parameters.

The end of filling should relate to a “strong but not uncomfortable need to void.” The largest voided volume on the FVC-BD may be an indicator for this volume, however with as yet unknown specificity, and PVR should be taken into account. “Strong desire to void” (SDV) should be indicated on the urodynamic graph. Permission to void is given when the pump is stopped (ST2002) and end of filling should be regarded as the beginning of the voiding phase. A specific marker on the urodynamics graph to indicate permission to void must be used however, if there is a delay between halting the pump and permission to void.

7.2.3 | Recommendations

The WG recommends that the person doing the cystometry knows the FVC-BD results as well as the results of uroflowmetry and PVR, prior to performing invasive urodynamics.

The WG suggests that the ICS maximum physiological filling rate is standard and suggests that “non physiological filling rate” is standardized on the basis of the individual patient's typical voided volumes (including estimation of the PVR volume) to prevent too fast filling and/or too large volumes.

The WG recommends use of the maximum physiological rate when comparability is relevant (eg, this may be required in prospective research cohorts, before and after intervention).

Parameters during cystometry depending on bladder volumes should be corrected for diuresis if relevant for clinical management or for scientific purposes.

The WG recommends that “permission to void” should always be marked on the urodynamic graph to indicate the beginning of the pressure-flow study. Stopping the fill pump is a more or less automatic marker, but when there is a delay between stopping the filling and this permission, a specific marker should be used to allow correct interpretation of the graphs after the test.

7.3 | How is the patient instructed to report sensations?

Prior to filling cystometry, patients are typically informed (written and verbal) that they will be asked to report the sensations they experience during the test. The ST2002

recommends that three sensation parameters be recorded during cystometry: first sensation of filling (FSF), first desire to void (FDV) and SDV. In addition, the patient may report sensation(s) that are considered to represent “urgency” (ST2002) which can be marked specifically. These sensory parameters have been confirmed as applicable, consistent, and reproducible in healthy persons and in patients with overactive bladder (OAB) syndrome.^{52–54,57,58} There is, however, conflicting data regarding the reliability and/or representativeness of bladder sensation reporting during cystometry.^{55–57,59,60} The use of a visual analogue scale (VAS) to grade the level of sensation has been shown to correlate well with some of the standard sensation parameters.⁶¹ Similarly, a keypad, allowing patients to indicate differing levels of sensation, had a good and reproducible association with filling volume.⁶²

7.3.1 | Conclusions

The ST2002 expert-based recommendation for the assessment of sensations during cystometry is reasonable and applicable as is demonstrated in various study reports.

7.3.2 | Discussion

The WG has decided not to change the ICS standard in favor of the use of VAS. However, despite introduction of standard terms in 2002, few studies published have reported cystometry filling sensations and the WG feels the need to reintroduce these and to add practice recommendations. It should be noted that the WG has not evaluated the relevance of the filling sensation parameters.

FSF should, at the beginning of the cystometry, be separated from the (urethral) sensations caused by the catheterization. The explanation to the patient may be that FSF is “Tell me the moment when you perceive that your bladder is not empty anymore”; FDV is (if little or no chronic PVR exists) usually roughly associated with FVC-BD “typical voided” volumes and can be asked as “Tell me when you have the sensation that normally tells you to go to the toilet, without any hurry, at the next convenient moment.” SDV is “. . . the moment that you, without any pain or any fear of losing urine, will not postpone the voiding; you will visit the nearest restroom also, for example, while shopping.” SDV may however occur suddenly and include the fear of leaking (or actual urine loss) in specific patients and patients should report this also. Correlating the results of cystometry volume and sensations with FVC-BD may provide background information regarding day-to-day sensory findings and bladder volumes and may also limit the risk of overfilling.

Fear of leakage, pain, or other signs or symptoms during the test should be specifically marked on the urodynamic graph.

7.3.3 | Recommendations

The WG recommends marking FSF, FDV, and SDV, during cystometry as recommended by ST2002, on the basis of explicit verbal instructions and communication before and during the test specified in this GUP, and reporting the results.

7.4 | Fluid-filled external transducers and catheter system

Current ICS standard cystometry and pressure-flow study requires fluid-filled catheters with external pressure transducers to be leveled at the height of the upper edge of symphysis pubis. (GUP2002, ST2002). The urodynamic pressure is therefore the excess pressure above atmospheric pressure at the hydrostatic level of the upper edge of the symphysis pubis. Some studies that have compared fluid-filled catheters with microtip sensor catheters or air-filled catheters have shown that the results of the cystometry using these alternative systems are not interchangeable with the current ICS standard.^{63–65}

7.4.1 | Conclusions

ICS standard urodynamic intravesical pressure (p_{ves}), abdominal pressure (p_{abd}) or other urodynamic pressure is the excess pressure above atmosphere at the hydrostatic level of the upper edge of the symphysis pubis. This is valid for all pressures recorded with fluid-filled lines.

The WG concludes that comparisons of micro-tip catheter systems (multicenter group averages) or air-filled catheters in vitro or in vivo (pairwise averages of two measurements) with ICS standard fluid-filled systems demonstrated that both systems give different results. The reports of these studies have concluded that systems are not interchangeable.

7.4.2 | Discussion

Fluid-filled external pressure systems referenced to the symphysis pubis are fundamentally different from the micro-tip or air-filled catheter systems, as the latter record pressure without a clear reference level. The use of ICS standard urodynamic pressures allows pressure related data to be comparable between patients and centers. Systematically obtained clinical evidence for the clinical reliability of micro-tip or air-filled catheter systems is scarce. Every urodynamic laboratory should be familiar with the potential artefacts of the specific system used for pressure measurement, and take the possibility of system- differences of up to 10 cm H₂O into account.⁶⁶ The WG considers that the availability of alternative systems has consequences for multi-center studies. Also the WG has considered generalizability of pressure values published in studies using

other than fluid-filled external pressure systems is undecided.

ICS guidelines on equipment performance provide minimum system requirements for pressure responses and calibration.^{2,66} Centers that utilize other pressure systems should provide reference values for their data.

7.4.3 | Recommendations

ICS standard cystometry is performed with a fluid-filled system with external transducers at the reference level of the upper edge of the symphysis pubis.

Urodynamic laboratories should ensure that the equipment, including the catheters and transducers, meet the requirements as explained in the ICS guideline on equipment performance.^{2,66}

Urodynamic laboratories should check the performance of their system at regular intervals and calibrate according to manufacturer recommendation, and as advised in the ICS guideline on equipment performance.⁶⁶

7.5 | Transurethral catheter

ICS standard invasive urodynamics is done with the thinnest possible (6–7F) transurethral double or triple lumen catheter or a suprapubic catheter on the basis of ST2002 and GUP2002.

7.5.1 | Discussion

The ICS recommendation, reiterated here above, is based on expert opinion and consensus. GUP2002 notes that the use of two separate catheters is “less convenient.” However, many studies since 2002 report the use of separate filling and pressure catheters and the removal of the filling catheter for stress provocation and/or for the pressure-flow study. Reported practice includes the range from 5 to 8F for the pressure recording catheter and usually $\pm 10F$ for the filling catheter. The WG has no arguments for discarding the use of double catheter systems at present but has again (after GUP2002) discussed the need to re-catheterize if the test needs to be repeated and also the necessity to interfere with the patient at the moment of SDV, just before the voiding. However, the excess cost of the double or triple lumen catheter is a disadvantage. No head to head comparisons have been performed and no new evidence has been published on the spectrum of advantages and disadvantages of two catheter technique versus the recommendations in GUP2002.

Publications applying results of invasive urodynamics sometimes report a high rate of expelled catheters and it is the WG's opinion that advice on catheter fixation, applicable for both intravesical (shown here for double lumen) and rectal catheters, will reduce that problem:

Men (left picture): Catheter is taped to the length of the penis over the catheter, without obstructing the meatus.

Women (right picture): Catheter is taped to the inner side of the labia or (similar in men and women) adjacent to the anus.



7.5.2 | Recommendation

ICS standard invasive urodynamics is done with the thinnest possible double lumen catheter. However, on the basis of the lack of evidence for inferiority of two catheter techniques, this alternative is considered acceptable.

The WG recommends finding evidence with specific studies to direct practice standardization and harmonization for the catheters used for invasive urodynamics.

The WG recommends fixation of the catheters as adjacent as possible to the anus and the urethral meatus with tape, without blocking the urinary meatus.

7.6 | Abdominal pressure catheter placement: rectal versus vaginal

Flaccid filled balloon which may be punctured or slowly perfused open end catheters in the rectal ampulla are used to measure abdominal (“perivesical”) pressure (GUP2002). The WG has discussed that “slowly perfused open end” should not be used because rectal filling may cause a sensation of need to defecate and may influence the result of urodynamics, though there is no research evidence on this topic.

In a prospective, randomized trial comparing open (without balloon) vaginal versus open rectal abdominal pressure 6F catheters in women undergoing external sensor, fluid fill cystometry, the authors noted no differences in discomfort or patient acceptability, however it was reported that women declined randomization on the basis of a preference for a vaginal catheter. Set-up time, catheter events affecting signal quality (including during provocation), or alteration in patients with vaginal prolapse were also not different. The report states that despite quality control measures (catheter repositioning and flushing of air bubbles, checking signal quality during and at end of study) only 13% of graphs all had optimum quality and a significant number of catheters was lost during the tests.⁶⁷

7.6.1 | Conclusions

Although limited evidence suggests that women may prefer vaginal reference catheter placement, the WG concludes that this is insufficient to demonstrate that this is a reliable alternative to rectal catheterization.

7.6.2 | Discussion

After bowel resection with anal closure, the stoma may need to be considered as the route to measure abdominal pressure, especially in men. There is no specific evidence, but the position of the catheter-tip is usually above the bladder in a stoma, and bowel activity may much more likely cause artefacts in those cases, hampering measurement of absolute abdominal pressures and detrusor subtraction pressure, and therefore, the interpretation.

The WG considered that full (pre) filling or overfilling of rectal catheters with a balloon, as widely used, is a significant source of abdominal pressure measurement error. The catheter and balloon should be filled with water in a way that all air is replaced and without causing any excess pressure inside the balloon. Rectal balloon catheters should not be re-filled after insertion and therefore should be punctured to prevent over-filling and measurement error.

7.6.3 | Recommendations

Rectal placement of a fully fluid-filled open, or punctured balloon catheter, to measure abdominal pressure should be considered the ICS standard.

The WG recommends that vaginal or stoma placement of the abdominal pressure catheter is used alternatively only if rectal catheter placement is impossible.

7.7 | Patient positioning for cystometry and pressure-flow

It was noted on the basis of a literature review that DO was detected with a consistently higher rate in the upright position compared to supine position. DO would have been missed in 76% of cases of cystometry was done in the supine position and 60% would have been missed if the study was done supine compared to seated. Having the patient stand after being filled increased the chance of detecting DO by 21%.⁶⁸ In a prospective study, urodynamic stress incontinence was detected in 55% if the women were sitting but only 2% if supine, while DO was detected in 55% when seated but only in 9% when supine.⁶⁹ Combined diagnosis (DO plus USI) was observed seated in 18%, and zero when supine. Volumes at the time of reporting—ICS-standard—filling sensations and cystometric capacity were lower for seated cystometry.² Position during cystometry may also be relevant for the need to change the position for the optimal pressure-flow study (see below).

7.7.1 | Conclusions

The detection of DO, the detection of urodynamic stress incontinence, and bladder volumes at reported bladder filling sensation are influenced by the position of the patient. Sitting or standing position appears to have a higher sensitivity for detecting these abnormalities.

7.7.2 | Discussion

The sitting or standing position is the most representative for daily life situations and is probably the least uncomfortable and/or embarrassing for the patient. Furthermore, in the sitting position the intra-rectal as well as the intravesical catheter are at similar levels in the pelvic cavity (and similar to the transducer) which makes reliable (better balanced) pressure and subtraction more likely. Seated or standing (men) cystometry also allows a smooth transition from cystometry to pressure-flow study when SDV is reached, causing little movement artefact.

7.7.3 | Recommendations

ICS standard cystometry is done in the vertical position (standing or normally seated) whenever physically possible.

A pressure-flow study is done comfortably seated (women, some men) or standing if that is preferred position (men).

7.8 | Reliability and need for repeat cystometry for confirmation

In a prospective study of invasive urodynamics in healthy, asymptomatic female volunteers, poor reproducibility of sensory volume markers (FSF and FDV) as well as Q_{\max} and $P_{\det Q_{\max}}$ between two cystometries done at the same session was reported.⁷⁰ Similarly, poor reproducibility of urodynamic results at short-term follow-up (1–5 months) was noted.⁷¹ In another prospective study of immediate repeat cystometry in patients with neurogenic LUT dysfunction, the authors noted wide 95% limits of agreement for differences in same session test parameters (maximum cystometric capacity, compliance, storage $P_{\det, \max}$, DLPP, Q_{\max} , voiding $P_{\det, \max}$, $P_{\det Q_{\max}}$).⁷² However, the study reported excellent reproducibility in the detection of DO. The authors suggested that one single urodynamic study may be inadequate to form the basis for clinical decisions in patients with spinal cord injury.⁷³

In a later single-center study in women with symptoms and signs of urinary incontinence (without neurological abnormalities), the reproducibility of immediate repeat cystometry plus pressure-flow analysis was overall good to excellent, with intra-class correlations of around 0.75 and few differences in urodynamic diagnosis between the first and second run. Nevertheless, these authors suggested that repetition of urodynamic tests is justified to ensure diagnosis.

In elderly men, the immediate or longer interval test retest variation is less with regard to pressure-flow analysis. However, it is not reported whether differences in cystometry values have been observed.^{74–78}

7.8.1 | Conclusions

Predominantly, single-center evidence suggests that immediate or longer term test- retest variation is sometimes large

for specific parameters (like sensation) but less with regard to pressure-flow variables, especially in elderly men.

There is no convincing evidence that the clinical diagnosis on the basis of the first cystometry is often changed on repetition of the test. There is no definite evidence that immediate repetition of an adequately performed urodynamic test “for confirmation” is required.

7.8.2 | Discussion

The WG considered that large test-retest variations may also reflect inadequately standardized methods of testing. Test retest data is scarce which was the reason to also include studies with patients with neurological abnormalities in the WG’s summary of the evidence. Measurement errors are a significant source of test-retest variation, but are seldom reported. The WG considers it prudent to repeat a technically adequate test when observations are not explainable in relation to the patient’s symptoms and signs, and especially when the urodynamic question is insufficiently answered and consequences for management are significant. Furthermore, the WG considers that some observations may be situational (eg, the inability to void during a test) and may not always be soluble.

7.8.3 | Recommendations

The WG does not recommend routine immediate repetition of invasive urodynamics “for confirmation” if the test was technically adequate, has been considered representative, and has answered the clinical question.

The WG recommends immediate repetition of the test when doubt exists as to whether the test has answered the clinical question.

The WG recommends repetition of a urodynamic test when technical errors and artefacts have been observed at immediate post-test analysis.

8 | PRACTICE OF PRESSURE-FLOW STUDIES AND AN UPDATE OF TERMS

8.1 | Introduction

An ICS subcommittee (ST1997) on standardization of terminology for pressure-flow studies revised and expanded diverse sections of the earlier ICS terminology.^{79,80} ST1997 identified and defined five relevant parameters with the preferred abbreviations to depict pressure-flow studies.

For urodynamic practice: the “pressure-flow study” (as defined above) begins immediately after permission to void (ST2002) and ends when the detrusor pressure has returned to the baseline value and/or the flow rate to zero and/or the

patient considers the micturition completed. Note that pressure-flow analysis is only validated for voluntarily initiated micturitions and not for incontinence.

The WG considered that the relevance of instruction, position and privacy for the patient while performing pressure-flow study is equal to uroflowmetry and we refer to both the paragraphs here above for the practice of uroflowmetry and/or cystometry for the practice of pressure-flow study.

8.2 | Discussion

There is an inevitable delay between the fluid stream leaving the bladder and hitting the flowmeter which should be taken into account when a pressure-flow study is analysed (ST1997; GUP2002).² The delay between urethral meatus and flowmeter should be reduced by placing the flowmeter as close to the meatus as possible for every voiding position. Reducing the meatus to flowmeter distance may also result in more relaxed voiding because the patient may experience less concern about spattering.

8.3 | Recommendation

The WG recommends, especially for the purpose of pressure-flow analysis, a shortest possible meatus-to-flowmeter distance, adjusted to the voiding position, but recommends correcting for delay between pressure and flow.

8.4 | Discussion and suggested terms

Presentation of pressure-flow studies should be with a plot of the flow (-delay corrected) rate (mL/s) on the X-axis and the (delay corrected) synchronous detrusor pressure (cm H₂O) on the Y-axis in addition to the time-based graphs (ST 1997).

ST1997 introduced “urethral function” and “urethral resistance (relation)” without precisely defining these as (new or standard) terms. The “(passive) urethral resistance relation” as a means of quantifying bladder outflow obstruction (in male patients with prostatic enlargement) was defined before ST1997.^{81,82} New ICS terms are desirable to acknowledge the relevance of the anatomical structures adjacent to the anatomically defined urethra per se, to describe outflow conditions during micturition (with or without further specifying anatomy) and the WG suggests introducing a specific (ICS) standard to further detail terms and practice for pressure-flow study analysis.

The terms bladder outlet obstruction and bladder outflow obstruction are already frequently used. The WG introduces **(NEW) Bladder Outflow Obstruction (BOO)** (“outflow” to recognize what is measured) with the definition: a (specified) cut-off of bladder outflow resistance based on the pressure flow relation (ratio) that is considered clinically relevant (the WG does not define cut-off values

but advises that the term should be preferred for both genders and all ages).

ST1997 also stated that the urethral function during voiding can be overactive, without further definition or specification. There is a lack of terminology with regard to specific diagnosis of voiding dysfunction, also here the here above mentioned specific new ICS standard is needed.

The WG suggests already now: **(NEW) Normal voiding function:** flow rate (and pressure-rise) are within normal limits, begin more or less directly after permission to void and ends with an empty bladder.

Bladder outflow physical properties may vary during one course of voiding and the WG suggests that new terms are introduced when analysis methods and cut-off values or pattern descriptions are provided to describe (as introduced in ST1997) “overactive urethral function during voiding.” We conclude that no commonly agreed parameter or pattern description exists to clinically quantify or qualify “(over-) active urethral function” (if) outflow properties vary during a voiding.

“Underactive detrusor” and “acontractile detrusor” are defined in ST1997 and ST2002 as different from “normal detrusor” during micturition. GUP 2002 has also introduced that contraction during micturition may vary, or may be variable. Within this context, the WG discussed that voiding may be influenced by mental state and, although evidence is lacking in the neuro-gyneco-urological literature, anxiety in the test situation for the patient may plausibly influence initiation of the voiding reflex^{83–85} and consequently affect detrusor function. The WG suggests **(NEW) “Situational inability to void”** and **“Situational inability to void as usual”** when in the opinion of the person performing the test, in communication with the patient, the attempted voiding has been not representative.

The WG here introduces the term **“detrusor voiding contraction”** for any analysis of combined pressure and flow (\pm other variables) that qualifies or quantifies the actual observed voiding. Following on to this: **“detrusor contractility”** is now suggested for any method that aims to quantify “intrinsic” detrusor muscle properties (eg, potential-maximum-force or velocity) by any method. We refer to, for example, stop-flow or interrupted-voiding tests and mathematical (extrapolation) or graphical analysis methods of pressure, flow and/or other parameters, such as, for example, the bladder working function.

Acknowledging the GUP2002, we suggest that the terms **“unsustained contraction”** (when waxing and waning) or **“fading contraction”** may be used when analysis methods and cut-off values or pattern descriptions are provided. We also acknowledge that no parameters to clinically demarcate normal, stable, or sustained detrusor contraction are available as yet.

8.5 | Recommendations

The WG has suggested some terms with the aim of improving communication with regard to pressure-flow analysis. However, the WG strongly recommends an updated ICS standard for pressure-flow analysis to ensure optimal ICS standardization of quantitative analysis (and standardization of diagnosis) of bladder outflow function as well as of detrusor voiding contraction diagnosis and/or detrusor contractility analysis for all patient groups.

9 | TECHNICAL AND CLINICAL QUALITY CONTROL DURING INVASIVE URODYNAMICS

9.1 | Introduction and evidence base

Quality control and standardization are an important part of urodynamics. Without training and standardization of equipment, and adherence to quality control and standards of urodynamic practice has been shown to be difficult.¹⁷ The consequence is a large inter-site variability.¹⁸ One national board has argued that maintaining expertise requires performing at least 30 urodynamic tests a year per urodynamicist and 200 tests in a department.^{19,20}

A number of recommendations for control during urodynamics has been provided in the GUP2002 and a number are renewed or added, in the recently published “ICS guidelines on urodynamic equipment performance.”² Furthermore, an overview of common features errors and artefacts has been published.^{66,86}

The WG has found no new evidence necessitating re-discussion of equipment requirements, labelling and scaling of traces in the graph and refers to earlier documents in this regard.^{1,2,5,79}

Typical signal patterns, such as straining, rectal contractions, coughing and DO are important in quality control and everyone who performs or evaluates urodynamic tests should be able to recognize these during the test.^{66,87,96–100} In diverse retrospective single and multicenter evaluations, it was demonstrated that the expert recognition and identification of specific patterns occurring in the urodynamic traces has required adaption or correction of the—initial—diagnoses.^{19,87–100}

9.2 | Conclusions

Expert evidence confirms that prevention, recognition and management of errors and recognition of artefacts are important elements of urodynamic quality control. Systematic urodynamic quality management, including plausibility analysis, is relevant before, during and after the test as well as while reporting the results of the test.

9.3 | Discussion

The WG considers that regular calibration of pressure measurement systems should be documented in each urodynamic laboratory and that, in general, new technologies need to prove their usefulness as well as accuracy compared to existing standards before clinical application.

9.4 | Recommendations

The WG recommends that everyone performing or evaluating urodynamics should be able to recognize usual pressure patterns and be able to perform continuous quality control during the test.

The WG recommends that training and a process of continuous knowledge maintenance as the basis for performing urodynamic tests should be established.

Terms related to the cystometry observations and evaluation.

Adequate set-up of the system and continuous quality monitoring are mandatory and all patterns and features occurring during the test should be recognized. Typical patterns may lead to recognition of pathophysiology or explain the perceived dysfunction. However, when an error or an artefact is observed during the test,⁵⁹ the person performing the test should act accordingly and prevent continuation in case of an error. The WG explains here for clarity that artefacts are, like rectal activity, in analogy with, for example, scattering on ultrasound imaging, more or less unavoidable. Errors are usually preventable or correctable.

Recommended terms to describe most common features, artefacts, and errors during invasive urodynamics: A fluid-filled pressure measuring system shows patient movement and external manipulation of the catheter. This causes signals or signal patterns that should be recognized during the test and at (re-) evaluation of graphs. Prevention of fluid leaks and air bubbles in the pressure tubing system is needed (GUP2002). This already starts before beginning the test while setting up the equipment. However, the effects of fluid leaks and air in the system on the pressures should be recognized at the beginning of the test and during the test also and should be corrected (GUP2002). Furthermore, they should also be recognized and reported during post-test analysis, if recognition and correction during the procedure has failed, to prevent mis-diagnosis.⁶⁶

Urodynamic laboratories should apply standard practice and therefore be aware of all potential features, errors, and artefacts that may occur when measuring with the fluid-filled system. Whoever is performing tests should be able to recognize artefacts and prevent, recognize, and correct errors.

The WG has listed terms here that are considered to be of use during the test and its evaluation. Many of the terms have been used in earlier ICS standardization documents, but usually not with precise definitions. While many terms refer to preventable or correctable problems, these features including artefacts should nevertheless also be recognized during evaluation after the test. The WG has opted for terms that are as descriptive as possible and is convinced that better definition and description of these errors and artefacts is a tool to improve practice. The features, patterns or events terms mentioned here should also be used in the ICS standard urodynamics report (see below).

Initial resting pressure (NEW) is the p_{ves} and the p_{abd} pressure at the beginning of the cystometry. To prevent reading measurements from a kinked catheter in an empty bladder with the catheter holes blocked with (insertion) gel and/or pushed against the bladder surface, the WG recommends (GUP2002) gentle flushing of both catheter channels and/or filling 20–30 mL of the bladder, before the initial resting intravesical pressures are considered to be “established.” Initial resting pressures should be within the physiological limits specified in previous manuscripts^{96,97} and GUP2002.

Dead signal (NEW): A signal that is not showing small pressure fluctuations and is not adequately responding on straining, patient movements, or coughing is reported as a dead signal.

Previously (GUP2002): “In principle, a good p_{det} signal requires only that p_{ves} and p_{abd} show the same fine structure and quality of signals before filling, during filling, and after voiding.”

Pressure drift (NEW): Continuous slow fall or rise in pressure, that is physiologically inexplicable.

Poor pressure transmission (NEW): Poor pressure transmission has occurred when the cough/effort pressure peak signals on p_{ves} and p_{abd} are not nearly equal.

Note: The WG does not define a new limit for not “nearly equal.”

Expelled catheter (NEW): When a catheter is expelled, this is observed as a sudden drop in either p_{ves} or p_{abd} , usually below zero.

Earlier ICS description: “If a sudden drop or increase occurs in either p_{ves} or p_{abd} signal, the usual cause is movement, blockage, or disconnection of a catheter.”

Expelled catheter is usually simply visible during the test and should provoke correction or repetition of the test. However, this term should also be used in post-test evaluation.

Catheter flush (NEW): When one of the catheters is flushed during the test a steep pressure rise is observed in that pressure line for one or two seconds followed by an immediate fall to resting pressure.

A catheter flush is not always necessary after a carefully performed set-up but is suggested in GUP2002.

Flushing of the catheter measuring channel may be considered necessary to wash away entrapped air, or the gel used during insertion or urethral mucus, from the measuring hole. The rectal catheter can only be flushed when an open or a punctured balloon catheter is used, and flushing should definitely not be done if a closed balloon is used (which is not ICS standard). A catheter flush should be marked accordingly, but flushes are normally unnecessary after the cystometry has continued after the first milliliter of filling.

Tube knock (NEW): Tube knock is observable as high frequency, short duration spikes visible in p_{ves} , p_{abd} , or both, and with spikes also usually visible in p_{det} .

Pump vibrations (NEW): Pump vibrations are visible as stable frequency oscillations of small but constant amplitude if the filling tube touches the pressure connecting tube (when a two catheter system is used) and the pump is switched on (switching of the pump can ascertain the situation).

Cough pressure peak (NEW): A cough pressure peak is recognizable during post-test evaluation as a phasic positive pressure change observed in p_{ves} and in p_{abd} .

Urodynamic stress test (NEW): The term urodynamic stress test is used for any physical effort of the person tested, to elevate abdominal pressure during cystometry, with the aim of examining (urodynamic) stress urinary incontinence.

ICS has defined urodynamic stress incontinence. Evidence is lacking (or conflicting) with regard to the preferred technique of urodynamic stress testing.

Note: The provocation method, the pressure measuring catheter(size) and method, the leak detection method as well as the absolute or relative (percentage of cystometric capacity) intravesical volume(s) while testing should be reported.

Leak point pressure (NEW): The leak point pressure (LPP) is the pressure (spontaneous or provoked) that has caused fluid to be expelled from the bladder at the moment that it is visible outside the urethra (may also be used for extra-urethral urine loss or stoma). This may refer to Abdominal, Cough or Valsalva LPP or Detrusor LPP.^{5,6,28,29} Provocation and pressure recording site (“type of LPP”) should be reported.

Diverse methods of LPP measurement have been published with a variety of combinations of provocation or pressure recording site/type and/or technique. Detrusor LPP and Valsalva LPP were defined in ST2002. However, no ICS (or commonly agreed) standard technique or protocol is available and a variety of terms and techniques are used (counts in PubMed (April 2015): Cough LPP: 21; Valsalva LPP: 226; Detrusor LPP: 64; Abdominal LPP: 98; Overactivity LPP: 0).

Cough associated detrusor overactivity (NEW): Cough associated DO is reported when the onset of the DO

(with or without leakage) occurs immediately following the cough pressure peak.

No precise definition of cough associated detrusor activity is available. “Cough induced DO” is sometimes reported, although the precise (patho-)physiology and/or relevance remain speculative.

Position change (NEW): A change in patient position, either active or passive (eg, tilting), is visible on the cystometry trace by a lasting change of equal magnitude in both p_{ves} and p_{abd} .

Note: A position change should be (is readily) noted during the test. Position change should be followed by readjustment of the external pressure sensors height to the standard so that the p_{ves} and p_{abd} -values are similar to the pressure values before the position change. A position change should not affect p_{det} . The position change pattern should be recognized during post-test evaluation of the cystometry.

Rectal contractions (NEW): Rectal contractions are temporary phasic increases in p_{abd} without synchronous change in p_{ves} resulting in negative deflections of p_{det} .

Previously (GUP-2002), “Rectal contractions are usually of low amplitude and may or may not be felt by the patient.”

Dropped p_{abd} at void (NEW): A drop in p_{abd} during voiding is reported during the voiding time, p_{abd} decreases below the previous resting pressure (as a consequence of pelvic (and abdominal) muscle relaxation).

Note: The WG considers that this phenomenon will affect the pressure-flow analysis result, because it affects p_{det} . This observation should be differentiated from expelled catheter (that usually results in a much larger pressure drop).

Straining (NEW): Straining is observable as a temporary increase in both p_{ves} and p_{abd} pressure. Straining may be associated with (patient-active) position change (such as repositioning from leaning backwards to upright).

Note: A short abdominal strain peak may in retrospect be indistinguishable from a position change or a cough.

After-contraction (NEW): An after-contraction, is a continued or new detrusor pressure rise immediately after flow ended. It is important to note if this occurs with the complete emptying of the bladder.

Note: Cough checking of (intravesical) catheter position is always required after pressure-flow. To separate the after-contraction pattern from expelled catheter or catheter tip (with measuring hole) bending in the outlet when the bladder empties, this cough check is specifically important when a p_{ves} increment after voiding is observed.

Previously published description: a pressure increase after flow ceases at the end of micturition.

10 | THE URODYNAMIC GRAPHS AND THE URODYNAMICS REPORT

10.1 | Introduction and evidence base

A standard urodynamics protocol contains diverse elements. Results of clinical analysis and evaluations are documented when a (ICS Standard) Urodynamic Test is ordered. An ICS-SUT should be followed by a urodynamics report. The WG has not found evidence with regard to the standardization of such a report and no evidence regarding the elements that it should contain.

ICS (ST2002) has acknowledged urodynamic observations, but has not been specific in the definition of the type of observations relevant for diagnosis or for urodynamic conditions or the elements of urodynamic testing to be reported. Furthermore, the ST2002 has only mentioned (or standardized) a few of the possible observations, out of the many that can be the result of a complete ICS-SUT. Contemporary urodynamic equipment is able to provide lists test data and/or graphs, but here too no standard exists for these.

GUP2002 has standardized the layout of the urodynamic graph. The WG presents elements for qualitative reporting of the results of a ICS-SUT to ensure a descriptive and objective urodynamic diagnosis or establishment of a urodynamic condition.

10.2 | Discussion

While it will not be possible to cover all possibilities in one standard urodynamics report, the report may be customized, for example, relevant to the final diagnosis the urodynamic evidence has to be reported. However, when a test is done, all results and observations should be systematically reported. It is good clinical practice to integrate the urodynamics report with what is known about the patient from history and other examinations and tests.

On the basis of expert experience and consensus, the WG lists qualitative elements to be included in the urodynamics report of an ICS SUT without standardizing the numerical values.

10.3 | Recommendations

The WG recommends that, in addition to the GUP2002 standard urodynamic graph, a [cited form ST1997] “plot of detrusor pressure against flow rate during voiding” should be provided, according to the example in this ICS standard (ST1997).⁷⁹ For the “ICS standard urodynamic test,” the WG recommends both (NEW) an “ICS standard urodynamic (time-based) graph” as well as (NEW) an “ICS standard pressure-flow plot” to be required elements in the ICS standard urodynamics report. The WG recommends

development of an ICS standard urodynamics report template.

<p>Furthermore, the WG recommends reporting as follows:</p> <ul style="list-style-type: none"> • Overall judgement of the <i>technical quality</i> and the <i>clinical reliability</i> of the test to represent the lower urinary tract function ‘as usual’, to be evaluated by the person who performed the tests. • Uroflowmetry: Voiding position, urge (before the test) and representativeness, as reported by the patient. • Introduction of catheters: sensation; (if occurring: pain), muscular (pelvic or adductor) defence and -perceptibly unusual-obstruction(s) during insertion. • Position(s) during cystometry and pressure flow study. • Patient’s ability to report filling sensations and/ or urgency and/ or urine loss. • Method of urodynamic stress test (if applicable). • Pressure-flow: position and representativeness as reported by the patient. • Accessory tests or measurements (if applicable -no further standard). • Representativeness of the tests to reflect the ‘usual LUT behaviour’ as reported by the patient. • Filling sensation -diagnosis. • Cystometry (detrusor) pressure pattern -diagnosis. • Pressure-flow -diagnosis (compared with uroflowmetry) includes: <ul style="list-style-type: none"> ◦ Bladder outflow function, or obstruction (and the method for assessment) ◦ Detrusor contraction, (and the method for assessment)
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11 | CONCLUSION

The ICS Standardisation WG has updated the International Continence Society’s Good Urodynamic Practice standard. This evidence-based ICS GUP2016 has defined terms and standards for the practice of urodynamics labs in general as well as for the (individual) practice of quality control during and after cystometry, and pressure-flow analysis. Furthermore, the WG has included recommendations for pretesting information and for patient information and preparation as well as recommendations for the urodynamics report. On the basis of earlier ICS standardisations and the available evidence, the practice of uroflowmetry, cystometry and pressure-flow study have been further detailed. The WG expresses the hope that implementation of this update of Good Urodynamic Practices will help to increase the quality of both individual clinical and research urodynamics.

12 | POTENTIAL CONFLICTS OF INTEREST

Dr. Rosier reports grants from Astellas, grants from Laborie/MMS/Tdoc, grants from ONO-Pharma, outside the submitted work; Dr. Guralnick reports personal fees from Astellas, other from InControl Medical, LLC, outside the submitted work; Dr. Lose reports grants from Coloplast, other from Astellas, other from Contura, outside the submitted work; Dr. Eustice has nothing to disclose; Dr. Hashim has nothing to disclose; Dr. Goldman has nothing to disclose; Ms. Dickinson has nothing to disclose; Dr. Schaefer has nothing to disclose.

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Good Urodynamic Practices: Uroflowmetry, Filling Cystometry, and Pressure-Flow Studies

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This is the first report of the International Continence Society (ICS) on the development of comprehensive guidelines for Good Urodynamic Practice for the measurement, quality control, and documentation of urodynamic investigations in both clinical and research environments. This report focuses on the most common urodynamics examinations; uroflowmetry, pressure recording during filling cystometry, and combined pressure–flow studies. The basic aspects of good urodynamic practice are discussed and a strategy for urodynamic measurement, equipment set-up and configuration, signal testing, plausibility controls, pattern recognition, and artifact correction are proposed. The problems of data analysis are mentioned only when they are relevant in the judgment of data quality. In general, recommendations are made for one specific technique. This does not imply that this technique is the only one possible. Rather, it means that this technique is well-established, and gives good results when used with the suggested standards of good urodynamic practice. *NeuroUrol. Urodynam.* 21:261–274, 2002. © 2002 Wiley-Liss, Inc.

Key words: urodynamics; standardisation; uroflowmetry; cystometry; pressure-flow studies

INTRODUCTION

A Good Urodynamic Practice comprises three main elements:

- A clear indication for and appropriate selection of, relevant test measurements and procedures
- Precise measurement with data quality control and complete documentation
- Accurate analysis and critical reporting of results

The aim of clinical urodynamics is to reproduce symptoms whilst making precise measurements in order to identify the underlying causes for the symptoms, and to quantify the related pathophysiological processes. By doing so, it should be possible to establish objectively the presence of a dysfunction and understand its clinical implications. Thus, we may either confirm a diagnosis or give a new, specifically urodynamic, diagnosis. The quantitative measurement may be supplemented by imaging (videourodynamics).

Urodynamic measurements cannot yet be completely automated, except for the most simple urodynamic procedure, uroflowmetry. This is not an inherent problem of the measurement itself, but is due to the current limitations of urodynamic equipment and the lack of a consensus on the precise method of measurement, signal processing, quantification, documentation, and interpretation. With the publication of this ICS Standardisation document on good urodynamic practice, it

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is expected that the necessary technological developments in automation will follow.

Urodynamics allows direct assessment of lower urinary tract (LUT) function by the measurement of relevant physiological parameters. The first step is to formulate the 'urodynamic question or questions' from a careful history, physical examination, and standard urological investigations. The patient's recordings of micturitions and symptoms on a frequency volume chart, and repeated free uroflowmetry with determination of post-void residual volume provide important

Urodynamic techniques were performed according to the 'Good Urodynamic Practice' recommended by the International Continence Society.

This report is from the Standardization Committee of the International Continence Society.

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noninvasive, objective information that helps to define the specific ‘urodynamic question’ or questions, prior to invasive urodynamics such as filling cystometry and pressure-flow studies.

Recommendations for good urodynamic practice are bullet pointed, inset, and printed in bold.

RECORDING MICTURITIONS AND SYMPTOMS

A *Micturition Time Chart* records the time of each micturition. The usefulness of such a record is significantly enhanced when the voided volumes are recorded in a *Frequency Volume Chart*. The *Bladder Diary* adds to this the relevant symptoms and events such as urgency, pain, incontinence episodes, and pad usage. Recording for a minimum of 2 days is recommended. From the recordings, the average voided volume, voiding frequency, and if the patient’s time in bed is recorded, day/night urine production and nocturia can be determined. This information provides objective verification of the patient’s symptoms, and furthermore, key values for plausibility control of subsequent urodynamic studies, for example, in order to prevent over-filling of the patient’s bladder.

UROFLOWMETRY

Uroflowmetry is noninvasive and relatively inexpensive. Therefore, it is an indispensable, first-line screening test for most patients with suspected LUT dysfunction. Objective and quantitative information, which helps one to understand both storage and voiding symptoms are provided by this simple urodynamic measurement.

Adequate privacy should be provided and patients should be asked to void when they feel a “normal” desire to void. Patients should be asked if their voiding was representative of their usual voiding and their view should be documented. Automated data analysis must be verified by inspection of the flow curve, artifacts must be excluded, and verification must be documented. The results from uroflowmetry should be compared with the data from the patient’s own recording on a frequency/volume chart. Sonographic estimation of post-void residual volume completes the noninvasive assessment of voiding function.

Normal Uroflow

Normal voiding occurs when the bladder outlet relaxes (is passive) and the detrusor contracts (is active). An easily distensible bladder outlet with a normal detrusor contraction results in a smooth arc-shaped flow rate curve with high amplitude. Any other shapes, such as curves that are flat, asymmetric, or have multiple peaks (fluctuating and/or intermittent), indicate abnormal voiding, but are not specific for its cause.

It is assumed that it is normal for the mechanical properties of a relaxed outlet to be constant, and that the properties can be defined by the dependency of the cross-sectional area of the

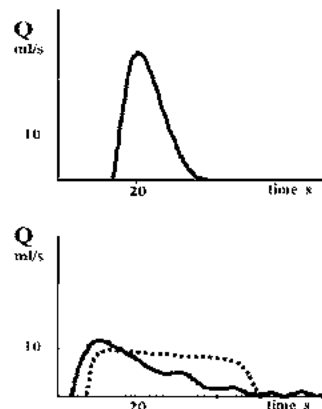


Fig. 1. Typical normal flow (top), constrictive flow (bottom, dotted line), compressive flow curve (bottom).

urethral lumen on the intraurethral pressure at the flow rate controlling zone (FRCZ). Typically, below the minimum urethral opening pressure (pmuo), the urethral lumen is closed. The lumen then opens widely with little additional pressure increase. With normal detrusor contractility and low intraurethral pressure, the normal flow curve is arc-shaped with a high maximum flowrate. (Fig. 1, top).

A normal flow curve is a smooth curve without any rapid changes in amplitude, because the shape of the flow curve is determined by the kinetics of the detrusor contraction, which arising from smooth muscle, does not show rapid variations. A decreased detrusor power and/or a constant increased urethral pressure will both result in a lower flowrate and a smooth flat flow curve. A constrictive obstruction (e.g., urethral stricture), with reduced lumen size results in a plateau-like flow curve. (Fig. 1, broken line).

A compressive obstruction with increased urethral opening pressure (e.g., benign prostatic obstruction) shows a flattened asymmetric flow curve with a slowly declining end part. (Fig. 1, bottom).

The same pattern may also originate from a weak detrusor in aging males and females. Fluctuations in detrusor contractility or abdominal straining, as well as variable outlet conditions, (e.g., intermittent sphincter activity) will lead to complex flow rate patterns.

Rapid changes in flowrate may have physiological or physical causes that owe to either changes in outlet resistance, for example, sphincter/pelvic floor contraction or relaxation, mechanical compression of the urethral lumen, or interference at the meatus, or to changes in driving energy, for example, abdominal straining. These intracorporeal causes lead to true flowrate changes. Rapid changes in flowrate may also be artifacts, when the flowrate signal is extracorporeally modified through interference between the stream and the collecting funnel, the flowmeter, movement of the stream across the

surface of the funnel, or patient movements. (see flow-curves in Figs. 3–8).

Accuracy of Uroflowmeters

Uroflowmetry measures the flow rate of the external urinary stream as volume per unit time in milliliters per second, (ml/s). The ICS Technical Report [Rowan et al., 1984] made technical recommendations with respect to uroflowmetry, but did not compare different flowmeters by specific testing. There are, however, differences in the accuracy and precision of the flow rate signals that depend on the type of flowmeter, on internal signal processing, and on the proper use and calibration of the flowmeter. The desired and actual accuracy of uroflowmetry should be assessed in relation to the potential information that could be obtained from the urinary stream compared to the information actually abstracted for clinical and research purposes. Some relevant aspects of the physiological and physical information contained in the urinary stream are outlined here.

The desired clinical accuracy may differ from the technical accuracy of a flow meter. The ICS Technical report recommended the following standards: a range of 0–50 ml/s for Q_{\max} , and 0–1,000 ml for voided volume, maximum time constant of 0.75 s; an accuracy of $\pm 5\%$ relative to full scale, although a calibration curve representing the percentage error over the entire range of measurement should be made available. However, technical specifications from the manufacturers are rare and often not in accordance with ICS recommendations: this situation should be rectified.

Furthermore, as most flowmeters are mass flow meters (e.g., a weight transducer or rotating disk), variations in the specific gravity of the fluid will have a direct influence on the measured flow rate. For example, urine of high concentration may increase apparent flow rate by 3%. With X-ray medium, the flow rate may be overestimated by as much as 10%. These effects should be corrected by calibration software.

Thus, since the overall accuracy of flow rate signals will not be better than $\pm 5\%$, it would not be meaningful to report a maximum flow rate to a resolution better than a full milliliter per second (ml/s). Under carefully controlled research conditions, a better resolution may be possible by flowmeter calibration and instrument selection. However, such improvements in resolution may not be required for routine clinical applications. The dynamic properties of most flowmeters will be good enough for free uroflowmetry. When pressure flow data are analyzed, however, the limitation in signal dynamics should be taken into account because they will be different for pressure than for flow. Flow signals have a much slower response, and are less accurate than pressure signals.

Problems in Urine Flow Rate Measurement

The problems in measurement, as well as the information that can be abstracted from the flow rate signal are rather dif-

ferent for free uroflowmetry compared to combined pressure/flow recordings.

In free uroflowmetry, the shape of the flow curve may suggest specific types of abnormality, but reliable, specific, and detailed information about the cause for abnormal voiding cannot be derived from a flow curve alone. Only when uroflowmetry is combined with intravesical and abdominal pressure recordings does it become possible, from the pressure–flow relationship, to analyze separately the contributions of detrusor contractility and bladder outlet function to the overall voiding pattern. (Figs. 3–8)

Urine flow rate measurement is affected by a number of important factors.

Detrusor Contractility

As the voiding function reflects the interaction between the relaxed outlet and the contracting detrusor, variation of both will affect the flow. For steady outflow conditions, all variations in flowrate are related to changes in detrusor activity alone. The detrusor contraction strength varies neurogenically and myogenically, and can cause significant variability in urine flow rate measurements. (Fig. 5).

Bladder Outflow Resistance

If detrusor, contractility is constant, then changes in outflow resistance will lead to changes in flow rate, for example, in patients with detrusor–sphincter dysynergia (Figs. 3, 7, 8).

Bladder Volume

As the bladder volume increases and the detrusor muscle fibers become more stretched, there is an increase in the potential bladder power and work associated with a contraction. This is most pronounced in the range from empty up to 150–250 ml bladder filling volume. It appears that at volumes higher than 400–500 ml, the detrusor may become overstretched and contractility may decrease again. Therefore, Q_{\max} is physiologically dependent on the bladder volume. This dependency will vary between individuals and with the type and degree of pathology, for example, in constrictive obstruction, Q_{\max} is almost independent of volume, and in compressive obstruction, the dependency becomes weaker with increasingly obstructed outlet conditions and lower flow rate.

Technical Considerations

The flow rate signal is influenced by the technique of measurement and by signal processing. The external urinary stream should reach the flowmeter unaltered and with minimal delay. However, any funnel or collecting device, as well as the flowmeter, will inevitably introduce modifications to

the flow rate recording. Physically, the external urinary stream breaks into drops not far from the meatus. This fine structure of the stream has a high frequency, which can be assessed by drop spectrometry, and contains interesting information. For standard uroflowmetry, however, such high frequencies should be eliminated by signal processing.

For free uroflowmetry, all intracorporeal modulations of the flow rate are physiological artifacts and should be minimized, for example by asking the patient to relax and not to strain. Nevertheless, certain dynamic patterns of intracorporeal modulations can provide information about functional obstruction, for example, typical patterns of the detrusor-sphincter dyssynergia, or abnormal straining. This information may be lost by excessive filtering or during analog to digital A/D conversion with a filter speed of less than 10 Hz. The precise interpretation of dynamic variations in the flow rate signal is only possible when the flow rate is viewed together with the simultaneously recorded pressure signals. Thus, only in combined pressure–flow recordings can the details of the flow signal be fully understood.

For the determination of the ‘true’ maximum flow rate value, particularly during free flow, such high frequency signal variations are more likely to be misleading, and consequently they should be suppressed electronically.

Recommendations for Uroflowmetry

In order to facilitate the recording of urine flow rate and pattern recognition of flow curves, it is recommended that graphical scaling should be standardized as follows:

- one millimeter should equal 1 s on the x-axis and 1 ml/s and 10 ml voided volume on the y-axis.

With respect to the technical accuracy of uroflowmeters, it is meaningful for routine clinical measurements to read flowrate values only to the nearest full ml/s and volumes to the nearest 10 ml.

In order to make electronically-read Q_{\max} values more reliable, comparable, and clinically useful, we recommend internal electronic smoothing of the flow rate curve. It is recommended that:

- a sliding average over 2 s should be used to remove positive and negative spike artifacts.

If curves are smoothed by hand, the same concept should be applied. That is, when reading Q_{\max} graphically, the line should be smoothed by eye into a continuous curve so that in each period of 2 s, there are no rapid changes. Such a smoothed, clinically-meaningful maximum free flow Q_{\max} will be different (lower) from the peak value in the flow rate recording of electronic instruments currently available. (see Figs. 2, 5, 6, 8).

It is recommended that:

- only flow rate values, which have been ‘smoothed’, either electronically or manually, should be reported.

If a maximum flow value is determined electronically by simple signal peak detection without the recommended electronic smoothing, it should be labeled differently, $Q_{\max,raw}$. Such raw data has meaning only if a detailed specification of the type of flowmeter used is given.

The interpretation of any dynamic variation (signal patterns) in free flow will rely on personal experience, can be only descriptive, and in general will remain speculative.

For the documentation of the results of uroflowmetry, the following recommendations are made:

- Maximum (smoothed) urine flow rate should be rounded to the nearest whole number (a recording of 10.25 ml/s would be recorded as 10 ml/s);
- Voided volume and post void residual volume should be rounded to the nearest 10 ml (a recording of a voided volume of 342 ml would be recorded as 340 ml);
- The maximum flow rate should always be documented together with voided volume and post void residual volume using a standard format: VOID: Maximum Flow Rate/Volume Voided/Post Void Residual Volume.

For example, the automatically detected flows, $Q_{\max,raw}$, are 16.6 and 21.3 ml/s with voided volumes 86 and 182 ml, respectively. The smoothed Q_{\max} values are 8 and 17 ml/s and should be reported with voided volumes of 90 and 180, respectively, and the estimated residuals as VOID1 = 8/90/0 and VOID2 = 17/180/20 (see Figs. 2, 5, 6).

The adoption of these standards will aid the interpretation of uroflowmetry results. If data are not available, then a hyphen should be used, for example, if only the voided volume is known, VOID:—/340/— or if the voided volume was missing, VOID: 10/—/90.

- If a flow/volume nomogram is used, this should be stated and referenced.

Uroflowmetry data from other than free flow, for example, measured in combination with intravesical pressure should be reported with an additional descriptive index, p, i.e., $Q_{\max,p}$, for pressure–flow recording.

INVASIVE URODYNAMICS: FILLING CYSTOMETRY, PRESSURE–FLOW STUDY OF VOIDING

Introduction

Invasive urodynamic procedures should not be performed without clear indications and the formulation of specific urodynamic question(s). This process will usually be aided by the a priori completion of a frequency volume chart and free uroflowmetry. There are certain key recommendations, which will lead to the performance of a successful urodynamic study.

- A good urodynamic investigation should be performed interactively with the patient. It should be established by

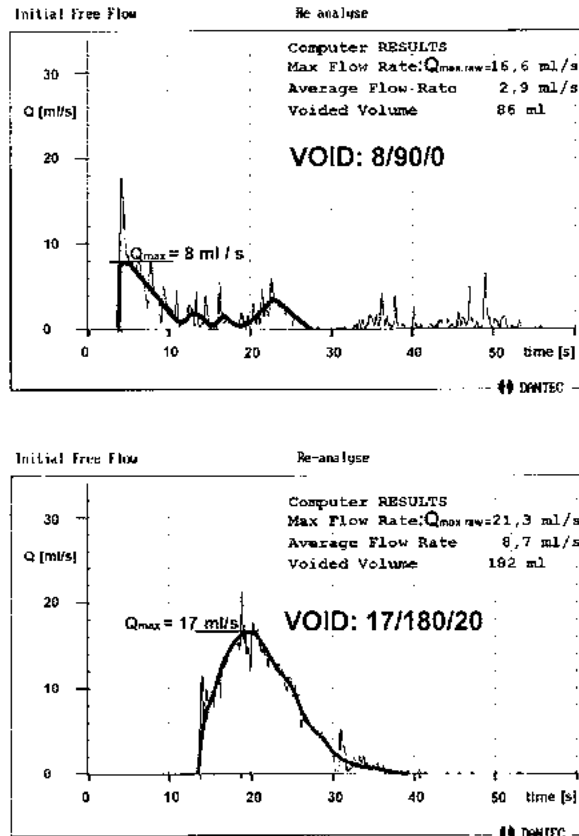


Fig. 2. Exclusion of artifactual spikes in the flow curve, $Q_{max,raw}$, and determination of a clinically relevant maximum flow rate, Q_{max} , by manual smoothing. The results from uroflowmetry should be reported in the standard format: $Q_{max}/V_{void}/V_{res}$.

discussion with the patient that the patient's symptoms have been reproduced during the test;

- There should be continuous and careful observation of the signals as they are collected, and the continuous assessment of the qualitative and quantitative plausibility of all signals;
- Artifacts should be avoided, and any artifacts that occur should be corrected immediately. It is always difficult and is often impossible to correct artifacts during a retrospective analysis. Furthermore, it is more time consuming than if the signals are continuously observed and tested at regular intervals and artifacts recognized during the urodynamic study and corrected.

At present, ambulatory urodynamic monitoring has to rely on retrospective quality control and artifact corrections. However, in principle, the same quality criteria apply for ambulatory urodynamic monitoring as for standard urody-

namics [van Waalwijk et al., 2000]. This makes a consensus on quality even more important, because only when such criteria are precisely defined can they be implemented in an "automated intelligent" ambulatory system.

Quality control relies on pattern recognition and a knowledge of normal values as well as prior identification of useful information obtained from noninvasive urodynamics and all other sources relevant for the urodynamic question. Thus, before invasive urodynamics, a frequency volume chart should be completed and multiple free flows should be evaluated. Useful information obtained from noninvasive testing includes typical voided volumes and post-void residual volumes as well as the expected values for Q_{max} . This information should be used for the control of subsequent invasive studies. Only by good preparation can it be assured that (a) the proper answers to the urodynamic questions will be obtained before the study is terminated and (b) necessary modifica-

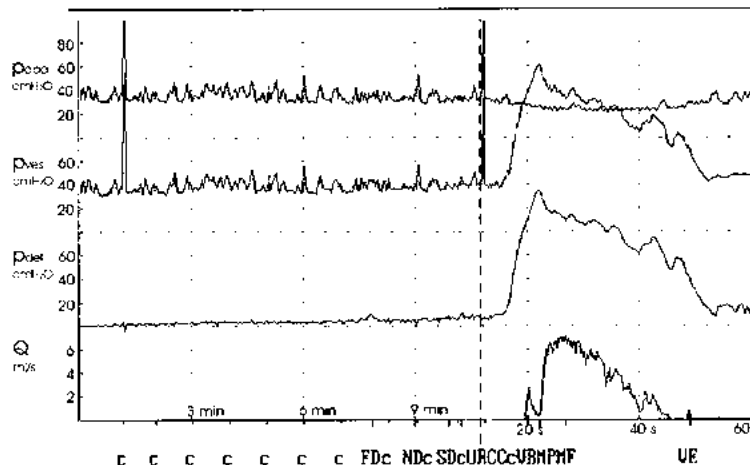


Fig. 3. Full recording of filling and voiding. Starting with initial values for p_{ves} , p_{abd} of 32 cmH₂O in the typical range for a standing patient with zero p_{det} ; testing signal quality with a vigorous cough at beginning, and regularly repeated (here less strong) coughs. Additionally, the pressure recordings show the typical pattern of a talking patient, while the p_{det} trace is unaffected; a weak contraction at first desire FD; another vigorous cough before voiding; beginning of flow shows dyssynergic sphincter activity as proven by decrease in flow with increase in p_{det} .

tions, additions, or repetitions of measurements will have been performed in order to derive the necessary information.

The effective practice of urodynamics requires: (a) a theoretical understanding of the underlying physics of the measurement, (b) practical experience with urodynamic equipment

and procedures, (c) an understanding of how to assure quality control of urodynamic signals, and (d) the ability to analyze critically the results of the measurements. Because urodynamics deals largely with mechanical measurements such as pressure and volume and their related changes in time, and

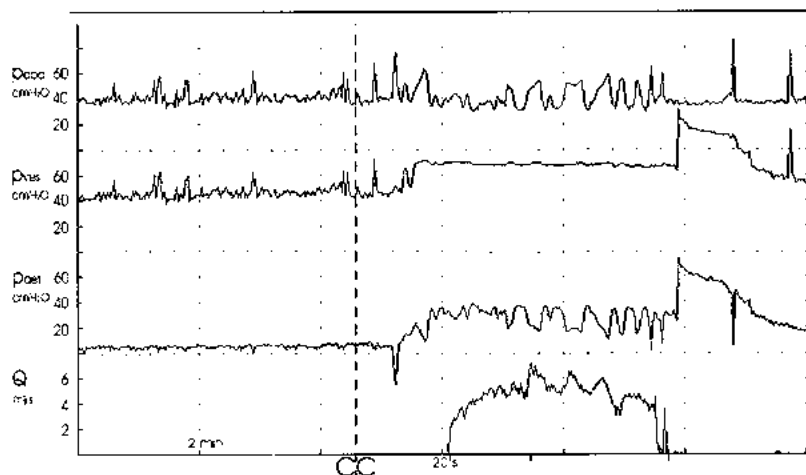


Fig. 4. Good recording quality until cystometric capacity CC is reached; at second cough before voiding the intravesical signal is lost (no response in p_{ves} , negative spike in p_{det}). Dead p_{ves} – signal during voiding, which is “live” again only at second cough after voiding. Thus, pressure–flow study is lost. Careful observation of signals would have made it possible to interrupt the study immediately when signal failed and correct this problem before voiding starts.

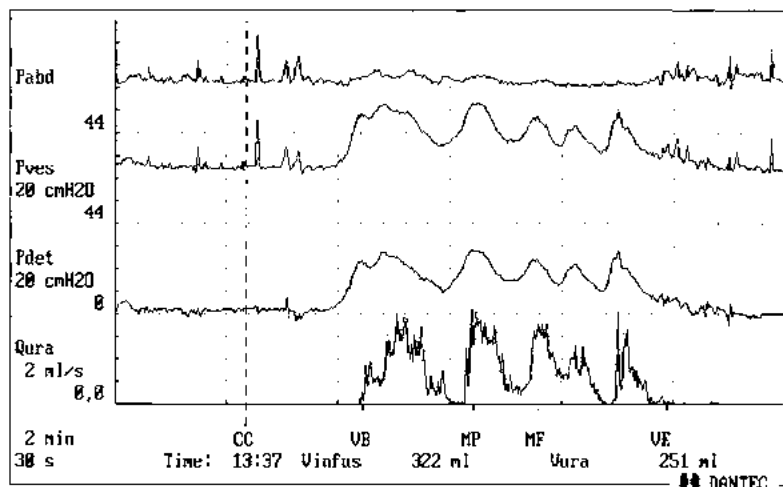


Fig. 5. Variable flowrate due to varying detrusor contraction strength. VOID: 7/250/70.

because many analytical models use mechanical concepts such as resistance to flow or contraction power, it is essential that the nature of these measurements and concepts, in particular for pressure and flowrate, are understood. Therefore, in addition to a comprehensive understanding of anatomy and physiology, some basic knowledge of biomechanics and physics is required.

The quality control of urodynamic measurements must be approached on a holistic basis. Different types and levels of data

quality and plausibility control should be used: (a) on a physical and technical level, (b) on a biomechanical level, and (c) on a pathophysiological clinical level. A common problem in urodynamics is that clinicians often proceed immediately to a clinical interpretation, i.e., to level c without a critical analysis of the potential pathophysiological information content, without considering the plausibility of the signals (level a), without considering the biomechanical context of the measurements (level b), and without taking into account the physical properties of the

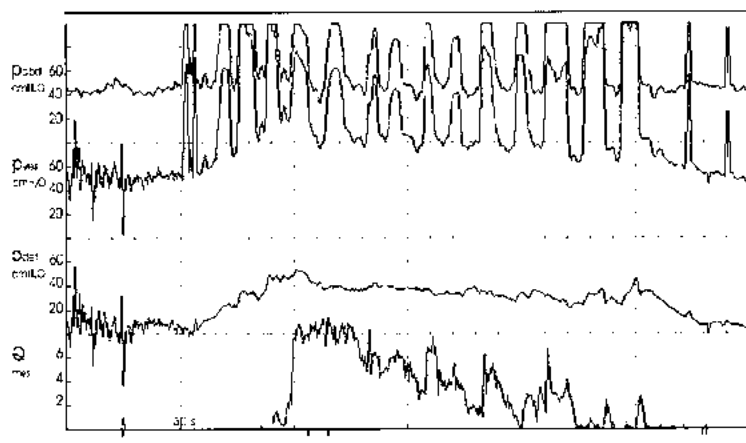


Fig. 6. The first part of the traces shows typical bi-phasic movement artifacts. The two coughs before voiding prove good recording quality. The typical picture of an unobstructed voiding: a weak detrusor contraction with P_{det} of 40 cmH₂O and a Q_{max} of 9 ml/s is supported by vigorous straining, which causes some variability in flow (VOID: 9/380/100).

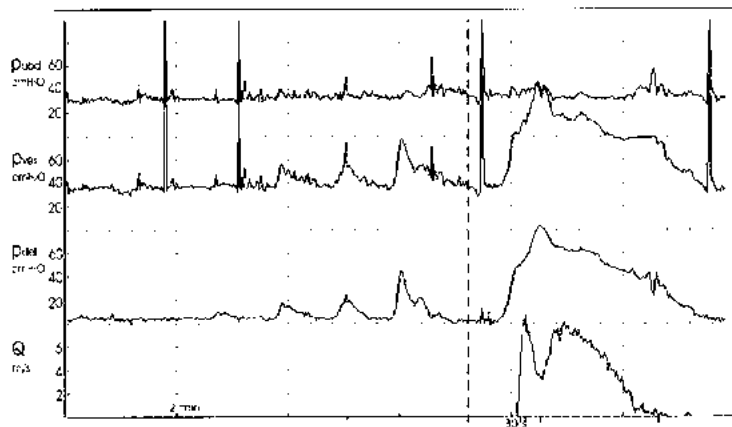


Fig. 7. A good recording showing the typical pattern of increasing detrusor overactivity and a dyssynergic event during voiding.

parameters, technical limitations, and accuracy of the signals. Therefore, it is recommended that:

- Invasive urodynamics should not be performed without precise indications and well-defined 'urodynamic questions' that are to be answered by the results of the urodynamic study.

Measurement of Urine Flow Rate During Pressure–Flow Studies

The usefulness of the concept of a FRCZ for data analysis requires that the recorded pressure and flow rate signal be synchronized with respect to the FRCZ [Griffiths et al. 1997]. Normally, no measurable time delay will exist between

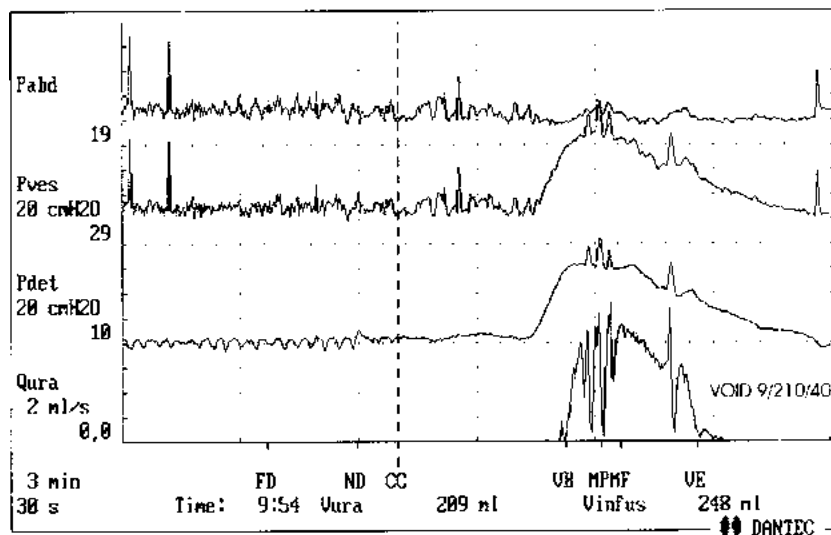


Fig. 8. High quality recordings allow detailed interpretation. The typical pattern of rectal activity becomes clearly visible in P_{det} . The flow artifacts can be identified as dyssynergic events and manually corrected from $Q_{max,raw} = 11.2$ ml/s to $Q_{max} = 9$ ml/s.

the intravesical pressure signal and the actual flow at the FRCZ. However, a significant delay is to be expected for the typical urodynamic flow rate recorded extracorporeally. This delay will vary with anatomy, pathology, flow rate, and the set-up for measurement. Our understanding of the actual dynamics of flow rate changes is limited, and the relatively slow response of most flow meters may not be sufficient to match the dynamics of the much-faster pressure signal. The actual time difference may be from 0.5 to 2 s; the time delay between urethral closure and the end of any flow recording may be much longer, particularly in prostatic obstruction and terminal dribbling than between the opening of the urethra and the start of a flow rate signal. Therefore, we recommend the use of more descriptive terminology for synchronizing pressure and flow values, such as $p_{\text{det},Q_{\text{beg}}}$ for the pressure at which flow begins instead of $p_{\text{det},\text{open}}$, and $p_{\text{det},Q_{\text{end}}}$ when flow ends instead of $p_{\text{det},\text{close}}$. The time delay correction needs to be considered when analyzing pressure flow studies [Griffiths et al. 1997].

In average, the maximum flow rate Q_{max} recorded during PF studies, ($Q_{\text{max},p}$), is lower than during free flow (Q_{max}). This, however, is not due simply to a mechanical increase of outflow resistance by the intraurethral catheter, because such a difference is also found in suprapubic PF studies. A difference has also been reported between $Q_{\text{max},p}$ during conventional and ambulatory urodynamics. This indicates more complex causes, possible psychogenic, but also physiologic, for example, that a difference in detrusor contraction strength may be involved, and that the fast filling rate used in clinical studies may lead to reduced contractility. This could also explain the difference in results between conventional and ambulatory studies.

Measurement of Intravesical and Abdominal Pressure

- It is recommended that there is strict adherence to the ICS standardization of zero pressure and reference height. Only then can pressure recordings be compared between patients and centers.

Zero pressure and reference height are concepts which are often confused in urodynamics. For example, by use of the misleading term “zero reference height”. As both are independent features of pressure, they must be considered separately, and both must follow recommended ICS methodology.

- Zero pressure is the surrounding atmospheric pressure.

Zero pressure is the value recorded when a transducer is open to the environment when disconnected from any tubes or catheters, or when the open end of a connected, fluid-filled tube is at the same vertical level as the transducer. Only then can a “set zero” or “balance” be performed.

- The reference height is defined as the upper edge of the symphysis pubis.

The reference height is the level at which the transducers must be placed so that all urodynamic pressures have the same hydrostatic component. It is often argued that it does not make a difference for the most relevant parameter, p_{det} , if the same error is introduced to p_{ves} and p_{abd} , as they tend to cancel each other out. This is not an acceptable argument. The hydrostatic pressure is real and important, and inevitably plays a role in any intracorporeal pressure recording. Many important aspects of quality and plausibility control, such as typical resting value ranges at different patient position, are based on the proper recording of pressures, and will not apply if pressures are not recorded according to ICS standards. Also, it is only meaningful to subtract one pressure from the other, for example ($p_{\text{ves}} - p_{\text{abd}} = p_{\text{det}}$), when both are recorded to the same reference level.

Pressure Transducers

Urodynamic techniques were developed using external pressure transducers connected to the patient with fluid-filled lines, allowing easier compliance with the standards of correct zero and reference height. Catheter mounted pressure transducers, so-called microtip transducer catheters have become popular due to their apparent higher accuracy, better dynamic resolution, and their apparent independence from hydrostatic pressure. A catheter mounted pressure transducer is an advantage for dynamic recordings of urethral pressures during coughing (stress profiles) as well as for ambulatory urodynamics in mobile patients. Here only the application of catheter mounted pressure transducers for intravesical and abdominal pressure recordings will be discussed as urethral pressures are dealt with in a separate report [Lose et al., 2002].

All aspects of urodynamic pressure recording outlined in the preceding section are valid and independent of transducer type. It is impossible to define the precise position of an intravesical and a rectal catheter mounted pressure transducers at to place them at any common level, and impossible to position them at the standard level of the upper boarder of the symphysis pubis. It has become popular to circumvent this problem by setting the catheter mounted pressure transducers to zero pressure when inside the body at the start of pressure recording. This, however, means that both the standard zero pressure as well the reference level are ignored, so that such recorded pressure cannot be compared between patients or centers. The fact is, the initial intravesical and abdominal resting pressures are real, are different between patients, and depend significantly on patient's position. Thus, there are significant potential errors; by ignoring the correct atmospheric zero pressure, an error of up to 50 cmH₂O, and as the reference height of the catheter mounted pressure transducers is usually undetermined, another potential error of 10 cmH₂O is possible for a full bladder can occur. In addition, when a study starts with zero abdominal pressure then the commonly observed abdominal pressure decrease at pelvic floor relaxation during voiding will evidently result in negative abdominal pressure values, and thus in p_{det} being higher than p_{ves} .

The same problems of apparent independence from the existing hydrostatic pressure also applies to air-filled catheters and/or connection tubings. Due to the absence of a water column between the balloon-covered opening on the catheter and the external transducer, the reference height in an air-filled system will refer to the position of the sensing balloon on the catheter and not to the external transducer.

- It is recommended that for intravesical and abdominal pressure recording external transducers connected to fluid-filled tubings and catheters be used. If microtip or air-filled catheters are used, any deviation from standard zero and reference level should be minimized and taken into account at the time of data analysis.

Urodynamic Catheters

Comparison between patients and urodynamic studies performed in different centers would be facilitated by the use of standard catheters. It is recommended that:

- For the measurement of intravesical pressure and for bladder filling, the standard catheter for routine urodynamics is a transurethral double-lumen catheter.

Only in small children and patients with severe constrictive obstruction (stricture) does suprapubic pressure recording have clear advantages. Intraurethral catheters should be as thin as possible, limited only by the practicality of insertion and by internal lumen sizes, which should be sufficiently large to avoid excessive damping of pressure transmission and to achieve the desired filling rate with standard pumps. A 6-Fr double lumen catheter is the smallest practical size at present.

The major advantage of a double lumen catheter is that the fill/void sequence can be repeated without the need for re-catheterization. Note that the use of a 6-Fr double lumen catheter can limit the infusion rate during cystometry to 20–30 ml/min, as a typical roller pump may not manage to transport a higher perfusion rate through such a small lumen. This can result in an incorrect filling volume being indicated by the machine, when the filling volume is calculated from the pump setting. For example, with a filling rate set at 60 ml/min and an actually achieved filling rate of 30 ml/min, the machine will show double the filling volume. Thus after voiding, a high calculated residual will occur. With some equipment, higher filling rates are possible; it is essential that any system should be critically tested to (a) measure the maximum filling rate that can be achieved by a particular catheter attached to an individual pump and (b) correct or calibrate the indicated infused volume.

The use of two separate tubes for filling and recording is less convenient. Removing the larger filling tube for voiding may appear to be an advantage because only a single small tube is left in the urethra. However, there are no data to suggest that, for example, in a compressive obstruction such as BPO, a 6-F catheter has detrimental influence on the pressure

or flow data. There are, however, data suggesting that results from a single study may be misleading. A double lumen catheter facilitates a second fill/void study to establish reproducibility. Re-introduction of the separate filling tube for a repeated study is more invasive and complicated.

- The use of a rectal balloon catheter is recommended for the measurement of abdominal pressure, p_{abd} .

Although there are various methods for the successful recording of abdominal pressures, a flaccid, air-free balloon in the rectal ampulla gives a suitable signal for p_{abd} to determine a meaningful p_{det} when p_{ves} is measured synchronously ($p_{det} = p_{ves} - p_{abd}$). In females, vaginal recording may be more acceptable and provides comparable results. The recording of p_{abd} allows the measurement of any abdominal (i.e., perivesical) pressure component during changes in intravesical pressure. The role of the balloon is to maintain a small fluid volume at the catheter opening and to avoid fecal blockage, which can prevent or impair pressure transmission to the transducer. Additionally, as the rectal ampulla and the vagina are not homogeneously fluid filled spaces, the balloon prevents pressure artifacts arising from contact between the catheter opening and the wall tissue. The balloon serves this function best when it is filled only to 10–20% of its unstretched capacity. Overfilling and elastic distention of the balloon is the most common mistake in abdominal pressure recording. The resultant high balloon (not abdominal) pressure will produce a misleading pressure reading. Such an artificially-elevated balloon distention pressure can be avoided by making a small hole in the balloon, although this is unnecessary if the balloon is filled properly as described above. It is also possible to record reliable abdominal pressure with a very slowly perfused (<2 ml/min) open ended catheter. However, excessive fluid volume in the rectal ampulla may cause problems.

Equipment: Minimum Requirements for Filling Cystometry and Pressure–Flow Studies of Voiding

The ICS has not yet specified definite technical standards in respect of minimum requirements for filling cystometry and pressure flow studies beyond the ICS Technical Equipment Report [Rowan et al. 1997] and the appendix to the ICS document on pressure flow [Griffiths et al., 1997], where a data exchange software standard is recommended. Some further aspects will be discussed in more detail here.

Equipment Recommendations

The minimum recommended requirements for a urodynamic system are:

- three measurement channels, two for pressure and one for flow;
- a display (on printer and/or monitor) and secure storage of three pressures (p_{abd} , p_{ves} , p_{det}) and flow (Q) as tracings against time;

- infused volume and voided volume may be shown graphically or numerically;
- on-line display of pressures and flow, with adequate scale and resolution; scales must be clearly given on all axes; no information should be lost electronically when tracings go off-scale on display;
- possibilities to record standard information about sensation and additional comments (event recording).

Meaningful plausibility assessment and quality control is possible only when the measured and derived signals are displayed continuously as curves over time, without delay (in real time), as the examination proceeds. Each displayed curve and number should be labeled according to ICS standards with clear scaling of amplitudes and the time axis. The following sequential position of tracings is suggested: p_{abd} at the top, then p_{ves} , p_{det} and Q (see Figs. 3–8). It is least important when p_{abd} goes off-scale and is cut off (Fig. 6). Additional parameters such as EMG, bladder filling, and voided volumes can be displayed either as curves or digitally as numbers.

The following minimum technical specifications are recommended:

- Minimum accuracy should be ± 1 cmH₂O for pressure and $\pm 5\%$ full scale for flow and volume;
- Ranges of 0–250 cmH₂O, 0–25(50) ml/s, and 1,000 ml for pressure, flow, and volume, respectively;
- The software must ensure that no information for pressures up to 250 cmH₂O and for flow rates up to 50 ml/s is lost internally even when not displayed and that off-scale values are clearly identified;
- An analog/digital (A/D) frequency of 10 Hz per channel as the lower limit for pressure and flow;
- A higher frequency (minimum 20 kHz) is necessary for recording EMG;
- Calibration of all measurements should be possible.

The scalings should be kept unchanged as much as possible, because urodynamic data quality control is based on pattern recognition, and the recognition of patterns depend on scaling. Therefore, it is recommended that:

- During recording and for analysis, minimum scaling for pressure be of 50 cmH₂O per cm, for flow 10 ml/s per cm, and for the time axis 1 min/cm or 5 s/mm during filling and 2 s/mm during voiding.

To enable a retrospective judgment of the curves, urodynamic measurements should be documented as curves over time with comments and explanations. It is usually insufficient to document urodynamic measurements by a few numerical values alone. The same amplitude of scaling should be used for all documentation, although the time axis may be compressed. Only if there is no relevant information to be lost by reducing resolution, for example, during filling, the time scale can be compressed.

For a print-out, maximum full scale deflections of 200 cmH₂O, 50 ml/s, and 1,000 ml are sufficient for pressure, flow and volume, respectively. In most cases, half the maximum full scale will be sufficient to show all relevant parts of curves. Line resolution should be better than 0.10 mm.

During interventions, for example, interruption of bladder filling or manipulation of catheters, the continuation of both measurement and recording must always be possible.

On-line recording of comments should be possible, to complete the documentation.

Calibration of Equipment

The need to calibrate pressure transducers, flowmeters, and pumps cannot be stated; simply “yes” if there is a need or “no” there is not. The specification of the manufacturer should be studied. Two aspects must be considered: the intended accuracy of the system and the investigator’s experience with the system. If a new system is installed or new transducers are being used, it is recommended that regular calibration be carried out. If experience with daily calibration shows that the potential error is small (e.g., < 2 cmH₂O), then it will be sufficient to calibrate once a month. However, calibration should not be ignored and good urodynamic equipment makes it technically possible to perform a calibration. Calibration should not be confused with simple ‘zero balancing’, which is only one part of a calibration. In addition to setting the zero, it must possible to check and adjust the amplitudes of all measurement channels, i.e., to calibrate all signals.

Calibration of a flowmeter can be achieved by pouring a precisely measured volume at a constant flow into the flowmeter, typically 400 ml in 20–30 s (at 15–20 ml/s) and checking the recorded volume. Special constant-flowrate bottles are available for flow calibration. Similarly, one can test a pump by measuring the time to deliver a known volume, for example, 100 ml into a measuring cylinder. It is recommended that pump calibration be performed with the filling catheter connected. Such a pump calibration can only be as good as the cylinder used, which needs to have good resolution and be accurate. Some measuring beakers that are usually available in clinics are not accurate.

Pressure Signal Quality Control: Qualitative and Quantitative Plausibility

It is very important to observe and to test signals carefully and to correct any problems before starting the urodynamic study. If the signals are perfect at the beginning of the study, they usually remain so without the need for major intervention. If the signals are not perfect, remedial action must be taken. If a quality problem does not disappear at once, when filling commences, it will usually deteriorate further during the study.

Conscientious observation of the patient and of the signals, in particular p_{det} during all parts of the study, together with

continuous signal testing, are the keys to high quality urodynamic. The first aim is to avoid artifacts and the second to correct the source of all artifacts immediately when they occur.

The following three criteria form the minimum recommendations for ensuring quality control of pressure recordings:

- Resting values for abdominal, intravesical, and detrusor pressure are in a typical range (see below);
- The abdominal and intravesical pressure signals are 'live', with minor variations caused by breathing or talking being similar for both signals; these variations should not appear in p_{det} ;
- Coughs are used (every 1 min. or, for example, 50 ml filled volume) to ensure that the abdominal and intravesical pressure signals respond equally. Coughs immediately before voiding and immediately after voiding should be included.

When standards are followed, i.e., with the transducer zeros set to atmospheric pressure, and the transducers placed at the level of the upper edge of the symphysis, a typical range for initial resting pressures values for p_{ves} and p_{abd} is (Schäfer, unpublished communications):

- supine 5–20 cmH₂O.
- sitting 15–40 cmH₂O.
- standing 30–50 cmH₂O.

Usually both recorded pressures are almost identical, so that the initial p_{det} is zero, or close to zero, 0–6 cmH₂O in 80% of cases and in rare cases up to 10 cmH₂O [Liao et al., 1999].

All initial pressure values should be verified and patients' position should be documented on the urodynamics trace.

All negative pressure values, except when caused by rectal activity, should be corrected immediately. It should always be kept in mind that p_{abd} is recorded not to know the actual rectal pressure, but to eliminate the impact of (abdominal) pressure changes on p_{ves} . The principal aim is to determine the detrusor pressure, p_{det} , which is the pressure in the bladder without the influence of abdominal pressure. Therefore, p_{det} cannot be negative.

By talking to the patient during the study, the proper dynamic response in the pressure signals can be observed and is "automatically" documented (see Figs. 3, 4, 8).

Problem Solving

If either detrusor or rectal contractions occur, the recorded pressures in p_{ves} and in p_{abd} will be different. Such changes can be identified and interpreted with sufficient accuracy and reliability only when the patient is observed and the relation between signal changes and patient sensation/activity are checked for plausibility and documented. Any pressure change caused by smooth muscle contractions will show a "smooth" pattern, (Figs. 5, 7, 8) i.e., there should be no rapid ("stepwise") changes (Fig. 4). If pressures increase or decrease step-wise, or with a constant slope over a long period of time,

a nonphysiological cause, such as catheter movement, should be considered.

If a sudden drop or increase occurs in either the p_{ves} or p_{abd} signal, the usual cause is the movement, blockage (Fig. 4), or disconnection of a catheter. When the patient changes position, sudden changes in resting values occur and are seen equally in both pressure signals. If p_{ves} (without change in p_{abd}) increases slowly—as typical for a low compliance bladder—it is important to test for any other possible cause for a slow pressure increase. One cause could be a problem with the intravesical catheter measurement, for example, the hole for the pressure conducting lumen is slowly moving into the bladder neck region. This should be assessed by asking the patient to cough, if there is no other apparent artifact. Furthermore, it is recommended that bladder filling is stopped, if the filling rate was above a physiological limit of 10 ml/min. If the value of p_{ves} drops after filling is stopped, it is likely that 'low compliance' was, at least in part, related to fast filling.

There are several common problems that must be solved before the study is started or when observed during a study:

Problem: Initial resting p_{det} is negative, for example, –5 cmH₂O Possible explanations:

- because p_{abd} is too high

Solution: If p_{ves} is in the typical range, and both pressures are 'live', open the valve in the abdominal line and drain 1 or 2 drops from the rectal balloon filling volume. This will usually cause p_{abd} to fall to a proper value. If not, gently re-position the rectal balloon and/or make a small hole in the balloon.

- because p_{ves} is too low

Solution: This may be due to air bubbles trapped in the catheter, the catheter not being in the bladder, or the catheter being blocked/kinked. Gently flush through the p_{ves} line (max. 10 ml). It is very important to flush slowly while observing the pressure signal because pressures above 300 cmH₂O may damage the transducer. If this does not solve the problem, add some more volume to the bladder via the filling lumen. If resistance to filling is high and it does not drain easily when opened, it will be necessary to check catheter position, and to re-position the catheter, if necessary.

Problem: Initial p_{det} too high, for example, 15 cmH₂O

Possible explanations:

The key problem here is indicated by the measurement of 15 cmH₂O. The situation is different from the clear statement that ' p_{det} cannot be negative', as we do not have a definite upper limit for the normal maximum 'resting' value for p_{det} . Thus, we can only follow the present guidelines that in most tests, in an empty bladder p_{det} is between 0–5 cmH₂O, and in some 90% it is between 0–10 cmH₂O. For any higher value, stringent plausibility checking must be applied. If the patient has no detrusor overactivity, a p_{det} of 15 cmH₂O is unlikely to be valid and there may be a signal problem. First

check, if p_{abd} and p_{ves} are in the expected ranges. For example, if in a standing patient, initial p_{ves} is 30 cmH₂O and p_{abd} is 15 cmH₂O, then by experience the value of p_{abd} is too low (because p_{abd} is too low). If in a supine patient p_{abd} is 10 cmH₂O and p_{ves} is 25 cmH₂O, then the value of p_{ves} is too high (because p_{ves} is too high). Check the zero balance and proper signal response to coughing for both signals.

- because p_{abd} is too low

Solution to p_{abd} being too low: Very slowly flush the rectal balloon with 1 or 2 ml.

- because p_{ves} is too high.

Solution to p_{ves} being too high: This problem can be related to a misplaced catheter, a kink in the catheter, or contact with the bladder wall in an empty bladder, which occludes the eyehole(s) of the catheter. Proceed according to the solution for p_{ves} being too high, in the first example above.

If no signal problem can be identified, the clinical study may be started, but the p_{det} signal deserves particular attention. If compliance is normal and the bladder normal at filling, then it is very important to record and check, for some period after the micturition, the post-voiding resting value of p_{det} . Only if an elevated p_{det} is perfectly reproducible for repeated filling and voiding studies can it be accepted. However, it is most likely that a high resting p_{det} will not be reproducible and will be corrected by the measures described above.

In summary, if any resting value or cough response does not fit the usual values or patterns, it should be corrected before bladder filling is started. If this is not possible, the signals must be observed even more carefully and every effort made to reveal the potential source of error or artifact during the study.

Retrospective Artifact Correction

In principle, a good p_{det} signal requires only that p_{ves} and p_{abd} show the same fine structure and quality of signals before filling, during filling, and after a voiding. (Figs. 3, 4, 7, 8) Both p_{ves} and p_{abd} must have the same zero and reference level. The most common mistake is to set (*balance*) the initial pressure values of p_{ves} and p_{abd} to zero with the catheters connected to the patient instead of setting zero to atmospheric pressure. This results in incorrect p_{ves} and p_{abd} . If this is done, urodynamic studies cannot be compared between centers and between patients. Although it may seem convenient and easy to start with a value of p_{det} as zero, this practice will lead to problems later in the test. As soon as pelvic floor relaxation occurs, which is particularly common during voiding, the value of p_{abd} , if starting at zero, becomes negative. With a negative p_{abd} , p_{det} will be higher than p_{ves} , a conceptually meaningless result. Furthermore, it will then be impossible to correct a negative p_{abd} . Cough tests at regular intervals, particularly before voiding and after voiding, document the dynamic response of the pressure channels and are fundamentally important.

A typical physiological artifact that can be easily recognized is a rectal contraction. Rectal contractions are usually of low amplitude and may or may not be felt by the patient (Fig. 8). The value of p_{abd} shows a phasic rise with no change in the p_{det} signal—a potentially confusing fall in p_{det} results from the electronic subtraction, but this is, of course, an artifact. Usually rectal contractions are relevant only because they may be misinterpreted as detrusor overactivity (Fig. 8); they have no relevance to voiding.

Biphasic spikes as a response to cough tests are another example of artifacts that are easy to correct. However, any other artifacts such as a signal which is nonresponding (dead), has stepwise changes in pressure, or has negative pressures, often cannot be corrected or can be corrected only with a lot of speculation about the underlying causes of the problem. Studies with such artefacts, should be repeated see the next section).

Retrospective corrections require the same strategies for plausibility control as during recording, but then they are much more difficult and less successful to perform.

A few common artifacts (e.g., rectal activity, biphasic spikes at cough tests, or insufficient p_{abd} response during straining) can be accepted during the study as they can be corrected retrospectively. Usually, this is easier to do manually than through a computerized system.

Urodynamic Computer Software

Computer applications should allow the easy use of even the most complicated analytical algorithms. However, most of the software offered by the urodynamic equipment industry is neither original nor validated. The software may, in fact, not do what the original developer(s) of the algorithm intended. Therefore, it is recommended that:

- When analytical urodynamic software is used to perform data analysis according to any published concept, the source of the software should be specified. It should also be clearly stated if the software has been validated, i.e., proven to provide results consistent with the algorithms to which the analyses are attributed.

STRATEGY FOR REPETITION OF URODYNAMIC TESTS

- It is recommended that a urodynamic test should be repeated if the initial test suggests an abnormality, leaves the cause of troublesome lower urinary tract symptoms unresolved, or if there are technical problems preventing proper analysis.

It may not be necessary, however, to repeat a study, which beyond any doubt, confirms the expected pathology, for example, detrusor overactivity which correlates with the patient's symptoms. However, if the study is inconclusive, then the

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consequences of not finding a clear answer to the urodynamic question(s) should be considered. If an invasive therapy is planned, the urodynamics should be repeated. Therefore, it is necessary to analyze the signals during the study and document the study immediately upon its conclusion. Only then is it possible to be sure that the urodynamic study is of a quality that answers the urodynamic question and provides an understanding about the patient's clinical problem. Therefore, it is recommended that:

- The urodynamic findings and the interpretation of the results should be documented immediately after the study is finished, i.e., before the patient has left the urodynamic laboratory. Doing so allows for a second test if required.

The analysis of a good study is easy and straight-forward. Indeed, an easy analysis actually is the key criterion for good urodynamics. A good study is one that is easy to read and one from which a any experienced urodynamicist will abstract the same results and come to the same conclusions. For computerized analyses, high data quality is even more important than for manual graphical data analysis. Efforts to achieve urodynamic data of high quality during the study will produce great benefits at the time of data analysis. The future development of urodynamic equipment and software should force investigators to conduct proper on-line data quality control. Analysis of ambulatory studies will remain problematic, as it is less easy to conduct on-line assessment of quality, and analysis is time consuming. Hence, it will be necessary to ask the patient to return, on another occasion, should the investigation require repeating, for whatever reason.

CONCLUSIONS

This is the first report of the ICS Standardization committee of Good Urodynamic Practice. The authors are well aware that this is just a first step and many more will have to follow. Only the essential aspects are considered, but if these basic standards are followed, the quality of urodynamic studies will be significantly improved.

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International Continence Society Guidelines on Urodynamic Equipment Performance

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These guidelines provide benchmarks for the performance of urodynamic equipment, and have been developed by the International Continence Society to assist purchasing decisions, design requirements, and performance checks. The guidelines suggest ranges of specification for uroflowmetry, volume, pressure, and EMG measurement, along with recommendations for user interfaces and performance tests. Factors affecting measurement relating to the different technologies used are also described. Summary tables of essential and desirable features are included for ease of reference. It is emphasized that these guidelines can only contribute to good urodynamics if equipment is used properly, in accordance with good practice. *NeuroUrol. Urodynam.* © 2014 Wiley Periodicals, Inc.

Key words: urodynamics; specification; standardization

INTRODUCTION

The International Continence Society (ICS) published a report on urodynamic equipment in 1987.¹ Since then, technology has changed dramatically, particularly in the application of computers to urodynamics. There is now the possibility that measurement accuracy may exceed clinical need, while new technologies being introduced to the market need benchmarks for assessment of their utility.

This article, developed under the auspices of the ICS Standardization Steering Committee, aims to:

- Summarize clinical performance requirements for urodynamic equipment.
- Relate these to specification and feature requirements.
- Develop technical specification ranges or limits from these requirements.
- Comment on different measurement technologies with respect to limitations and artefacts.
- Propose a set of tests/requirements for assessment of systems.

The readership is intended to be purchasers (to check features are actually necessary), designers (to state what is clinically required) and users (to check that equipment is actually performing). Included, therefore, are technical details, summary lists and some basic descriptions.

This document was developed according to the published methodology of the International Continence Society Standardization Steering Committee.² The group commissioned for this report developed an outline of proposed content and revised this in the light of a workshop held at the ICS Annual Scientific Meeting in Glasgow, UK in August 2011. The subsequent text was reviewed by manufacturers of urodynamic equipment before a final draft was discussed at a

workshop during the ICS meeting in Barcelona, Spain in August 2013.

The guideline contains the following sections, which include clinical requirements, measurement technologies and calibration techniques for each parameter. There are also tables for system requirements (features necessary for valid urodynamic measurements) and recommendations (features supportive of good practice).

- Uroflowmetry and voided volume.
- Infused volume.
- Pressure measurement (with special considerations of each parameter measured).
- EMG.
- User interface (recording, display and analysis).
- Standardized performance tests.

The ICS emphasizes that these guidelines can only contribute to good urodynamics if equipment is used properly. For that reason, they should not be assumed to be sufficient in isolation,

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but only alongside training and practice carried out according to the ICS Good Urodynamic Practices document.³

The basic requirement of a standard urodynamic system is that it is able to measure at least two simultaneous pressures and, in real time, calculate detrusor pressure, defined as the simultaneous difference between intravesical and abdominal pressures. Furthermore a standard urodynamic system is usually capable of measuring the flow rate of the voided volume and regulating the rate of fluid infusion. In practice there are a number of other measurements, depending on the clinical demands and the urodynamic investigation being carried out, including urethral pressure or electromyography (EMG). Simultaneous recording of pressure measurements with imaging can be required. Other measurements, such as bladder wall thickness, detrusor perfusion, and sound recording are also being researched. This document, however, is limited to equipment performance for the measurement and recording of flow, volume, pressure and EMG only.

When new urodynamic equipment appears on the market, it is recommended that its function is tested with specific equipment in specialized centers. Such tests are described in the section Recommendations for Standardized Performance Tests. All urodynamic equipment should be calibrated and its performance should be tested with procedures that can be carried out by simple means that are readily available. These tests are described in the relevant sections below. When in use, correct calibration of the equipment should be verified regularly.

UROFLOWMETRY AND VOIDED VOLUME (see Tables I and II)

Clinical Requirements

Accuracy. The accuracy of flow measurement must be sufficient to capture physiological variation. We suggest equipment should be twice as accurate as test-retest variation in individual subjects as a minimum. Studies which have measured test-retest variation have found differences of 1.4–3.3 ml/sec.^{6,7} Accuracy should therefore be approximately ± 1 ml/sec for flow measurement over the clinically important range. In voided volume there should be a resolution of 2 ml or less in order to register leakage, while $\pm 3\%$ error from true value is acceptable (range taken from market survey carried out by authors). This accuracy value must incorporate all variations due to hysteresis, linearity and temperature between 10 and 40°C.

Range. The range of flow measurement necessary is 0–50 ml/sec, with a volume range of 0–1,000 ml.⁵ Accuracy should be maintained over this range. The expected clinical range for voiding time is between 14 and 54 sec,⁸ while gaps between flows in the same void can occur. Equipment documentation should thus state after what time interval it automatically stops recording and should allow for flows at least 120 sec long.

TABLE I. Essential Requirements for Uroflowmetry

Parameter	Guideline value
Accuracy for flow rate	± 1 ml/sec
Accuracy for voided volume	The greater of $\pm 3\%$ of true value or ± 2 ml
Range for flow rate	0–50 ml/sec
Range for voided volume	0–1,000 ml
Maximum duration of flow recordable	≥ 120 sec
Minimum flow recordable	≤ 1 ml/sec
Bandwidth of flow measurement	0 to between 1 and 5 Hz

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TABLE II. Desirable Features of Uroflowmetry Equipment

Documentation should state the minimum recordable volume change or flow rate
Equipment should allow the user to set the expected density of voided fluid
Equipment with load cells should not be damaged by loads less than 5 kg
Equipment should allow the user to reset the volume recorded to zero between voids during a test
Documentation should clearly state what filtering or integration is used in signal processing
Equipment should display the delay value used when synchronizing urine flow with pressure signals, preferably allowing modification of the value
An adjustable height urine collection funnel is recommended
In order to reduce flow artefacts, good delivery of the urine stream to the meter is recommended

TABLE III. Essential Requirements for Filling Volume Measurement

Parameter	Guideline value
Accuracy	The greater of 1–5% of true value or ± 1 ml/min
Range	0–1,000 ml
Range of rate of infusion	0–100 ml/min, adjustable during filling
Sample rate of volume measurement	≥ 2 Hz

Registering minimum flow. It is important that a flowmeter registers clinically relevant low flow rates, for instance in the case of severe bladder outlet obstruction or terminal dribble. Not registering low flow rates may fail to trigger the autostart or terminate the reading prematurely resulting in inaccurate volume measurement and an incomplete clinical picture (especially in the case of uroflowmetry carried out alone). Flowmeters would be expected to measure at least down to the lowest level of accuracy, that is, a flow of 1 ml/sec. It is not essential that flowmeters should measure slower urine loss than this, for example as may occur during leakage, but the minimum recordable volume change or flow rate should be documented.

Frequency response. Flow is the result of relatively slow detrusor muscle contractions. The risetime constant of isometric contractions of strips of bladder muscle is in the order of 2 sec⁹ and that of isovolumetric bladder contractions in patients is comparable.¹⁰ Therefore the upper limit of the bandwidth of a flow measurement system (to -3 dB) need not be higher than 0.1 Hz and a sampling rate of 0.2 Hz should be adequate to record urine flow rate. However, a higher sampling rate would be desirable to allow the more common artefacts to be represented and recognized³ and a measurement bandwidth from zero to between 1 and 5 Hz is recommended.

Measurement Technologies

Flow and voided volume information are interdependent, as one is normally calculated from the other. Currently, load cell

TABLE IV. Desirable Features of Filling Volume Measurement

Equipment should allow the user to calibrate infusion rate and/or filled volume
Equipment should alert the user to infusion tube or pump blockage
Systems measuring filled volume using a load cell should allow the user to set fluid density and to set filled volume when changing containers

(gravimetric) or rotating disc technologies are commonly used. The dipstick method of measuring flow uses a capacitive technique to measure urine depth in the collecting vessel.¹ However, although technically validated, no reports about its use and reliability in clinical practice have been published. Drop spectrometry,¹¹ which determines flow by counting the rate of drops of urine leaving the meatus, was technically too demanding and clinically unreliable.⁵ We therefore describe only the load cell and the spinning disc methods.

The load cell flowmeter. Load cell (or gravimetric) flow meter technology is used by the majority of commercial flow meters,^{1,2} and measures the weight of the fluid during voiding. Knowing the density of the fluid enables volume to be calculated, while flow is rate of change of volume. The weighing scale should be in a horizontal position for reliable measurement, which is a potential problem when the equipment is fixed to a urodynamic chair or videourodynamic unit. In practice, a load cell is more vulnerable to errors in its zero point than its sensitivity, and damage normally manifests as a fixed offset in voided volume. For this reason, and because it is not always convenient to empty the flowmeter between voids, a "Set zero volume" function should be available. Equipment should use load cells that will not be damaged by loads less than 5 kg.

The spinning disk flowmeter. In a spinning disk or momentum-flux flowmeter, the urine stream falls on a rapidly spinning disk and the flow rate is measured by the power needed to keep the rotation speed constant. The spinning disk flowmeter thus measures mass flow; as with the load cell, the density of the fluid is required in order to calculate volume flow. Volume voided is calculated by integration of the flow rate. The design of these flowmeters must allow effective cleaning.

Flow Signal Conditioning and Processing

Urine flow is not continuous; by the time the stream reaches the meter, it has broken into a series of droplets. Therefore a stage of low-pass filtering typically with a cut-off frequency of 1 Hz is added (market survey carried out by authors). Equipment documentation should therefore clearly state what filtering or integration is used, and guide the user as to the effects of this filtering on the display of flow parameters.

Calibration of Flowmeters

Calibration. Empty the flowmeter. Set volume to zero and fluid density to one on the recording device. Pour a known volume of water, of the order of 300 ml, into the flowmeter at an approximately constant flow rate of 15 ml/sec. For a spinning disk flowmeter, pour it at the funnel wall, not directly on the disk. Set the recording device to register the known volume. On a load cell flowmeter the process can equally well be carried out using a known weight instead of a known volume of water.

Verifying calibration. The calibration of the flow measurement system should be verified regularly, for example, once every 10 urodynamic measurements. This may be done by applying the appropriate calibration procedure as described above, but rather than setting the recording device to the known volume, the volume reading is verified. If the reading is more than 20 ml different from the poured volume, recalibration of the system is recommended.

An alternative, easy method to verify calibration is to pour the urine that is collected in the flowmeter into a measuring beaker and check the volume. Another method uses an easily

constructed constant flow bottle to verify the flow rate reading.¹³

If frequent recalibration is necessary, the flow transducer might need to be replaced. The effort and time involved for regular verification should be balanced with the risk that all the flow rate values measured since the previous verification test are incorrect. Verifying calibration may also be necessary after calibration, since in some equipment the process of calibration can alter the zero reading. In these cases it may be necessary to repeat the calibration cycle several times in a series of successive and increasingly accurate approximations.

Uroflow and Voided Volume Artefacts

Liquid density error (load cell and spinning disk). The volume flow rate is calculated by assuming the density of urine is approximately 1 g/ml. If using a denser contrast medium or if the patient is particularly dehydrated, the indicated flow rate will be proportionally high. A prompt or display of liquid density setting, and the capacity for the user to change this, is recommended.

Momentum artefact (load cell). The stream of urine has momentum that is registered as a force by a load cell. This is indicated as an abrupt change in volume and a brief surge at the start of flow. The size of the effect will depend on the amount and velocity of urine hitting the load cell, the resultant movement of liquid in the jug, and the filtering in the electronics. Momentum artefact can be reduced, for example by fitting a baffle and by a funnel spout that reaches into the jug. These slow the urine flow at the impact with the load cell, but cause a time delay in the flowmeter.

Low flow (spinning disk). In spinning disk flowmeters, flow is measured and integrated to give volume. Integration is sensitive to small input offsets that are equivalent to a low but constant flow into the device. These small input offsets must be identified and rejected. The corollary is that the signal produced by very low urine flow rates can be missed, and this can be a clinically important effect, masking a long, dribbling flow. See the section Registering minimum flow for recommendations.

Time delay (all designs). There is inevitably a delay between a change in bladder pressure and the corresponding change in flow rate being detected. This is caused by mechanical delays due to urethral compliance and due to the urine flowing down into the flow sensor, particularly when the collection funnel is dry. The low-pass filter in the flow meter electronics will introduce a further delay. A total delay of 0.4–0.6 sec has been shown to be normal.¹⁴ This delay is of no importance for plain uroflowmetry, but is relevant when synchronous pressure measurements are made during voiding cystometry. Systems should display the delay value to the user, and possibly allow modification.

FILLED (INFUSED) VOLUME (see Tables III and IV)

This section clearly does not apply to ambulatory urodynamic equipment, where natural filling occurs during the test.

Clinical Requirements

Accuracy. Measurement of infused volume should be accurate to within $\pm 5\%$.³ Accuracy of greater than 1% is unlikely to be clinically useful. However, for very low filling rates, for instance in children or in urethral pressure profiles, accuracy to only 1 ml/min will be required. These accuracy values must

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incorporate all variations due to hysteresis, linearity and temperature between 10 and 40°C.

Range. Typically, even for repeated cystometry, the filled volume is unlikely to be more than 1,000 ml, so the measurable volume should be between 0 and 1,000 ml. The equipment should enable the disregarding of the weight of the bag or bottle used for fluid. For filling rate, the ICS defines the maximum physiological filling rate as body weight in kilogram divided by four, expressed as ml/min. This is routinely exceeded in clinical practice, and much lower rates are used in children. Nevertheless it is rare that more than 100 ml/min be infused, and faster rates will in any case be limited by catheter diameter. The filling rate is often reduced during the test if the patient shows signs of detrusor overactivity, so the rate must be adjustable during filling. The required range is therefore 0–100 ml/min.

Frequency response. If 100 ml/min is the maximum required filling rate, then for 5% volume accuracy a sample should be recorded faster than every 3 sec. Considering other factors affecting accuracy, a frequency response of up to 1 Hz will therefore be acceptable.

Measurement Technologies

Infused fluid is normally saline or contrast medium and the volume is either estimated by counting pump head revolutions or deduced from the decrease in bag weight. The section User Interface, Analysis and Post-Processing discusses how software might correct for residual volume and diuresis to estimate actual bladder volume.

Infusion pump. The infusion pump is normally of the peristaltic type where a series of rollers compress a flexible tube to drive the saline. This is susceptible to errors due in particular to variations in tube cross-section and downstream resistance. Equipment should therefore allow checking and calibration of infusion rate, often simply done by running the pumped fluid into a flowmeter. Many peristaltic pumps will turn even when the downstream tube is completely blocked, so equipment should register this error and alert the user. Because of this potential for error, load cell measurement of infused volume is advised.

Load cell. A load-cell arrangement measures actual infused volume by weighing the infusion bag. As with the flowmeter, contrast medium is denser than saline and will lead to over-indication of the filled volume if its density is not taken into account. Fluid density settings must therefore apply to both voided and filled volumes alike. In the case of voided volume, the effect of mixing contrast with saline or urine should be considered. Calibration is achieved by measuring known weights or volumes of fluid.

Where a load cell is used, there is a very obvious artefact generated when an empty fluid container is swapped for a full one. In terms of the unprocessed signal, the filled volume will increase by a few tens of ml as the container is removed, then return to approximately zero when the new bag is fitted.

Urodynamics systems should therefore have some means to correct this artefact.

It is known that filling with cooled fluid can promote detrusor contraction.¹⁷ Equipment may therefore allow warming of the infused fluid to body temperature, though there is no conclusive evidence that this significantly affects the results of the cystometry. Historically, CO₂ gas has been used in place of saline to fill the bladder. Simultaneous pressure measurements are possible but it is not possible to measure flow rate or voided volume when using CO₂ gas infusion.

MEASUREMENT OF PRESSURE (see Tables V and VI)

Pressure in urodynamic studies is conventionally measured in centimeters of water (cmH₂O), a unit based on the pressure exerted by a column of water of measured height. A unit of cmH₂O is equivalent to 98.07 Pascals (Pa), the standard unit of pressure.

Since pressure signals are sensed, transmitted, and recorded in different forms, when quoting specifications for pressure measurement, values should be quoted for the entire system, that is, transducers, catheters and processing together. The type of catheter should be specified, for example, “measured using 7Fr water-filled double lumen catheter” and ideally also the internal diameter of the pressure measurement lumen.

Clinical Requirements

Accuracy. The accuracy of pressure measurement must be sufficient to capture physiological variation. We suggest equipment should be twice as accurate as test–retest variation in individual subjects. Studies which have measured this have found mean differences of 2.8 cmH₂O⁷ and 10 cmH₂O⁶. This suggests systems should be accurate to between 1.5 and 5 cmH₂O for p_{det} , and thus between 1 and 2.5 cmH₂O for p_{ves} and p_{abd} (rounding to the nearest 0.5 cmH₂O). These accuracy values must incorporate all variations due to hysteresis, linearity, and temperature between 10 and 40°C, even in catheter-mounted transducers that are calibrated at room temperature then used at body temperature.

Range. An acceptable range for pressure measurement would be 0–250 cmH₂O.³ In addition it is useful for water-filled catheters to allow a certain amount, say 30 cmH₂O, of negative pressure to be registered while the patient is temporarily lower than the level of the transducers. Certain events, such as flushing catheters, may apply a pressure significantly higher than the working range (called an overload pressure) to the transducer. Larger diameter syringes are safer in this regard, as they are less likely to generate high overload pressures. It is suggested that the application of pressures up to 5,000 cmH₂O must not damage the transducer or alter the calibration in the working range by more than 1%.

Frequency response. Most clinically relevant pressure signal changes in urodynamics occur below 3 Hz frequency, including the majority of the power spectrum of a cough.¹⁸ Even though a

TABLE V. Essential Requirements for Pressure Measurement

Parameter	Guideline value
Accuracy	The greater of $\pm 3\%$ of true value or ± 1 cmH ₂ O
Range	–30–250 cmH ₂ O (water-filled systems) 0–250 cmH ₂ O (other systems)
Bandwidth of pressure measurement (whole system)	0 to ≥ 3 Hz, equal on both channels
Required feature when water filled catheters are used and patient positions are changed during the test	Equipment must allow reference levels to be reset

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TABLE VI. Desirable Features of Pressure Measurement Equipment

Equipment should allow users to compare easily current pressure values with starting (baseline) pressures
The point in time at which baseline pressures are recorded should be able to be set by the user
Equipment should allow the user to see abdominal, intravesical and detrusor pressures concurrently
Equipment should record when calibration has been carried out to enable later checks on performance and use

cough has frequency components up to 14 Hz,¹⁹ registering the equal transmission of this signal by both pressure lines is clinically more important than measuring its precise maximum pressure value. To adequately register the presence of a cough signal, therefore, the bandwidth of the whole system (including catheters) should be at least 3 Hz. A higher bandwidth, however, may allow the more common artefacts to be represented and recognized.

Pressure Measurement Technologies

In urodynamics, the pressures to be measured are in internal cavities with limited access: the bladder, vagina, rectum or stoma, or urethra. Therefore the transducer will be associated with a catheter and tubing to gain access to the measurement site. Three different transducer arrangements are in common use, all of which require the setting of zero pressure (by convention to atmospheric pressure) and calibration. Only with external transducers and water-filled catheters, however, can the reference height be consistently known, and thus p_{ves} and p_{abd} repeatably and comparably measured.

Water-filled catheter and external transducer. This is recommended by the ICS.³ A water-filled catheter or balloon is passed to the measurement site, with pressure transmitted along that catheter and connecting tubing to a transducer that is external to the patient. Even when set up correctly, a water-filled system is sensitive to being tapped or jostled, but responds reasonably well to fast changes in pressure.²⁰

With a continuous column of liquid along the catheter, the pressure at the transducer is the same as that in the body *at the vertical level of the transducer*, regardless of where the catheter tip is. By convention the transducer is leveled to the pubic symphysis, an anatomical landmark for the bladder, and the zero point set to atmospheric pressure. The patient can move between supine, standing and sitting during the course of a test. Urodynamics equipment using water-filled measurement should therefore have the facility to move the transducers vertically in order to bring the transducers level with the symphysis pubis, if the patient is required to change position during the test. Alternatively, some other method of resetting the reference level is required.

Catheter-tip transducers. With catheter-tip transducers, the transducer is mounted in the tip of the catheter which is passed to the site of measurement. The pressure signal is converted to a voltage which is then amplified. A high measurement bandwidth (fast response) can be achieved with little or no movement artefact using catheter-tip transducers. However the transducer needs to be small, which makes it relatively difficult and expensive to manufacture.

The position of the catheter tip will affect the measurement. At the top of the bladder or rectum, the measured pressure will be typically 10 cmH₂O lower than at the bottom; there is no easy way to correct for this positioning error. Systems should

therefore display clearly the pressure values at the start of the test so this artefact can be taken into account.

Air-filled catheter and external transducer. This arrangement is similar to the water-filled system with an external transducer, except that the catheter is filled with air, and a small balloon covers the opening at the end. The low density of air can be neglected, and the pressure is transmitted directly from the balloon at the catheter tip to the transducer. Therefore functionally, it is more similar to the catheter-tip transducer, suffering from the same uncertainty in positioning the catheter tip in the bladder or rectum. Again, therefore, it is important that the equipment allows the user to register the pressure readings at the start of the test.

There is little or no artefact due to knocking the line, but at the expense of a slowed frequency response. Air-filled catheters behave like an overdamped system, which can result in a delayed and diminished pressure response to rapidly changing pressures.²⁰

Pressure Signal Conditioning and Processing

Signal conditioning would normally consist of two phases: low-pass filtering to remove high frequency artefacts, then subtraction of p_{abd} from p_{ves} to give p_{det} . The two processes are linear and can be applied in either order. However, the separate p_{abd} and p_{ves} traces are of interest, and therefore it is beneficial to filter them separately, that is, filtering before subtraction, which requires that the filters in the two channels be similar in frequency response.

Abdominal pressure signals such as a cough contain components at frequencies in excess of 10 Hz, and indeed there are some investigations, such as a cough urethral pressure profile, in which a faster frequency response is required. In this case, a higher sampling rate of approximately 100 Hz would be required if clinical precision demands this. Note that the entire system must also support the higher measurement bandwidth when required, which may exclude some arrangements.

Calibration of Pressure Transducers

During calibration two different pressures are set by exposing the catheter tip or sensor to two different well defined pressures. The calibration becomes more accurate when the pressure difference between the two pressures is larger (a pressure difference of at least 50 cmH₂O is recommended). It may be necessary to go into some manufacturer-designed calibration routines or use one of the calibration devices available from some manufacturers. It is hoped that publication of this document will induce manufacturers to implement adequate means for calibration and include means for recording when calibration has been carried out. Calibration routines should be available for all measurement channels.

Verifying calibration. The calibration of pressure measurement systems should be verified regularly, for example, once every 10 urodynamic measurements for non-disposable transducers. This may be done by applying the appropriate calibration procedure as described in this section, but rather than setting zero level and the pressure reading at a defined height/depth, the pressure readings with the catheter at these levels are verified. If the pressure readings are more than 2 cmH₂O different from the applied pressures, recalibration of the system is necessary. If frequent recalibration is necessary the transducer or catheter might need to be replaced. The effort and time involved for regular verification should be balanced with the risk that all the pressure values measured since the

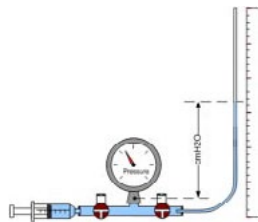


Fig. 1. Calibration of water-filled catheter by filling the line.

previous verification test are incorrect. Verifying calibration may also be necessary after calibration since in some equipment the process of calibration can alter the zero reading. In these cases it may be necessary to repeat the calibration cycle several times in a series of successive approximations.

Calibration of water-filled catheters with external transducers. The external transducer is connected to the recording device. Open both three-way valves to the outside air to make sure that the transducer with air-filled dome cover is exposed to atmospheric pressure, and set the zero level at the recording device. Open the valves to the syringe and the line, and completely fill the system with bubble-free water until the water level in the line is a defined level above the transducer, at least 50 cm (Fig. 1). Set that level at the recording device.

Alternatively, a water-filled pressure measuring system may be calibrated by keeping the amount of water in the line constant and moving the line up and down (Fig. 2). With the water level at the level of the transducer, set the recording device to zero. Raise the line so that the water level is at a defined level, at least 50 cm above the transducer, and set that level at the recording device.

The transducer may also be calibrated by putting the line in a water-filled container, noting that the pressure measured reflects the height difference between the water level in the container and the transducer (not the end of the catheter).

Calibration of catheter-tip transducers. Mount the catheter on a tripod (Fig. 3). Set zero on the recording device, while holding the catheter tip in the air. Place the catheter tip in a container, and fill to at least 50 cm above the catheter tip. Note the height of the water level above the sensor and set that level at the recording device. (Note that lowering the holder and catheter into a prefilled container will raise the water level, so measure the height with the holder and catheter submerged).

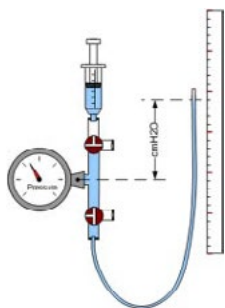


Fig. 2. Calibration of water-filled line by moving the line.

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Calibration of air-filled catheters. Mount the catheter on a tripod (Fig. 3). Place the catheter balloon in a container and fill to at least 50 cm above the catheter balloon. Set zero on the recording device. Fill the balloon with air (repeatedly charging and discharging the balloon without properly emptying will result in a pressure rise inside the balloon and compromise the pressure measurement). Note the height of the water level above the balloon and set that level at the recording device. (Note that lowering the holder and catheter into a prefilled container will raise the water level, so measure the height with the holder and catheter submerged).

Pressure Artefacts

Since there is redundancy in having two pressure channels, most artefacts in urodynamic pressure measurements can be recognized and dealt with through proper quality control.

Reference level errors. Catheter-tip transducers and air-filled transducers will have an error due to their unknown and changing height within the bladder, which is difficult to correct. The same errors can occur in abdominal pressure measurements, resulting in potentially greater error when subtracting to obtain detrusor pressure. The trace display should therefore allow easy comparison of current pressure values with starting (referred to as “baseline”) values, in order to allow the operator to compensate for initial pressure offset. It is not recommended that this offset be set to zero in software at the start of the test, as this process changes one pressure reading from its real value.

Air bubbles. Air bubbles introduce two issues with water-filled catheters. First, the non-uniform density of fluids in the catheter will introduce an offset to pressure measurements. The size of the offset depends on the difference in height between the two ends of the bubble, which changes as the catheter is moved and as the measured pressure changes. Second, water is incompressible and pressure changes are transmitted without flow of water. Air bubbles are compressible; a change in pressure requires flow to compress or expand the air bubble. The bubble becomes a low pass filter that dampens the frequency response of the catheter. Note that this problem does not affect air-filled catheters to the same degree, because the opposition to flow offered by air is very low. Equipment should allow the operator to compare easily the size of pressure changes on all traces, in order for instance to test for the presence of air bubbles using a cough.

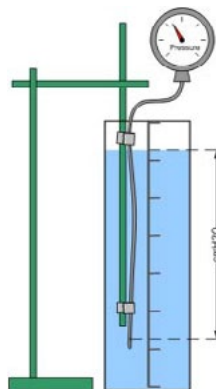


Fig. 3. Calibration of catheter-tip and air-filled transducers.

Dislodged catheter. A dislodged catheter that has moved from the measured body cavity can be identified by good quality control, since the measurement in the affected catheter will stop responding to coughs. If the catheter has moved significantly, the measurement may also show a dramatic offset from its baseline value. Again therefore, the trace display should allow comparison with baseline values during the test.

Incomplete pressure transmission. At the start of filling, it is sometimes the case that intravesical pressure is not recorded correctly, possibly due to the sensor touching the wall of an empty bladder. Equipment should therefore allow users to fill the bladder a small amount before baseline values for pressure are recorded, rather than automatically assigning baseline values at the start of filling.

Incomplete cough cancellation. With water-filled catheters, it is usual that the bladder line is of smaller diameter than the abdominal line. In these circumstances the characteristics of the two lines will be different, with the abdominal line usually having the faster frequency response. Therefore the complete cancellation of a cough in the detrusor trace may be difficult and any automatic processing should treat a symmetric biphasic wave on the detrusor trace as being of acceptable quality.

Artefacts with separate lines. With separate filling and measurement catheters, there will be a positive pressure offset in p_{ves} if the measuring catheter is not disengaged from its insertion position in the filling catheter hole ("piggy-back") before filling commences, or if filling flow faces directly onto the measurement point. This artefact disappears if the infusion pump is stopped.

Single Lumen Artefact. If both filling and pressure measurement are done through the same lumen of a catheter, the positive pressure from the filling pump will add an offset to the value measured, and if a roller pump is used this offset is variable and confusing. Pressure measurements should therefore be made only when the pump is not running. Alternatively, if continuous measurements are required, calibration may be done when the pump is running, or users compensate by subtracting the offset, but only when the pump is running. This artefact disappears if the infusion pump is stopped.

Dual-lumen artefact (pump). Dual-lumen water-filled catheters are susceptible to a filling artefact in which the pressure generated by the infusion pump affects the pressure in the parallel measuring lumen, particularly at high filling rates. The effect is due to peristalsis from the pump interacting with the compliance of the thin catheter wall, and is manifested as a rhythmic signal from the pump rollers superimposed on the p_{ves} signal. This artefact too disappears if the infusion pump is stopped.

Abdominal Pressure Special Considerations

Catheters in the rectum, vagina, or an abdominal stoma give an approximation to the pressure surrounding the bladder. In particular, the use of rectal transducers in urodynamics makes the assumption that they give a good measure of resting abdominal pressure.²² However, the rectal transducer will often measure rectal contractions. These will be manifested as positive waves on abdominal pressure and thus negative-going waves on resting detrusor pressure that may sometimes appear to be substantially below zero. Equipment should therefore allow the user to see all pressure traces concurrently and negative p_{det} readings should be displayed and not clipped to zero.

Urethral Pressure—Special Considerations

In some circumstances, it may be requested to quantify the pressure along the length of a dry urethra. Some authors report

making measurements using a solid-state catheter-tip transducer coated in an aqueous lubricating gel.²³ In the Brown and Wickham method,²⁴ a water-filled catheter is passed *per urethram* then withdrawn using a catheter puller, typically at 2–5 mm/sec. Meanwhile, continuous pressure measurements are made. Since the distal urethra is dry, the line must be perfused with saline, typically at 2–5 ml/min. Equipment that supports urethral pressure measurement should enable perfusion and withdrawal rates within these ranges. As systems perform differently at different rates and with different catheters, centers should maintain a consistent and clearly defined protocol when making urethral pressure measurements.

EMG (see Table VII)

Electromyography (EMG) measurements can contribute to the interpretation of urodynamics studies in that they document the relationship between pressure and/or flow as well as the activity of the pelvic floor and striated sphincter. Consequently EMG measurements, particularly when associated with the investigation of neuropathic disorders of the lower urinary tract, can be of critical importance. In the past, needle electrodes have been used to investigate individual muscle action potentials, usually inserted in the anal sphincter providing a record of motor unit activity of the group of muscles. While not exactly reflective of pelvic floor muscle activity, needle or wire electrodes remain the current gold standard of documenting skeletal muscle activity. However needle electrodes are invasive, technically difficult to insert and are not pleasant for the patient. Therefore in centers that use it, EMG measurement is limited to surface electrodes measuring the activation of the pelvic floor muscles.

All skeletal EMG signals have a relatively high bandwidth, typically from 10 Hz up to 1 kHz. The EMG amplitude from surface electrodes is comparatively low, nominally from 10 to 100 μ V, and depends greatly on skin cleaning, electrode placement and patient morphology in terms of the amount of fat between electrode and muscle to be monitored. Given the small signal amplitude, the amplifier properties are important. In particular, it should have a high input impedance in excess of 100 MOhms, and common-mode rejection ratio (CMRR) in excess of 80 dB.¹ A notch filter at mains frequency is recommended.

In most cases, the high bandwidth of the EMG is addressed by using a rectify-integrate (iEMG) or a root-mean-square circuit that gives a low-bandwidth estimate of the EMG amplitude or envelope. When displayed graphically this gives a line trace where in some cases, subtle or slow changes can be missed and filtering can lose the phase relationship with the pressure or flow signals. In fact, the original EMG can be deliberately under-sampled at typically 100 Hz, which loses some information content, but nevertheless gives a distinctive EMG appearance when displayed at the timescale of urodynamic traces.

TABLE VII. Essential Requirements of EMG Measurement Equipment (Where Fitted)

Parameter	Guideline value
Minimum impedance	100 MOhms
Minimum CMRR	80 dB
Required feature	EMG processing and display variable to suit clinical need

USER INTERFACE (see Table VIII)

Operation

Equipment should be designed such that operation is ergonomic and safe. Surfaces likely to come into contact with clinical materials should be easy to clean, while the physical layout should be stable and allow easy access. The equipment design should be such that technicians at the user's institution can carry out electrical safety checks without causing damage to the equipment.

Recording

Data should be recorded and stored in such a way that the study can be displayed in the same way at a later date, preferably on other equipment as well. Electronic marking of events is important for analysis of studies at a later date, as artefacts and real events can easily get confused if they are not permanently annotated on the original soft copy. The position of event markers should be adjustable after the test has finished, and the meaning of any abbreviations used for their labels should be clear. The ability to enter further diagnostic information such as post void residual volume and the results of related diagnostic tests may be useful in order to display all related information to clinicians. The ability to export in plain data format (.txt or .csv) should be available. Also required is the ability to integrate with popular electronic medical software and to export in the ICS standard format (.ics).²⁵ For data protection purposes, the system should store data securely, or allow the user's institution network to do so. Backing up of data onto remote systems or media and connection to the hospital data network should be facilitated. Data recovery in the event of power failure would be an advantage.

Display

The ICS suggests that urodynamic tests should be displayed on a 1 mm = 5 sec scale for filling and 1 mm = 2 sec for voiding.³ This allows resolution of short scale events, easy visual comparison of multiple studies and prevents misinterpretation of traces due to scaling issues. Line thicknesses on screens and on printouts should allow the clear visualization of clinically important details, and these thicknesses should not represent values greater than the accuracies recommended above. A variable on-screen scale allows both visual summary of the whole test, as well as close inspection of detailed features, but default scales and layout should conform to ICS recommendations.³ The system must allow for simultaneous display of all pressure traces. For those integrating fluoroscopy, temporal synchronization or embedding of the image are necessary features. For ambulatory equipment, the option of a real time display of pressure is helpful, in order to check the setting up of transducers.

Analysis and Post-Processing

Automated analysis is an optional extra which, if included, should not be affected by artefacts (e.g., Q_{max} caused by knocking the flow meter, p_{max} from cough). If summary statistics and automated analysis are provided, the user should have the ability to check the values for feasibility and change the relevant ones if necessary. This implies that software should not filter or remove artefacts, but should be able to ignore them for analysis. Results of validation of any automated analyses should be available.²⁶ Established nomograms and calculated parameters may also be provided. A facility to estimate bladder volume using post-void residual, infused and voided volumes may be a useful tool, though inaccuracies in these measurements, along with any urethral infusion, diuresis, and leakage will confound calculation.²⁷

RECOMMENDATIONS FOR STANDARDIZED PERFORMANCE TESTS

Testing of new technologies for pressure and flow rate measurement should be done by a specialized center prior to introduction to the market to ensure that they have sufficient accuracy, linearity, minimal hysteresis and temperature dependence, and an appropriate frequency response, as well as consistent performance throughout the lifetime of the system. These tests should be performed using all components of the system as they will be utilized clinically since, for example catheter size and length can affect the frequency response of a pressure measurement system. Potential users should utilize the results of these tests to determine if a new technology would provide sufficiently accurate measurements for their needs prior to purchase.

A single study can be utilized to test linearity and hysteresis by production of a linear increase in pressure or flow rate followed by a linear decrease in pressure or flow rate. For pressure, this can be accomplished using a fluid-filled pressure chamber in which the pressure can be tightly controlled. For flow rate, this can be accomplished using a controllable flow pump.

Frequency response can be determined by changing pressure or flow rate in a controllable manner such that different frequencies are tested. Two such standard tests for measuring the frequency response of a pressure measuring system are the pop test and the frequency ramp test.²⁰ For the pop test, a piece of latex, similar to a balloon, is tightly stretched over the top of an air-filled chamber in which pressure sensing catheters are placed. The chamber is then pressurized to a standard pressure and the latex bulges out in response. The latex is then popped with a pin or needle, dropping the pressure in the chamber to zero (equal to barometric pressure in the room) nearly instantaneously. This test is therefore sometimes called a step test because of the sudden drop to zero pressure. This test enables measurement of the response of a pressure sensing

TABLE VIII. Essential Requirements of User Interfaces

Parameter	Guideline
Access and cleaning	Equipment laid out ergonomically
Display	Should allow for later review with line thicknesses representing smaller values than recommended measurement accuracy
Data export	Text/spreadsheet format, ICS format and electronic patient record interface
Data storage	Backup facility and option for network connection required Secure data storage should be made possible
Image capture and display	Simultaneous recording and playback with pressure traces required, if images are used
Display scales	Clearly displayed and adjustable
Event marking	Required
Automated analyses	Relevant parameters should be controlled by user, not fixed

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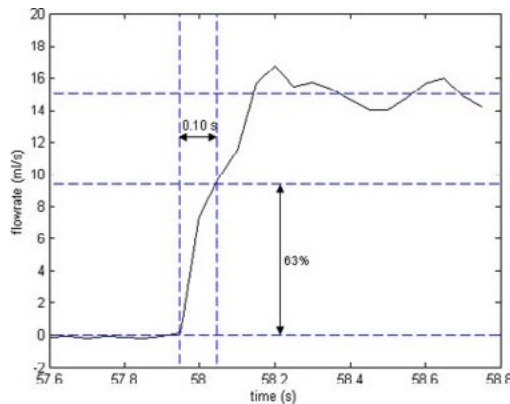


Fig. 4. Simple test for flow meter signal response. The rise time to 63% of final value should be less than 0.16 sec.

system to a sudden change in pressure. For the frequency ramp test the pressure in the pressure chamber is rapidly changed and a range of relevant sinusoidal frequencies are examined. Zero to 20 Hz is sufficient to assess urodynamic pressure measurement systems. Sophisticated software is required to characterize the pressure measurement system from the resultant data, but if done well, an accurate determination can be made and the system can be characterized by its resonant frequency and/or the -3 dB frequency as illustrated with regard to a flowmeter step test (Fig. 4).²⁸ The resultant data from these tests can also be used to determine if the pressure sensing system constitutes an under- or over-damped recording system.²⁰ If the system is underdamped, the resonant frequency ought to be outside the working range of the system (greater than 20 Hz in this case). If the system is overdamped, it ought to have adequate slew rate to respond in a timely fashion to pressure changes within the working range of frequencies.

To test simply flowmeter frequency response, put the flowmeter under a running tap, and adjust the tap until the flowmeter indicates approximately 15 ml/sec. Intercept the stream for approx. 4 sec with a plastic cup. Then quickly remove the cup again, and record the flow signal for 4 sec more. Figure 4 shows a detailed recording of the time interval when the cup was removed, using a spinning disk flowmeter. Since we require a cutoff frequency of at least 1 Hz (see Table I), the time taken to rise from zero to 63% of the final value should be at most 0.16 sec.

A frequency ramp test can test new flow rate technologies by creating sinusoidal changes in flow rate whose frequencies change through the working range of flow rate frequencies, that is, 0–5 Hz as stated earlier.

Temperature dependence can be tested by performing the linearity and hysteresis test and the frequency response test at different temperatures within the working range of the system.

Disposable systems do not need to demonstrate lifetime consistency since they are marketed for single use only. Durable systems ought to be tested to ensure they have a consistent response throughout their recommended lifetime, which can be defined either according to time by utilizing an expiration date, or according to number of uses. Repetition of a simulated urodynamics test interleaved with periodic repetition of the

above benchmarking tests could determine the appropriate lifetime of a new technology, regardless of how lifetime is ultimately defined. Change of less than 1% throughout the lifetime of a system would be expected, after periodic recalibration has been undertaken.

SUMMARY

The review contained in this article allows clinical requirements for a standard urodynamics system to lead to technical recommendations. Equipment can be over-specified (e.g., more accuracy than is required) or under-specified (unable to achieve necessary performance). It is hoped that this document will be helpful to purchasers, users and manufacturers in avoiding these errors. Purchasers can use the lists of required features to check the suitability of equipment for urodynamics. Users can perform the tests described to check ongoing performance and calibration. Manufacturers can be guided by this technical summary of clinical need when introducing new designs or techniques. The document may also encourage the establishment of standard tests for urodynamic equipment, leading to both procurer and operator assurance, and also patient benefit.

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An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the assessment of sexual health of women with pelvic floor dysfunction

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Aims: The terminology in current use for sexual function and dysfunction in women with pelvic floor disorders lacks uniformity, which leads to uncertainty, confusion, and unintended ambiguity. The terminology for the sexual health of women with pelvic floor dysfunction needs to be collated in a clinically-based consensus report.
Methods: This report combines the input of members of the Standardization and Terminology Committees of two International Organizations, the International Urogynecological Association (IUGA), and the International Continence Society (ICS), assisted at intervals by many external referees. Internal and external review was developed to exhaustively examine each definition, with decision-making by collective opinion (consensus). Importantly, this report is not meant to replace, but rather complement current terminology used in other fields for female sexual health and to clarify terms specific to women with pelvic floor dysfunction.

Eckhard Petri and Joseph Lee belongs to Standardization and Terminology Committees IUGA.

Kristene Whitmore belongs to Standardization and Terminology Committees ICS.

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Dr. Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

Results: A clinically based terminology report for sexual health in women with pelvic floor dysfunction encompassing over 100 separate definitions, has been developed. Key aims have been to make the terminology interpretable by practitioners, trainees, and researchers in female pelvic floor dysfunction. Interval review (5-10 years) is anticipated to keep the document updated and as widely acceptable as possible.

Conclusion: A consensus-based terminology report for female sexual health in women with pelvic floor dysfunction has been produced aimed at being a significant aid to clinical practice and a stimulus for research.

KEYWORDS

female pelvic floor dysfunction, female sexual health, terminology

1 | INTRODUCTION

The terminology in current use for sexual function and dysfunction in women with pelvic floor disorders lacks uniformity, which leads to uncertainty, confusion, and unintended ambiguity. Comprehensive and precise description will aid this situation, leading to more accurate reporting. For example, many definitions are used to describe dyspareunia; few are specific as to the location or etiology of the pain. Women may be treated for sexual complaints from a large array of providers including physicians, psychologists, psychiatrists, or sex therapists. While other fields have standardized terminology regarding diagnoses of sexual dysfunction in women without pelvic floor dysfunction, these diagnoses and descriptions do not include descriptions of conditions commonly encountered by the urogynecologist or others who treat women with pelvic floor disorders, such as coital incontinence. More standardized terminology would aid inter-disciplinary communication and understanding, as well as educate our providers on standardized terminology used in other fields.

Existing published reports document the importance of including the assessment of sexual function. For example, while Haylen et al¹ offers definitions of symptoms, that document does not comment on how to further evaluate sexual function or incorporate it into the assessment of women with pelvic floor dysfunction. Assessment of how pelvic floor dysfunction treatment affects sexual health and how to measure changes in sexual health are important to the practice of urogynecology. Ideally, terminology should be consistent between practitioners who treat women with sexual dysfunction and those who treat pelvic floor disorders. Terminology presented in this document will align with current terminology documents and a literature terms analysis will be included in the process.

This report contains;

1. Definitions of sexual function relevant to the treatment of pelvic floor dysfunction and terminology developed to designate the anatomic location of the symptom.
2. Terminology currently accepted as standard outside the field of urogynecology will be referenced, as these terms will allow urogynecologists to communicate effectively with other practitioners providing care to women with sexual dysfunction and pelvic floor disorders.
3. Assessment of sexual dysfunction of women with pelvic floor disorders including the history and physical exam necessary to assess women reporting sexual difficulties which may or may not be related to their pelvic floor dysfunction including physical exam, imaging, nerve testing, as well as descriptions of how sexual dysfunction is related to other pelvic floor disorders, such as urinary and anal incontinence and pelvic organ prolapse.
4. Management of sexual dysfunction in women with pelvic floor disorders is described including conservative, surgical, and pharmacological management. Management of sexual dysfunction may be provided by different disciplines working in this field. Terminology related to the different types of therapy will be specified and distinguished. In addition, surgical and non-surgical management strategies are defined and described.
5. The working group consisted of stakeholders in sexual function including urogynecologists, sex therapists and physiotherapists and the document was vetted through the wider membership of IUGA and ICS. The working group includes optimal methods of reporting sexual function research in women with pelvic floor dysfunction. Currently no single document collates all elements required for diagnoses in the area of female sexual function in women with pelvic floor dysfunction in a comprehensive way. This report includes a full outline of the terminology for all

symptoms, signs, ordered clinical assessments, the imaging associated with those investigations, the most common diagnoses, and terminology for different conservative and surgical treatment modalities.

Like all the other joint IUGA-ICS female-specific terminology reports, every effort has been made to ensure this Report is:

1. User-friendly: Able to be understood by all clinical and research users.
2. Clinically-based: Symptoms, signs, and validated assessments/investigations are presented for use in forming workable diagnoses for sexual health and associated dysfunctions.
3. Origin: Where a term's existing definition (from one of multiple sources used) is deemed appropriate, that definition is included and duly referenced.
4. Able to provide explanations: Where a specific explanation is deemed appropriate to explain a change from earlier definitions or to qualify the current definition, this will be included as an addendum to this paper (*Footnote a,b,c. . .*). Wherever possible, evidence-based medical principles have been followed. This Terminology Report is inherently and appropriately a definitional document, collating definitions of terms. Emphasis has been on comprehensively including those terms in current use in the relevant peer-reviewed literature. Our aim is to assist clinical practice, medical education, and research. Some new and revised terms have been included. Explanatory notes on definitions have been referred, where possible, to the "Footnotes" section.

Acknowledgement of these standards in written publications related to female pelvic floor dysfunction, should be indicated by a footnote to the section "Methods and Materials" or its equivalent, to read as follows: "Methods, definitions and units conform to the standards jointly recommended by the International Continence Society and the International Urogynecological Association, except where specifically noted."

2 | OVERVIEW OF SEXUAL FUNCTION AND DYSFUNCTION

Over 40% of women will experience a sexual problem over the course of their lifetime. A sexual complaint meets the criteria for a diagnosis when it results in personal distress or interpersonal difficulties. With regard to sexual complaints that reach the level of a diagnosable sexual disorder, recent epidemiologic surveys place the prevalence of diagnosable sexual disorders at approximately 8-12%.²

2.1 | Normal sexual function and models of sexual response

"Normal" sexual function can be determined using a variety of standards and is therefore difficult to define. Multiple models have been developed to describe normal or healthy sexual function. In 1966, Masters and Johnson proposed a linear model of sexual response based on their observations of the physiologic changes that occurred in men and women in a laboratory setting. Their model consisted of four stages: excitement, plateau, orgasm, and resolution. Subsequently, Kaplan and Lief independently modified this model to include the concept of desire as an essential component of the sexual response. Basson introduced an intimacy-based circular model to help explain the multifactorial nature of women's sexual response and that desire is responsive as well as spontaneous. This model further allows for the overlap between desire and arousal and is ultimately the basis for the DSM 5 combined disorder, Female Sexual Interest, and Arousal Disorder (FSIAD).

2.1.1 | Screening and diagnosis

Sexual concerns should be addressed routinely. Many women are hesitant to initiate discussions but still want their provider to open the dialogue about sexual problems. When a provider opens this dialogue, he/she acknowledges and prioritizes the role that sexual health plays in overall wellbeing. A variety of questionnaires can be used to help identify women who suffer from sexual problems. These questionnaires are a useful adjunct to the patient history and physical examination in the diagnosis of sexual disorders.

Once a sexual problem has been brought up and/or identified, it is important that it is adequately assessed. Though time is limited in the clinical setting, it is important to ask questions that help determine the true nature of problem. When the patient presents with low desire, a detailed description of her problem, including the onset, duration, and severity of her symptoms, should be obtained. Her level of distress should be determined. Open-ended questions allow the patient to provide information essential for accurate diagnosis and the development of an appropriate treatment plan. If there is not enough time to have a complete discussion, a return visit should be scheduled to specifically focus on her sexual concerns.

2.1.2 | History and physical exam

A comprehensive medical and psychosocial history, preferably of both partners, is essential.³

A completed medical history can identify conditions that contribute to her symptoms. The gynecologic history is also a vital component in the diagnosis. Components of the sexual

history should include direct questions about sexual behavior, safe sex practices, and whether or not there is a history of sexual abuse. Sexual history taking should always be conducted in a culturally sensitive manner, taking account of the individual's background and lifestyle, and status of the partner relationship. A history of current medications should be taken. It should be noted in what way the additional pelvic floor symptoms interfere with sexual function. Medications as antihypertensive agents (alpha blockers, beta blockers, calcium channel blockers, antidiuretics) chemotherapeutics, drugs that act on the central nerve system and anti-androgens may interfere with sexual function.⁴ A history and physical examination with special attention to atrophy, infections, scar tissue, and neoplasms should be performed. Motor and sensory neurological function should be assessed. Clinical signs of urinary and fecal incontinence should be noted and provocation tests such as a cough stress test performed. For women with pelvic neurological disease a detailed neurological genital exam is necessary, clarify light touch, pressure, pain, temperature sensation, anal and vaginal tone, voluntary contraction of vagina and anus as well as anal and bulbocavernosus reflexes.⁵ Basic laboratory testing should be performed such as serum chemistry, complete blood count, and lipid profiles to identify vascular risk factor as hypercholesterolemia, diabetes, and renal failure.⁴

2.2 | Pelvic floor disorders and sexual dysfunction

The effects of pelvic floor disorders (PFDs) including urinary (UI) and anal incontinence (AI) and pelvic organ prolapse (POP) on sexual function remain debatable with some studies showing no and others a negative impact.^{6–8} This variability can be attributed partly to the fact that the populations studied, as well as the methodology and the type of questionnaires used, are different between the studies. These discordant findings can also be attributed to the complexity of human sexual function which is subject to a host of influences. Despite conflicting published data, in general most PFDs are thought to negatively affect sexual health. Pelvic floor symptoms have been shown to be associated with low sexual arousal, and infrequent orgasm and dyspareunia.⁷ Up to 45% of the women with UI and/or lower urinary tract symptoms (LUTS) complain of sexual dysfunction with 34% reporting hypoactive sexual desire, 23% sexual arousal disorder, 11% orgasmic deficiency, and 44% sexual pain disorders (dyspareunia or non coital genital pain).⁹ Sexual function is related to women's self-perceived body image and degree of bother from pelvic organ prolapse (POP).¹⁰ Genital body image and sexual health are related in women with stage 2 or greater POP^{11–13} particularly in the domains of sexual desire and satisfaction. Women with anal incontinence (AI) have similar rates of sexual activity but poorer sexual function than

women without.^{12,14} An estimated 16% to 25% of women with chronic pelvic pain experience dyspareunia often leading to sexual avoidance.¹⁵ High pelvic floor muscle tone and sexual dysfunction are related.¹⁶ In women with PFDs there is a positive association between pelvic floor strength and sexual activity and function.¹⁷

Resolution of symptoms after successful treatment of PFDs often improves sexual function and/or women's wellbeing as measured on pelvic floor condition specific measures. After surgery for stress urinary incontinence (SUI) sexual function was unchanged in 55.5% of women, improved in 31.9% and deteriorated in 13.1%.¹⁸ The resolution of coital incontinence is closely correlated to patient's degree of sexual satisfaction and preoperative coital incontinence has been suggested as a prognostic factor for improvement of sexual function after surgery.¹⁹ Most women who undergo surgery for POP report unchanged sexual function.²⁰

3 | SYMPTOMS OF SEXUAL FUNCTION SPECIFIC TO PELVIC FLOOR DYSFUNCTION

3.1 | Symptom

Any morbid phenomenon or departure from the normal in structure, function, or sensation, experienced by the woman and indicative of disease or a health problem. Symptoms are either volunteered by, or elicited from the individual, or may be described by the individual's caregiver.¹ Sexual symptoms may occur in combination with other pelvic floor symptoms such as urinary, fecal, or combined incontinence or pelvic organ prolapse (POP) or pelvic pain.

3.2 | Vaginal symptoms

1. Obstructed intercourse: Vaginal intercourse that is difficult or not possible due to obstruction by genital prolapse or shortened vagina or pathological conditions such as lichen planus or lichen sclerosis.
2. Vaginal laxity: Feeling of vaginal looseness.¹
3. Anorgasmia: Complaint of lack of orgasm; the persistent or recurrent difficulty, delay in or absence of attaining orgasm following sufficient sexual stimulation and arousal, which causes personal distress.³
4. Vaginal dryness (NEW): Complaint of reduced vaginal lubrication or lack of adequate moisture in the vagina.

3.3 | Lower urinary tract sexual dysfunction symptoms

1. Coital urinary incontinence: urinary incontinence occurring during or after vaginal intercourse^a

2. Orgasmic urinary incontinence (NEW): urinary incontinence at orgasm
3. Penetration urinary incontinence (NEW): urinary incontinence at penetration (penile, manual, or sexual device)
4. Coital urinary urgency (NEW): Feeling of urgency to void during vaginal intercourse.
5. Post coital LUT symptoms (NEW): Such as worsened urinary frequency or urgency, dysuria, suprapubic tenderness.
6. Receptive urethral intercourse (NEW): Having a penis penetrating one's urethra (urethral coitus).^b

3.4 | Anorectal sexual dysfunction symptoms²⁸

1. Coital fecal (flatal) incontinence: Fecal (flatal) incontinence occurring with vaginal intercourse (see related definition "Coital fecal urgency").
2. Coital Fecal Urgency: Feeling of impending bowel action during vaginal intercourse.
3. Anodyspareunia: Complaint of pain or discomfort associated with attempted or complete anal penetration.²⁸
4. Anal laxity: Complaint of the feeling of a reduction in anal tone.

3.5 | Prolapse specific symptoms

1. Abstinence due to pelvic organ prolapse: Non engagement in sexual activity due to prolapse or associated symptoms.^c
2. Vaginal wind (Flatus): Passage of air from vagina (usually accompanied by sound).
3. Vaginal laxity: Feeling of vaginal looseness.^d
4. Obstructed intercourse: vaginal intercourse is difficult or not possible due to obstruction by genital prolapse or shortened vagina or pathological conditions such as lichen planus or lichen sclerosis.

3.6 | Pain symptoms

1. Dyspareunia: Complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration.^{1,e}
2. Superficial (Introital) dyspareunia: Complaint of pain or discomfort on vaginal entry or at the vaginal introitus.
3. Deep dyspareunia: complaint of pain or discomfort on deeper penetration (mid or upper vagina)
4. Vaginismus (NEW): recurrent or persistent spasm of vaginal musculature that interferes with vaginal penetration.^f
5. Dyspareunia with penile vaginal movement: pain that is caused by and is dependent on penile movement.

6. Vaginal dryness: Complaint of reduced vaginal lubrication or lack of adequate moisture in the vagina.^g
7. Hypertonic pelvic floor muscle: A general increase in muscle tone that can be associated with either elevated contractile activity and/or passive stiffness in the muscle.^{4,35,h}
8. Non coital sexual pain (NEW): pain induced by non coital stimulation.ⁱ
9. Post coital pain (NEW): pain after intercourse such as vaginal burning sensation or pelvic pain.
10. Vulvodynia: vulvar pain of at least 3 months' duration, without clear identifiable cause, which may have potential associated factors.³⁷

3.7 | Specific postoperative sexual dysfunction symptoms

- 1 De novo sexual dysfunction symptoms (NEW): new onset sexual dysfunction symptoms (not previously reported before surgery)
- 2 De novo dyspareunia (NEW): dyspareunia first reported after surgery or other interventions
- 3 Shortened vagina (NEW): perception of a short vagina expressed by the woman or her partner
- 4 Tight vagina (NEW):
 - Introital narrowing: vagina entry is difficult or impossible (penis or sexual device)
 - Vaginal narrowing: decreased vaginal calibre.
- 5 Scarred vagina (NEW): perception by the partner of a "stiff" vagina or a foreign body (stitches, mesh exposure, mesh shrinkage) in the vagina
- 6 Hispareunia: male partner pain with intercourse after female reconstructive surgery.^j

3.8 | Other symptoms

1. Decreased libido or sexual desire (NEW): Absent or diminished feelings of sexual interest or desire, absent sexual thoughts or fantasies, and a lack of responsive desire.^{1,3} Motivations (here defined as reasons/incentives) for attempting to become sexually aroused are scarce or absent. The lack of interest is considered to be beyond the normative lessening with lifecycle and relationship duration.
2. Decreased arousal (NEW): Persistent or recurrent inability to achieve or maintain sexual excitement. This may be expressed as lack of excitement, lack of lubrication, lack of vaginal and clitoral engorgement, or lack of expression of other somatic responses.^{1,3,k}
3. Anorgasmia or difficulty in achieving orgasm (NEW): Lack of orgasm, markedly diminished intensity of

orgasmic sensations or marked delay of orgasm from any kind of stimulation.^{1,3}

4 | SIGNS

4.1 | Sign

Any abnormality indicative of disease or health problem, discoverable on examination of the patient: an objective indication of disease or health problem.¹ Not all observed changes are associated with pathology from the point of view of the patient, and not all require intervention. The genital examination is often informative and in women with sexual dysfunction can often be therapeutic. A focused genital examination is highly recommended in presence of dyspareunia, vaginismus, neurological disease, genital arousal disorders, history of pelvic trauma, acquired or lifelong orgasmic disorder.^{4,1} The internal examinations are generally best performed with the woman's bladder empty.¹ Examination should be performed and described including vaginal length, calibre and mobility, presence of scarring and/or pain and estrogenization, and whether or not there is vaginal or labial agglutination. The location of any vaginal pain should be noted. Pelvic organ prolapse should be evaluated at it may influence sexual function by both affecting body image and vaginal symptoms during sexual activity.³⁹ If the patient has had an operation in which a synthetic mesh is utilized then mesh may be felt in the vagina which may or may not be associated with symptoms.⁴⁰ Bimanual examination should be performed to make observations for any pelvic mass or unusual tenderness by vaginal examination together with suprapubic palpation. Examination of the pelvic floor muscles may elicit signs pertaining to female sexual dysfunction. If dyspareunia, vaginismus, or history of pelvic trauma are present, completing internal exams is difficult and may be impossible. Assessing for presence of vulvar pain via a gentle, introital palpation, or performing a "Q-tip touch test" of the introitus is recommended prior to any internal examination.

4.2 | Perineal/vulval/urethral inspection and/or examination

1. Vulval gaping: non-coaptation of vulva at rest, commonly associated with increased size of genital hiatus.
2. Deficient perineum/cloacal-like defect: A spectrum of tissue loss from the perineal body and rectovaginal septum with variable appearance. There can be a common cavity made up of the anterior vagina and posterior rectal walls or just an extremely thin septum between the anorectum and vagina.²⁸

3. Urethral: Prolapse, caruncle, diverticulum.

4. Vulval agglutination: Labial lips fused.^m

4.3 | Vaginal examination

1. Vaginal agglutination: defined as condition where the walls of the vagina are fused together above the hymen.
2. Vulvo-vaginal hypoesthesia: Reduced vulvo-vaginal sensitivity to touch, pressure, vibration, or temperature.^{4,34,35,n}
3. Vulvo-vaginal hyperaesthesia: Increased vulvo-vaginal sensitivity to touch, pressure, vibration, or temperature
4. Pudendal neuralgia: elicited or described by the patient as burning vaginal and vulva pain (anywhere between the anus and the clitoris) with tenderness over the course of the pudendal nerve.^{1,o}

4.4 | Examination of pelvic floor muscles^{1,p}

1. Muscle tone: In normally innervated skeletal muscle, tone is created by "active" (contractile) and "passive" (viscoelastic) components clinically determined by resistance of the tissue against stretching or passive movement.^{47,48}
2. Normal pelvic floor muscles: Pelvic floor muscles which can voluntarily and involuntarily contract and relax.
3. Overactive pelvic floor muscles: Pelvic floor muscles which do not relax, or may even contract when relaxation is functionally needed, for example, during micturition or defecation.
4. Underactive pelvic floor muscles: Pelvic floor muscles which cannot voluntarily contract when this is appropriate.
5. Non-functioning pelvic floor muscles: Pelvic floor muscles where there is no voluntary action palpable.
6. Pelvic floor muscle spasm or pelvic floor myalgia: defined as the presence of contracted, painful muscles on palpation and elevated resting pressures by vaginal manometry.⁴⁹ This persistent contraction of striated muscle cannot be released voluntarily. If the contraction is painful, this is usually described as a cramp. Pelvic floor myalgia (a symptom) may be present with or without a change in PFM tone (a sign).
7. Pelvic floor muscle tenderness: occurrence of the sensation of pain or painful discomfort of the pelvic floor muscles elicited through palpation.
8. Hypertonicity: A general increase in muscle tone that can be associated with either elevated contractile activity and/or passive stiffness in the muscle.^{47,48,50} As the cause is often unknown the terms neurogenic hypertonicity and non-neurogenic hypertonicity are recommended.
9. Hypotonicity: A general decrease in muscle tone that can be associated with either reduced contractile activity and/

or passive stiffness in the muscle. As the cause is often unknown the terms neurogenic hypotonicity and non-neurogenic hypotonicity are recommended.⁴⁸

10. Muscle strength: Force-generating capacity of a muscle.^{48,51} It is generally expressed as maximal voluntary contraction measurements and as the one-repetition maximum (1RM) for dynamic measurements.^{52,53}
11. Muscle endurance: The ability to sustain near maximal or maximal force, assessed by the time one is able to maintain a maximal static or isometric contraction, or ability to repeatedly develop near maximal or maximal force determined by assessing the maximum number of repetitions one can perform at a given percentage of 1 RM.^{48,54}

4.5 | Urogenital aging (NEW): genitourinary syndrome of menopause—(GSM)^{94r}

1. Pallor/erythema: Pale or erythematous genital mucosa
2. Loss of vaginal rugae: Vaginal rugae flush with the skin
3. Tissue fragility/fissures: Genital mucosa that is easily broken or damaged
4. Vaginal petechiae: A petechia, plural petechiae, is a small (1-2 mm) red or purple spot on the skin, caused by a minor bleed (from broken capillary blood vessels)
5. Urethral mucosal prolapse: Urethral epithelium turned outside the lumen
6. Loss of hymenal remnants: Absence of hymenal remnants
7. Prominence of urethral meatus vaginal canal shortening and narrowing: Introital retraction
8. Vaginal dryness: Complaint of reduced vaginal lubrication or lack of adequate moisture in the vagina.

4.6 | General examination

Identify chronic systemic diseases and their treatments (eg, Diabetes, Multiple Sclerosis, Depression, Hypertension, lichen sclerosis) which can be associated with sexual dysfunction.

4.7 | Neurological examination

For women with neurological disease affecting the pelvic nerves clarify light touch, pressure, pain, temperature sensation, and vaginal tone, voluntary tightening of the anus and vagina, anal and bulbocavernosus reflexes.⁵⁵

5 | INVESTIGATIONS QOL; MEASUREMENT OF SEXUAL FUNCTION/HEALTH

While some physiologic measures of sexual activity and function exist, most are not readily available in the clinical or

research setting, and many do not accurately reflect patient rating of improvement. Therefore, measurement of sexual activity and function is largely limited to self-report and the use of sexual diaries or event logs, clinician-administered interviews, or questionnaires. The US Food and Drug Administration drafted guidelines in 2016 which support the use of event logs and diaries as the primary measures for the evaluation of the efficacy of interventions. Further, they specified that diaries and event log should record “Sexually Satisfying Events (SSE)” and that the number of SSE’s may be used as a primary endpoint in efficacy trials. Unfortunately, these measures do not correlate well with patient report of improvement using other validated sexual function and quality of life measures.⁵⁶ Personal interviews are time consuming and have wide variation in application making the reliability of findings suspect.

The FDA also recommended the use of patient reported outcomes for evaluation of sexual function. Most clinicians and researchers feel that questionnaires are the most accurate in measuring sexual function. Sexual function questionnaires include measures which were developed to include concepts important to women with pelvic floor dysfunction and those that were developed to address sexual health in women without pelvic floor dysfunction. In general, pelvic floor condition specific measures are more likely to be responsive to change than measures that are not condition specific, although both have been used in the evaluation of women with pelvic floor dysfunction. In addition, some questionnaires contain individual items or domains relevant to sexual function, such as the King’s Health Questionnaire, which has a domain specific to sexual function.

Increasingly, other measures, including those that evaluate body image, also impact sexual function and are associated with pelvic floor dysfunction. Measurement of these confounders may be important in order to assess the impact of pelvic floor dysfunction on sexual health.

5.1 | Sexual diaries

A daily log of sexual thoughts, activities; supported by the US FDA as a primary outcome measure for the efficacy of interventions to evaluate sexual function.

5.2 | Event logs

Record individual sexual events or activities. Each event is classified as a “sexually satisfying event (SSE)” or not. Event logs record individual events rather than activities on a daily basis.

5.3 | Sexually satisfying event

This term is coined by the US FDA, and is defined by the individual completing the questionnaire. The FDA stated that

TABLE 1 Sexual function questionnaires

Instrument	Description	Number of items	ICI* Grade	Condition-specific
ICIQ-FLUTSsex (BFLUTS) (International Consultation on Continence Questionnaire- Female Lower Urinary Tract Symptoms Sex) ⁵⁷	Female sexual matters associated with urinary symptoms and related bother	4	A	Yes
GRISS (The Golombok-Rust Inventory of Sexual Satisfaction) ⁵⁸	Anorgasmia, vaginismus, impotence, and premature ejaculation, avoidance, dissatisfaction and non-sensuality, infrequency and no communication about sex	28	A	No
ICIQ-VS (International Consultation of Incontinence Questionnaire -Vaginal Symptoms) ⁵⁹	Assess effects of vaginal symptoms of sexual quality of life	14	B	Yes
PISQ (Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire) ⁶⁰	Evaluates sexual function in women with incontinence and prolapse	31	B	Yes
PISQ-12 (short form version of the PISQ-31) ⁶¹	Evaluates sexual function in women with incontinence and prolapse	12	Not rated	Yes
PISQ IR (IUGA- revised version of the PISQ) ⁸	Evaluates sexual function in women with incontinence and prolapse includes evaluation of women with anal incontinence as well as women who do not report sexual activity	33	Not rated	Yes
FSFI (Female Sexual Function Index) ⁶²	Assesses multiple dimensions of sexual function	19	A	No
SFQ (Sexual Function Questionnaire) ⁶³	Assess the impact of OAB on sexual health function in the male and female population	31	C	Yes
SQOL-F (Sexual Quality Of Life-Female) ⁶⁴	Assess the impact of female sexual dysfunction of quality of life	18	B	Yes

*International Consultation on Incontinence.

the term “satisfying” and what activities will be classified as a sexual encounter should be defined but did not supply a definition.

5.4 | Questionnaires

Psychometric properties of some tools are reported in Table 1.⁶⁴

1. Pelvic Floor Condition specific sexual function measures: A validated sexual function measure which is developed to include concepts relevant women with pelvic floor dysfunction.
2. Generic sexual function measures: A validated measure that was developed to evaluate sexual function but does not contain items relevant to pelvic floor dysfunction such as coital incontinence or vaginal looseness.

6 | INVESTIGATIONS; MEASUREMENT OF PHYSIOLOGIC CHANGES

Physical investigations aim to evaluate different causes of sexual dysfunction and include investigations that focus on

the vascular, neurologic, musculoskeletal, and hormonal systems. The clinical utility of these investigations in the routine assessment of female sexual health needs further validation. In many instances, these investigations are utilized in the research setting. Supplemental Table S1 reviews the validity and reliability testing of physiologic investigations.

6.1 | Vascular assessment

Sexual arousal results in increased blood flow allowing genital engorgement, protrusion of the clitoris and augmented vaginal lubrication through secretion from the uterus and Bartholin's glands and transudation of plasma from engorged vessels in the vaginal walls. Several instruments are available to measure blood flow during sexual stimulation.^{65,66} Inadequate vasculogenic response may be related to psychological factors as well as vascular compromise due to atherosclerosis, hormonal influence, trauma, or surgery.

1. Vaginal photoplethysmography: A tampon shape intra-vaginal probe equipped with an incandescent light that projects toward the vaginal walls is inserted; the amount of light that reflects back to the photosensitive cell provides a measure of vaginal engorgement which can be expressed as

vaginal blood volume or vaginal pulse amplitude depending on the mode of recording.^{67,68} Likewise, labial and clitoral photoplethysmography can also be evaluated.^{69,70}

2. Vaginal and clitoral duplex Doppler ultrasound: The anatomical integrity of clitoral structures and the changes in clitoral and labial diameter associated with sexual stimulation can be evaluated in B mode.⁷¹ Movement of the blood relative to the transducer can be expressed as measurement of velocity, resistance, and pulsatility.⁷² Blood flow in arteries irrigating the clitoris and the vagina are more commonly assessed during sexual stimulation.^{71,73,74}
3. Laser Doppler imaging of genital blood flow: An imager positioned close to the vulva allows the assessment of skin/mucosae microcirculation at a depth of up to 2-3 mm.⁷⁵ This method has been used to assess response to sexual stimulation and correlated with subjective arousal.⁷⁵ It has also led to a better understanding of microvascular differences in women with provoked vestibulodynia compared to asymptomatic controls.⁷⁶
4. Magnetic resonance of imaging of the genito-pelvic area: Evaluation of the increase in clitoral structure volume related to tissue engorgement occurring during arousal.⁷⁶
5. Measurements of labial and vaginal oxygenation: A heated electrode and oxygen monitor are used to evaluate the arterial partial pressure of oxygen (PO₂) transcutaneously.^{78,79} The temperature of the electrode is kept at a constant elevated temperature by an electric current. Increase in blood flow under the electrode results in more effective temperature dissipation (heat loss) with the result that more current is needed to maintain the electrode at its prefixed temperature. The changes in current provide an indirect measurement of blood flow during sexual stimuli.^{79,80} The electrode also monitors oxygen diffusion across the skin.^{78,79}
6. Labial thermistor: Temperature measurement evaluated with a small metal clip attached to the labia minora and equipped with a sensitive thermistor.^{80,81}
7. Thermography or thermal imaging of the genital area: Evaluation of genital temperature using a camera detecting infrared radiation from the skin during sexual stimulation.⁸² This method has been correlated with subjective arousal.⁸³

6.2 | Neurologic assessment

Related to intact sensation, neurological innervation is important for arousal and orgasm. Peripheral neuropathy or central nervous system disorders (eg, diabetic neuropathy, spinal cord injury) may lead to anorgasmia and decreased

arousal.⁸⁴⁻⁸⁶ Different approaches can be used to evaluate motor and sensory neurological function.

1. Functional magnetic resonance imaging: Investigation of neural activation in anatomically localized cerebral regions evaluated through monitoring subtle changes in regional cerebral blood flow that occur with activation of the neurons. These patterns of activation and deactivation are used to examine the cerebral and cognitive response to sexual stimulation.⁷⁷
2. Quantitative sensory testing: Assessment of the sensitivity by applying different stimuli (light touch, pressure, temperature, or vibration) using an ascending or descending method in order to evaluate the detection threshold. These methods can be used to evaluate different vulvo-vaginal sites including the clitoris, labia minora, and majora as well as vaginal and anal margins.^{84,87,88}
3. Reflex examination: Evaluating sacral arc integrity, the bulbocavernosus reflex can be elicited by squeezing the clitoris and assessing the contraction of the anal sphincter.⁸⁹ The external anal reflex is tested by repetitive pricking delivered to perianal skin and observing anal sphincter contraction.⁸⁹ Latencies can also be evaluated by stimulating the nerve and evaluating muscle response through a needle electrode.⁹⁰

6.3 | Pelvic floor muscle assessment

Assessment of pelvic floor muscle (PFM) function involves evaluating the tone, strength, endurance, coordination, reflex activation during rises in intra-abdominal pressure as well as the capacity to properly relax this musculature. These muscles are involved in sexual function as PFM contraction occurs during arousal and intensifies with orgasm and PFM tone is related to vaginal sensation.⁹¹⁻⁹³ Superficial PFMs such as the bulbospongiosus and ischiocavernosus are also involved in erection of the clitoris by blocking the venous escape of blood from the dorsal vein.⁹⁴ Thus, reduction in PFM strength and endurance has been related to lower sexual function.^{95,96} Likewise, PFM hypotonicity may be related to vaginal hypoesthesia, anorgasmia, and urinary incontinence during intercourse⁹ while hypertonicity may lead to dyspareunia.^{97,98}

1. Pelvic floor manometry: measurement of resting pressure or pressure rise generated during contraction of the PFMs using a manometer connected to a sensor which is inserted into the urethra, vagina, or rectum. Pelvic floor manometric tools measuring pressure in either mmHg, hPa, or cmH₂O can be used to assess resting pressure, maximal squeeze pressure (strength), and endurance.⁹⁹ Details about recommendations to ensure validity of pressure measurements are provided elsewhere.⁹⁹

2. Pelvic floor dynamometry: measurement of PFM resting and contractile forces using strain gauges mounted on a speculum (a dynamometer), which is inserted into the vagina.^{100–102} Dynamometry measures force in Newton (N). Several parameters such as tone, strength, endurance, speed of contraction, and coordination can be evaluated.^{100–102}
3. Pelvic floor electromyography (EMG): the recording of electrical potentials generated by the depolarization of PFM fibers. Intra-muscular EMG consists in the insertion of a wire or needle electrode into the muscle to record motor unit action potentials while surface EMG requires electrodes placed on the skin of the perineum or inside the urethra, vaginal, or rectum. EMG amplitude at rest and contraction can be recorded.
4. Pelvic floor ultrasound imaging: evaluation of PFM morphology at rest, during maximal contraction and Valsalva. Several parameters pertaining to assess the bladder neck and anorectal positioning and hiatus dimensions can be measured.^{103–105}

6.4 | Hormonal assessment

Hormones such as estrogen, progestin, and androgen influence sexual function and imbalance may lead to various symptoms including decreased libido, lack of arousal, vaginal dryness, and dyspareunia.^{106, 107, 107} Depending on the underlying suspected conditions associated with sexual dysfunction, hormonal investigations such as estradiol (or FSH if symptoms of deficiency), serum testosterone, dehydroepiandrosterone acetate sulphate (DHEAS), free testosterone, dihydrotestosterone, prolactin, and thyroid function testing may be considered.¹⁰⁸ Moreover, the evaluation of vaginal pH and vaginal maturation index (ie, percentage of parabasal cells, intermediate cells, and superficial cells) can be helpful in women with vulvovaginal atrophy as it has been shown to be correlated with patient's symptomatology.¹⁰⁹

7 | COMMON DIAGNOSES

The Diagnostic and Statistical Manual of Mental Disorders fifth edition (DSM-5), the International Classification of

TABLE 2 Sexual dysfunction diagnoses

Diagnosis	Description
DSM—5 Diagnoses (American Psychiatric Association)	
Female Sexual Interest/Arousal disorder	Lack of, or significantly reduced, sexual interest/arousal as manifested by 3 of the following: <ol style="list-style-type: none"> 1. Absent/reduced interest in sexual activity 2. Absent/reduced sexual/erotic thoughts or fantasies 3. No/reduced initiation of sexual activity and unresponsive to partner's attempts to initiate 4. Absent/reduced sexual excitement/pleasure during sexual activity in almost all or all (75-100%) sexual encounters 5. Absent/reduced sexual interest/arousal in response to any internal or external sexual/erotic cues (written, verbal, visual) 6. Absent/reduced genital or non-genital sensations during sexual activity in almost all or all (75-100%) sexual encounters
Genito-Pelvic Pain/Penetration disorder	Persistent or recurrent difficulties with 1 or more of the following: <ol style="list-style-type: none"> 1. Vaginal penetration during intercourse 2. Marked vulvovaginal or pelvic pain during intercourse or penetration attempts 3. Marked fear or anxiety about vulvovaginal or pelvic pain in anticipation of, during, or as a result of vaginal penetration 4. Marked tensing or tightening of the pelvic floor muscles during attempted vaginal penetration.
Female orgasmic disorder	Presence of either of the following on all or almost all (75-100%) occasions of sexual activity: <ol style="list-style-type: none"> 1. Marked delay in, marked infrequency of, or absence of orgasm. 2. Markedly reduced intensity of orgasmic sensations
Joint terminology from the International Society for the Study of Women's Sexual Health and the North American Menopause Society	
Genitourinary Syndrome of Menopause	The genitourinary signs and symptoms of menopause that arise from decreasing level of estrogens and other steroids. This includes burning and irritation of reproductive organs and structures, dryness, pain with intercourse and urinary urgency, dysuria and recurrent infections.

Diseases 10th edition (ICD-10), and the Joint Terminology from the fourth International Consultation of Sexual Medicine (ICSM) all have proposed diagnoses for sexual disorders in women. Many of the diagnoses from the various societies overlap; we have chosen the diagnoses from the DSM 5, as well as the diagnosis of genitourinary syndrome of menopause as these diagnoses seem most relevant to the population of women with pelvic floor dysfunction, as shown in Table 2.

The DSM 5 has combined disorders that overlap in presentation and reduced the number of disorders from six to three. Hypoactive sexual desire disorder (HSDD) and female sexual arousal disorders (FSAD) have been combined into one disorder, now called Female Sexual Interest/Arousal Disorder (FSIAD), based on data suggesting that sexual response is not always a linear, uniform process, and that the distinction between certain phases, particularly desire and arousal, may be artificial. Although this revised classification has not been validated clinically and is controversial, it is the new adopted standardization. One reason offered for the new diagnostic name and criteria were clinical and experimental observations that sexual arousal and desire disorders typically co-occur in women and that women may therefore experience difficulties in both.^{110,111}

The DSM-IV categories of vaginismus and dyspareunia have been combined to create “genito-pelvic pain/penetration disorder” (GPPPD). Female Orgasmic Disorder remains its own diagnosis. The DSM 5 has also changed the relevant specifiers of these disorders with the goal of increasing objectivity and precision and to avoid over-diagnosis of transient sexual difficulties. In particular, all diagnoses now require a minimum duration of approximately 6 months and are further specified by severity.

Genitourinary syndrome of menopause (GSM) is a new term introduced by the International Society of Sexual Medicine to describe a variety of symptoms which may be associated with sexual health. Although not validated, this diagnosis was introduced in an effort to improve communication between providers and patients regarding symptoms which may be difficult to discuss. While not a sexual dysfunction diagnosis, given the age of women who typically develop pelvic floor dysfunction, symptoms associated with GSM may be relevant to the assessment of the sexual health of women with pelvic floor dysfunction.

For each of the DSM-5 diagnoses, providers should indicate whether or not the condition is lifelong or acquired, generalized or situational, and rate the severity as mild, moderate or severe in terms of the distress it causes. All of the diagnoses, except for the pain diagnoses, need to meet the criterion that it has been present for 6 months, causes significant distress, and are not a consequence of non-sexual mental disorder, severe relationship distress and are not solely or primarily attributable to a medication or underlying illness.¹¹² For genitourinary syndrome of menopause, not all

signs and symptoms need be present, but the symptoms must be bothersome and not better accounted for by another diagnosis.¹¹³

8 | TERMS FOR CONSERVATIVE TREATMENTS

8.1 | Lifestyle modification

Alterations of certain behaviors may improve sexual function. These include weight loss, appropriate sleep, adequate physical fitness, and management of mood disorders.^{114–118} Vulvovaginal pain may be treated by dietary changes and perineal hygiene (avoiding irritant soaps, detergents, and douches), although data are conflicting.¹¹⁹ Dietary modifications may be disorder specific including low oxalate diet as reduction in dietary levels of oxalate may improve symptoms of vulvodynia,¹²⁰ or a bladder friendly diet with reductions in acidic foods and bladder irritants may treat bladder pain and associated sexual pain.^{121,122}

8.2 | Bibliotherapy

Use of selected books and videos to aid in treatment and reduce stress. Shown to improve sexual desire.^{123,124}

8.3 | Topical therapies

Lubricants and moisturizers—Application of vaginal lubricant during sexual activity or vaginal moisturizers as maintenance may assist with atrophic symptoms and dyspareunia.^{125–127} Examples of some lubricants are described below, although no one lubricant or moisturizer has been adequately studied to recommend it over others. Additionally, not all products are available in all countries.

- Essential arousal oil: Feminine massage oil applied to vulva prior to activity. Some evidence to support efficacy in treatment of sexual dysfunction, including arousal and orgasm, compared with placebo.^{128,129}
- Vulvar soothing cream: Non-hormonal cream containing cutaneous lysate, to be applied twice daily. Study shows improvement in vulvar pain with use compared to placebo.^{130,131}
- Prostaglandin E1 analogue, may help increase genital vasodilation. Ongoing trials to determine efficacy in arousal or orgasmic dysfunction.^{131–133}

8.4 | Psychological intervention

Counseling and therapy are widely practiced treatments for female sexual dysfunction.^{114,134} Even when a sexual

problem's etiology and treatment is primarily urogenital, once a problem has developed there are typically psychological, sexual, relationship, and body image consequences and it may be tremendously validating and helpful for these women to be referred to counselors or therapists with expertise in sexual problems. Psychological interventions include cognitive behavioral therapy (CBT), sex therapy, and mindfulness training. While there is insufficient evidence with regard to controlled trials studying the efficacy of psychological treatment in women with sexual dysfunction, the available evidence suggests significant improvements in sexual function after intervention with traditional sex therapy and/or cognitive behavioral therapy.

Specific techniques include:

- Sex therapy: Traditional treatment approach with aim to improve individual or couple's sexual experiences and reduce anxiety related to sexual activity.¹¹⁴
- Cognitive-behavioral therapy: Incorporates sex therapy components but with larger emphasis on modification of thought patterns that may interfere with sexual pleasure.¹¹⁴
- Mindfulness: An ancient eastern practice with Buddhist roots. The practice of "relaxed wakefulness," and "being in the moment," has been found to be an effective component of psychological treatments for sexual dysfunction.^{135–137}

8.5 | Non-pharmacologic treatments

- Clitoral suction device: Non-pharmacological treatment, this is a battery-operated hand held device, designed to be placed over the clitoris. It provides a gentle adjustable vacuum suction with low-level vibratory sensation. Intended to be used three or more times a week for approximately 5 min at a time, this therapy has been shown to increase blood flow to the clitoral area as well as to the vagina and pelvis.¹¹⁷ Small non-blinded studies have shown it may significantly improve arousal, orgasm, and overall satisfaction in patients with sexual arousal disorder.^{137,138}
- Vaginal dilators: Vaginal forms or inserts, dilators are medical devices of progressively increasing lengths or girths designed to reduce vaginal adhesions after pelvic malignancy treatments or in treatment of vulvar/vaginal pain.^{139,140} Can be useful for perineal pain or introital narrowing following pelvic reconstructive repairs, however, routine use after surgery not supported.¹⁴¹ Dilators can also be used for pelvic floor muscle stretching (ie, Thiele massage) and was found helpful in women with interstitial cystitis and high-tone pelvic floor dysfunctions.¹⁴²

- Vaginal vibrators, external and internal: May be associated with improved sexual function, data controversial.^{143,144} Possibility that use of vibrators for self-stimulation may negatively impact sexual function with partner related activity.¹⁴⁵
- Vaginal exercising devices: Pelvic muscle strengthening tools in form of balls, inserts or biofeedback monitors. May improve pelvic floor muscle tone and coordination by improving ability to contract and relax. Studies are lacking assessing their use without concurrent physical therapy.
- Fractional CO2 laser treatment: Use of thermoablative laser to vaginal mucosa may improve microscopic structure of epithelium.^{146–148} This results in increased thickness, vascularity, and connective tissue remodeling, which can improve climacteric symptoms. Although long term data are lacking, some studies have shown significant improvements in subject symptoms of vaginal dryness, burning, itching, and dyspareunia as well as quality of life.^{147,149,150}

8.5.1 | Alternative treatments

- Acupuncture: Ancient Chinese practice that involves insertion of small needles into various points in the body in an effort to heal pain or treat disease. It may help with stress reduction, pelvic pain, and sexual dysfunction.^{122,151,152}

8.5.2 | Physical therapy

Manual therapy: Techniques that include stretching, myofascial release, pressure, proprioceptive neuromuscular facilitation, and massage applied externally on the perineum and internally to increase flexibility, release muscle tensions and trigger points in the pelvic floor muscles. It was found to be effective to improve sexual function in women with pelvic floor disorders in recent meta-analysis and systematic review.^{17,153,154} These therapies have also been found helpful in women with genito-pelvic pain.¹⁵⁵

- Pelvic muscle exercises with or without biofeedback: May improve sexual function in women with pelvic floor disorders¹⁵⁴ or pain.¹²²
- Dry needling: Placement of needles without injection in myofascial trigger points.¹⁵⁶
- Trigger point injections
 - i. Anesthetic: Injection of local anesthetics, often Lidocaine, directed by trigger point palpation, can be external or transvaginal.^{156–158}
 - ii. Botox: Injection of Botulinum toxin type A, a potent muscle relaxant, into refractory myofascial trigger points to reduce pelvic pain.^{122,156,157}

8.6 | Prescription treatments

8.6.1 | Hormonal

- Estrogen: Available via prescription for both systemic use (oral or transdermal preparations); or locally use (creams, rings, or tablets). May assist with overall well-being, sexual desire, arousal, and dyspareunia.^{117,127,159} Role for topical use in treatment of post-surgical atrophy or mesh extrusion.¹⁶⁰
- Ospemifene: Selective estrogen receptor modulator for treatment of moderate to severe dyspareunia related to vulvar and vaginal atrophy, in postmenopausal women.^{161–163} Acts as an estrogen agonist/antagonist with tissue selective effects in the endometrium
- Testosterone: Not approved for use in women in the USA or UK, may be available in other countries. Variety of preparations including transdermal, oral, or pellet administration. Long term safety unknown, studies suggest improvements in satisfying sexual events, sexual desire, pleasure, arousal, orgasm, and decreased distress.^{114,127,133}
- Tibolone: Synthetic steroid with estrogenic, progestogenic, and androgenic properties. It is not currently available in the USA. Studies have suggested a positive effect on sexual function with use.¹⁵⁹
- Prasterone: dehydroepiandrosterone suppository available as a vaginal insert. It has been shown to be efficacious when compared to placebo in decreasing vulvovaginal atrophy.¹⁶⁴

8.6.2 | Non hormonal

- Bremelanotide; formerly PT-141- Melanocortin agonist, initially developed as a sunless tanning agent, utilizes a subcutaneous drug delivery system. Treatment significantly increased sexual arousal, sexual desire, and number of sexually satisfying events with associated decreased distress in premenopausal women with FSD.¹⁶⁵
- Serotonin receptor agonist/antagonist; Flibanserin-5-hydroxytryptamine (HT)1A receptor agonist and 5-HT2A receptor antagonist, initially developed as antidepressant. Challenges in FDA applications, due to possible long term risks. Studies show improved sexual desire, satisfying sexual events, and reduced distress.^{166,167}
- Dual control model in differential drug treatments for hypoactive sexual desire disorder and female sexual arousal disorder:
 - i. Testosterone in conjunction with phosphodiesterase type 5 inhibitor (PDE-5)
 - ii. Testosterone in conjunction with a 5-HT1A agonist

May be able to target physiologic and subjective measures of sexual functioning in a more specific manner. Premise of

two types of HASDD subjects: low sensitivity to sexual cues, or prone to sexual inhibition. Tailoring on demand therapeutics to different underlying etiologies may be useful to treat common symptoms in women with lack of sexual interest and provide the appropriate therapy. Testosterone is supplied as a short acting agent 4 h prior to sexual event to lessen the side effect/risk profile.^{168–171}

- Apomorphine: Nonselective dopamine agonist that may enhance response to stimuli.^{133,172}
- Antidepressants and Neuropathics: Include tricyclic antidepressants, and anticonvulsants, may be useful in treating sexual pain, and vulvar pain.^{120,122}
- Bupropion: Mild dopamine and norepinephrine reuptake inhibitor and acetylcholine receptor antagonist, it may improve desire and decrease distress or modulate Selective Serotonin Reuptake Inhibitor (SSRI) induced FSD.¹⁷³

Supplemental Table S2 presents studies evaluating the effect of various treatments on sexual dysfunction.

9 | SURGERY

9.1 | The effect of pelvic reconstructive surgery for prolapse and incontinence on sexual health

Women with pelvic floor dysfunction commonly report impaired sexual function, which may be associated with the underlying pelvic floor disorder. Treatment of the underlying disorders may or may not impact sexual function.¹³ While both urinary incontinence and pelvic organ prolapse affect sexual function, prolapse is more likely than urinary incontinence to result in sexual inactivity. Prolapse is also more likely to be perceived by women as affecting sexual relations and overall sexual satisfaction. This perception is independent of diagnosis or therapy for urinary incontinence or prolapse.^{29,174,175} Very little is known about the impact of fecal incontinence on sexual function.¹⁴ The effect of pelvic reconstructive surgery on sexual function has increased but there is need for more focused research.^{30,176} Overall, randomized trials are lacking, varied outcome measures are used among studies.¹⁸ There is a lack of reporting per DSM-IV/DSM 5 categories and a lack of long-term follow-up. Level of Evidence (LOE) is poor in many studies, and sexual dysfunction is usually reported as a secondary outcome measure. While any surgery can impact sexual function postoperatively, most commonly performed pelvic floor surgeries were not designed with the intent to improve sexual function. In general, successful surgical treatment of incontinence or prolapse may improve sexual symptoms associated with the underlying disorder. For example,

coital incontinence improves after sling surgery, but whether it impacts other aspects of sexual function such as orgasm, desire, or arousal is unclear.¹⁸ Surgery for prolapse may improve underlying symptoms of laxity or embarrassment from bulge, which in turn may improve sexual function, but does not seem to have a direct impact on other aspects of sexual function. A small but significant number of patients will develop pain or other sexual disorders following surgery. These pain disorders spring from a variety of causes including those caused by the use of grafts. Prediction of who will develop these pain disorders is challenging. A recent paper which evaluated the effect of vaginal surgery on sexual function reported that women overall reported improved function, decrease in dyspareunia rates, and that de novo dyspareunia rates were low at 5% at 12 months and 10% at 24 months.¹⁷⁷ Nonetheless, assessment of sexual activity and partner status and function prior to and following surgical treatment is essential in the evaluation of surgical outcomes. Because of the negative impact of pain on sexual function, assessment of sexual pain prior to and following procedures should also be undertaken.

9.2 | Female genital cosmetic surgery

A number of surgeries have been developed that aim to improve sexual function by altering the appearance and/or the function of female genital tract. Evidence supporting the efficacy and safety of these procedures is lacking. In addition, standardized definitions of these procedures may help foster high quality research, standardization of technique, and outcome measurement in this field, but is currently lacking, and beyond the scope of this document. These procedures include, but are not limited to, labioplasty, vaginoplasty, laser vaginoplasty, perineoplasty, laser rejuvenation, clitoral de-hooding, labia majora augmentation, G spot amplification, laser treatment of vulvovaginal atrophy, and platelet risk plasma treatments.

10 | CONSIDERATIONS FOR REPORTING IN RESEARCH

Sexual health should be included as an outcome for reporting research related to pelvic floor dysfunction; this is particularly important in the case of surgical interventions as adverse or advantageous sexual function outcomes would likely impact patient's choice and satisfaction with interventions. The IUGA ICS Joint Report on terminology³⁹ for reporting outcomes of surgical procedures for POP described in detail items to be considered when reporting outcomes for prolapse surgical intervention.¹⁸ De novo painful intercourse following prolapse surgery should be classified as described in these documents. While pain and its impact on sexual function is

important, assessments limited to descriptions of sexual pain are not an adequate assessment of sexual health, and absence of pain should not be inferred to indicate that sexual function is intact or changed.

At a minimum, sexual activity status should be assessed. Assessment of sexual activity status should be self-defined and not limited to women who engage in sexual intercourse. In addition, it is important to not assume the gender of the woman's partner. When reporting level of sexual activity, authors should report numbers of all patients who are sexually active (or inactive), with and without pain, pre- and post intervention.

In addition to sexual activity status, its associated level of bother should be documented. Use of validated patient reported outcome questionnaires to further assess the quality of sexual function should also be considered. These and other self-reported outcomes including sexually satisfying events and sexual diaries are described in Section 4, in this document. Assessment of the impact of pelvic floor disorder treatment on women's sexual partners should also be considered. Conditions, among others, that commonly impact sexual function include hormonal status, body image, underlying medical conditions, and history of sexual abuse. Researchers may want to consider inclusion of these outcomes.

11 | LIMITATIONS

This document includes a broad overview of terms important in the diagnosis and treatment of women with pelvic floor disorders. We have not included an in-depth description of all sexual disorders as this is beyond the scope of this document. Some disorders such as the persistent vulvar pain and vulvodynia are described elsewhere and we have tried to reference these documents as appropriate.³⁷ Not all management strategies presented are supported by robust evidence as to their efficacy; we have tried to include the data that supports interventions as it is available. In addition, there are ongoing debates regarding terms and diagnoses. For example, subsequent to the publication of the DSM-5, the International Consultation on Sexual Medicine (ICSM) in 2015,¹⁸⁰ and the International Society for Study of Women's Sexual Health (ISSWSH)¹⁸¹ published consensus papers on the nomenclature for female sexual dysfunctions. Based on the available evidence regarding clinical presentation, risk factors, and treatment response, both organizations recommended maintaining desire and arousal as distinct and separate clinical entities.

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COMPLIANCE WITH ETHICAL STANDARDS

Disclaimer: Any products/companies referred to in this document are not necessarily recommended or endorsed by the ICS or IUGA.

CONFLICTS OF INTEREST

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ENDNOTES

^a Coital incontinence is defined as a complaint of involuntary leakage of urine during or after coitus. Coital incontinence seems to be an aggravating factor that women generally describe as humiliating.¹ The prevalence of urinary incontinence during intercourse has been evaluated to range from 2% to 56%, depending on the study population (for eg, the general population or a cohort of women with incontinence), the definition used (any leakage, weekly, on penetration, during orgasm, only severe leakage) and the evaluation method used (questionnaire, interviews). In a literature review reported in 2002 that covered English-language papers from 1980 to 2001, Shaw²¹ reported a 2-10% prevalence of coital incontinence in randomly selected community samples. The physio pathological mechanisms involved have been widely debated,²² with bladder overactivity conventionally being implicated in orgasmic incontinence and SUI in penetration incontinence. In the past 5 years, studies however, have underlined the role of the urethral sphincter in coital incontinence, which is thought to be crucial even in women with detrusor overactivity and orgasmic incontinence.²³ The penetration form of coital incontinence is largely associated with urodynamics findings of

SUI, whereas orgasmic incontinence might be associated with both detrusor overactivity and SUI.^{23,24} Nevertheless, among women with OAB, orgasmic incontinence is more common than penetration incontinence. Coital incontinence on penetration can be cured by surgery in 80% of women with urodynamically proven SUI. Similarly, orgasmic incontinence can respond to treatment with anticholinergics in 59% of women with detrusor overactivity.^{25,26}

^b Rare condition mostly described in women who have genital abnormalities such as micro perforate hymen.²⁷

^c A third of sexually active women with POP complain that their prolapse interferes with sexual function.^{29,30} However, it has been shown that women with POP have comparable rate of sexual activity to similarly aged individuals without POP.^{31,32}

^d A recent survey of IUGA members noted that 57% of responders considered vaginal laxity a bothersome condition that impacts relationship happiness and patient's sexual functioning. The most frequently cited (52.6%) location responsible from laxity was the introitus and the majority of respondents (87%) thought both muscle and tissue changes were responsible.³³

^e Dyspareunia rates reported in the literature range from 14 % to 18%.³⁴

^f There is often (phobic) avoidance and anticipation/fear/experience of pain, along with variable involuntary pelvic muscle contraction. Patients with vaginismus could present with severe fear avoidance without vulvar pain or fear avoidance with vulvar pain. Structural or other physical abnormalities must be ruled out/addressed.³⁵ There is controversy of whether or not this term should be retained; the Diagnostic and statistical manual of mental disorders 2013 proposed to replace dyspareunia and vaginismus with the term "Genito-Pelvic Pain/ Penetration Disorder (GPPPD)."³⁶

^g Decreased vaginal lubrication is often involved in pain with sexual activity among postmenopausal women, women with hypo-estrogenic states for other reasons or after pelvic surgery and may result in persistent or recurrent vaginal burning sensation with intercourse (penile or any device).⁴

^h A non-relaxing pelvic floor that is mainly associated with dyspareunia. See 4.4.⁸

ⁱ In certain disorders such as genital herpes, vestibulitis, endometriosis, or bladder pain syndrome, pain may also occur after non coital stimulation.⁴

^j The term "Hispareunia" has been first suggested by Brubaker in one editorial to describe partner dyspareunia after sling insertion.³⁸

^k It has been suggested that a distinction could be made between women with sexual arousal concerns that are psychological or subjective in nature (ie, absence of or markedly diminished feelings of sexual arousal while vaginal lubrication or other signs of physical response still occur), those that are genital (impaired genital sexual arousal—reduction of the physical response), and those that include complaints of both decreased subjective and genital arousal.^{1,4}

^l A normal examination is highly informative to the women and can be of reassurance value.⁴

^m Other conditions that may influence sexual function are fissures, vulval excoriation, skin rashes, cysts, and other tumors, atrophic changes or lichen sclerosis, scars, sinuses, deformities, condylomata, papillomata, hematoma.

ⁿ Increased blood flow in the vaginal walls associated with arousal increases the force in the vaginal walls, which drives transudation of

NaCl+-rich plasma through the vaginal epithelium, coalescing into the slippery film of vaginal lubrication and neutralizing the vagina's usually acidic state.³³ Reduced vulvo-vaginal sensitivity has been associated with sexual dysfunction and neurologic impairment.³⁴

^o Sitting often exacerbates the pain, which may be relieved in the supine position. Presentation may be unilateral or bilateral in presentation.

^p Intra-vaginal or intra-rectal assessment palpation is useful to provide a subjective appreciation of the PFM. PFM tone can be evaluated and defined as hypotonic, normal, and hypertonic,⁴¹ or assessed using Reissing's 7 point scale from -3 to +3.⁴² Squeeze pressure or strength during voluntary and reflex contraction can also be graded as strong, normal, weak, absent, or alternatively by using a validated grading system such as Brink's scale or the PERFECT scheme.⁴²⁻⁴⁴ These scales also include quotations of muscular endurance (ability to sustain maximal or near maximal force), repeatability (the number of times a contraction to maximal or near maximal force can be performed), duration, co-ordination, and displacement. Each side of the pelvic floor can also be assessed separately to allow for any unilateral defects and asymmetry.⁴² Voluntary muscle relaxation can be graded as absent, partial, complete, delayed.⁴² The presence of major morphological abnormalities of the puborectalis muscle may be assessed for by palpating its insertion on the inferior aspect of the os pubis. If the muscle is absent 2-3 cm lateral to the urethra, that is, if the bony surface of the os pubis can be palpated as devoid of muscle, an "avulsion injury" of the puborectalis muscle is likely.⁴⁵ Tenderness can be scored during a digital rectal (or vaginal) examination of levator ani, piriformis and internal obturator muscles bilaterally, according to each subject's reactions: 0, no pain; 1, painful discomfort; 2, intense pain; with a maximum total score of 12.⁴⁶

^q GSM is a syndrome associated with aging that results in alkalization of vaginal pH, changes in the vaginal flora, increased parabasal cell on maturation index and decreased superficial cells on wet mount or maturation index. In addition, there is a loss of collagen, adipose, and water-retention of the vulva which results in loss of elasticity, generalized reduction in blood perfusion of the genitalia. The vaginal epithelium may become friable with petechiae, ulcerations, and bleeding after minimal trauma.⁴⁸

^r Two classification systems for complications following prolapse surgery, includes the more generic Modified Clavien Dindo¹⁷⁸ and the more specific IUGA ICS classification of complications related to insertion of grafts/prosthesis⁴⁰ or use of native tissue.¹⁷⁹ These classification systems did include pain related to prolapse surgery complications which was sub-classified depending on whether pain was at rest, provoked during examination, during sexual activities, physical activities, or spontaneous.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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An International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction

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Introduction and hypothesis There has been an increasing need for the terminology on the conservative management of female pelvic floor dysfunction to be collated in a clinically based consensus report.

Methods This Report combines the input of members and elected nominees of the Standardization and Terminology Committees of two International Organizations, the International Urogynecological Association (IUGA) and the International Continence Society (ICS), assisted at intervals by many external referees. An extensive process of nine rounds of internal and external review was developed to exhaustively examine each definition, with decision-making by collective opinion (consensus). Before opening up for comments on the webpages of ICS and IUGA, five experts from physiotherapy, neurology, urology, urogynecology, and nursing were invited to comment on the paper.

Results A Terminology Report on the conservative management of female pelvic floor dysfunction, encompassing over 200 separate definitions, has been developed. It is clinically based, with the most common symptoms, signs, assessments, diagnoses, and treatments defined. Clarity and ease of use have been key aims to make it interpretable by practitioners and trainees in all the different specialty groups involved in female pelvic floor dysfunction. Ongoing review is not only anticipated, but will be required to keep the document updated and as widely acceptable as possible.

Conclusion A consensus-based terminology report for the conservative management of female pelvic floor dysfunction has been produced, aimed at being a significant aid to clinical practice and a stimulus for research.

KEYWORDS

consensus, conservative management, female, pelvic floor dysfunction, terminology

This document is being published simultaneously in *Neurourology and Urodynamics* (NAU) and the *International Urogynecology Journal* (IJU), the respective journals of the sponsoring organizations, the International Continence Society (ICS) and the International Urogynecological Association (IUGA). IJU DOI: 10.1007/s00192-016-3123-4

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INTRODUCTION

There is currently no single document addressing the conservative management of female pelvic floor dysfunction in a comprehensive way. The report is based on, and follows on from, the terminology proposed by the International Continence Society (ICS) Standardization of Terminology of Lower Urinary Tract Function,¹ the Standardization of Terminology of Pelvic Floor Muscle Function and Dysfunction: Report from the Pelvic Floor Clinical Assessment group of the International Continence Society,² and the International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Floor Dysfunction.³

The terminology in current use related to conservative management generally lacks uniformity, often because different disciplines use their own terminology. The range of terms in use can lead to uncertainty, confusion, and unintended ambiguity. It hampers the ability to build a body of literature concerning conservative interventions, e.g., the terms “behavioral therapy,” “lifestyle intervention,” “conservative treatment,” “nonsurgical treatment,” “physiotherapy,” “biofeedback,” and “pelvic floor muscle exercise” are often used interchangeably and, at times, incorrectly, to describe both the same and different interventions. A more standardized terminology would aid interdisciplinary communication and understanding.

Existing published reports address some of the aspects of this topic, but there are some areas of terminology currently lacking standardization, e.g., Messelink et al.² and Haylen et al.³ refer to evaluation and diagnostic terminology, but not to treatment terminology.

There is a need for a more extensive description of the management of the pelvic floor and pelvic floor muscle (PFM) dysfunction than is currently provided in existing terminology reports. With the development of the evidence base for conservative therapies in the management of pelvic floor dysfunction (PFD), especially treatment of conditions such as incontinence and pelvic organ prolapse (POP), terminology linked with these managements has evolved, but with regional and discipline variations. A consensus on currently accepted terminology is required. Elements in the title of the document need to be defined:

Conservative: restricted to nonsurgical and nonpharmacological approaches.

Management: includes the following aspects:

- a) Assessment: including history and physical examination and investigations
- b) Diagnosis
- c) Prevention
- d) Treatment of pelvic floor dysfunction

Pelvic floor: structures located within the bony pelvis, i.e., urogenital and anorectal viscera, PFM and their connective tissues, and nerves and blood vessels.

Pelvic floor dysfunction: following on from Messelink et al.'s report from the Pelvic Floor Clinical Assessment Group of the ICS,² this report will focus on the terminology of the management of pelvic floor function and dysfunction, including bladder and bowel dysfunction, pelvic organ prolapse (POP), sexual dysfunction, and pelvic pain.⁴ Terminology regarding pelvic pain and anorectal dysfunction related to PFM dysfunction aligns with the current working groups on chronic pelvic pain and anorectal dysfunction. Terminology includes symptoms, signs, and investigations (expanding on Messelink et al.'s paper²; diagnoses of PFM-related conditions (avoiding duplication with Haylen et al.³); prevention and treatment (including new therapies, e.g., exercise and adjunctive therapies, including equipment, and lifestyle modifications not covered by Messelink et al.² or Haylen et al.³

Additional descriptions related to the terms used in this manuscript are:

Clinicians/practitioners: conservative management of PFD may be provided by clinicians or practitioners of different disciplines, commonly physiotherapists/physical therapists, nurses, midwives, and medical doctors. However, other professions, e.g., fitness instructors and personal trainers, may also play a role in education, health promotion, and prevention of PFD. Terminology related to the accepted names of professions and the different types of therapies must be specified and distinguished (e.g., “physiotherapy” as a management provided by a registered physiotherapist, as distinct from “conservative therapy” and “exercises”/“biofeedback,” which may be provided by any clinician). The emphasis in this document will be on management commonly undertaken by clinicians practicing conservative management.

Multidisciplinary approach: relating to, or involving, two or more disciplines that are usually considered distinct,⁵ e.g., physical therapy, urology, gynecology

Gender: with the increasing specificity and complexity of female diagnosis and management it can be argued that a gender-specific report is needed. However, many of the terms defined in this report are not gender-specific and are the same for males, e.g., PFM training and electrical stimulation. This report does not preclude an additional future report on male pelvic floor dysfunction

METHODOLOGY

All working group members were asked to provide terms that they knew existed in the area. After the first “brainstorming activity,” all terms were listed and grouped according to introduction, symptoms, signs, examination methods, investigations, diagnosis, prevention, and treatment. All members were given the text to which to add

more terms. Additional searching for omitted terms in existing terminology papers of the ICS and IUGA, Cochrane reviews, and the 2013 ICI document⁶ was undertaken. Existing definitions of established terms from general medicine,^{7,8} physiotherapy,⁵ and exercise science were used where available. Only in situations where there was no existing terminology were new definitions introduced. We have not referred to or described the responsiveness, reliability, and validity of the measurement methods of symptoms, signs, and evaluations, nor have we acknowledged the evidence for the treatment efficacy of any of the therapies defined.

Agreement on the definitions was reached by consensus. Wherever possible, evidence-based principles were followed. However, this was a challenge in conservative management, as there are many suggested therapies that do not have proven effectiveness.^{9,10} Discussion meetings with representatives of the IUGA and ICS were held at the following annual meetings: IUGA Brisbane 2012, ICS Beijing 2012, IUGA Dublin 2013, ICS Barcelona 2013, IUGA-AUGS Washington DC 2014, and IUGA Nice 2015.

It is recommended that acknowledgment of these standards in written publications related to the conservative management of female pelvic floor dysfunction is stated as follows: “Methods, definitions, and units conform to the standards jointly recommended by the IUGA/ICS Joint Report on the Terminology for the Conservative and Nonpharmacological Management of Female Pelvic Floor Dysfunction, except where specifically noted.”

ASSESSMENT

Symptoms

Symptom: any morbid phenomenon or departure from the normal in structure, function or sensation, experienced by the woman and indicative of disease or a health problem. Symptoms are either volunteered by, or elicited from the individual, or may be described by the individual's caregiver.³

Existing (defined) symptoms

1. Urinary incontinence (UI) symptoms³
2. Bladder storage symptoms³
3. Sensory symptoms³
4. Voiding and postmicturition symptoms³
5. POP symptoms³
6. Symptoms of sexual dysfunction³
7. Symptoms of anorectal dysfunction^{3, endnote 1}
8. Lower urinary tract infection UTI³

Lower urinary tract pain and/or other pelvic pain^{endnote 2}

1. Pain (in general): “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”.¹¹
2. Tenderness: sensation of discomfort with or without pain; discomfort elicited through palpation, indicates unusual sensitivity to pressure or touch.¹²
3. Acute pain: pain related to acute trauma, infection or other well-defined disease processes or conditions.
4. Chronic pain: persistent or continuous/recurrent pain for at least 6 months. If non-acute and central sensitization pain mechanisms are well documented, then the pain may be regarded as chronic, irrespective of the time period.^{13,14}
5. Myalgia: muscle pain. Pelvic floor myalgia (a symptom) may be present with or without a change in PFM tone (a sign).^{endnote 3}
6. Myofascial pain: pain caused by the presence of trigger points within muscles or their fascia.^{15, endnote 4}

Signs

Sign: any abnormality indicative of disease or a health problem, discoverable on examination of the patient; an objective indication of disease or a health problem.¹

Existing (defined) signs

1. Urinary incontinence signs:³
 - a) UI³
 - b) Stress (urinary) incontinence³
 - c) Urgency (urinary) incontinence³
 - d) Extraurethral incontinence³
 - e) Stress incontinence on prolapse reduction (occult or latent stress incontinence)³
2. Pelvic organ prolapse signs:³
 - a) Uterine/cervical prolapse³
 - b) Vaginal vault (cuff scar) prolapse³
 - c) Anterior vaginal wall prolapse³
 - d) Posterior vaginal wall prolapse³
3. Other pelvic examinations/signs:³
 - a) Vulval abnormalities³
 - b) Urethral mucosal prolapse³
 - c) Urethral caruncle³
 - d) Urethral diverticulum³
 - e) Total vaginal length (TVL): the distance from the posterior fornix to the hymen.¹⁶
 - f) Valsalva maneuver: the action of attempting to exhale with the nostrils and mouth, or glottis closed.⁷ Valsalva

is usually performed with digital closure of the nose, as when trying to equalize pressure in an airplane. Straining/bearing down may have a similar meaning to Valsalva; however, in practice, straining/bearing down may be interpreted as meaning pushing downward and trying to relax the pelvic floor, as when defecating.

- g) Bimanual pelvic examination³
 - h) Perineal elevation: inward (ventrocephalad) movement of the vulva, perineum, and anus during, for example, PFM contraction.
 - i) Perineal descent: excessive dorsocaudal movement of the vulva, perineum, and anus, for example, during coughing, Valsalva or straining.^{3,17}
 - j) Trophic: promoting cellular growth, differentiation, and survival.⁸ This is the normal status of an organ, tissue or cell with regard to nutrition, size, number, form, and function. A trophic urogenital tract is usually well-estrogenized.
 - k) Atrophic: decrease from previous normal size of the body or a part, cell, organ, or tissue. An organ or body part's cells may be reduced in number, size or both. Atrophy of some cells and organs is normal at certain points in the life cycle. Other causes include malnutrition, disease, disuse, injury, and hormone over- or underproduction.^{8, endnote 5}
4. Anal signs¹⁸
5. Abdominal signs
- a) Bladder fullness/retention: abdominal palpation or suprapubic percussion may indicate a full bladder; however, in overweight patients this may not be easily detected.
 - b) Pelvic bone irregularities: indication of a previous fracture or sacral agenesis.
6. Neurological signs: abnormalities of the nervous system detected by physical examination that reflect an underlying neurological disease or injury. Examples of abnormal signs may include altered sensation, muscle tone or reflexes. If present, the patient should be referred for a full neurological examination.

Pelvic floor muscle function signs

1. Normal PFM: have a level of constant resting tone (except just before and during voiding and defecation), symmetry, and the ability to voluntarily and involuntarily contract and relax.
2. Normal PFM contractile function: a constriction and inward (ventrocephalad) movement of the pelvic openings. Normal, well-functioning pelvic floor muscles may demonstrate some (controlled or limited) downward

dorsal perineal movement in response to increased intra-abdominal pressure in the absence of incontinence or POP.

3. Muscle tone: state of the muscle, usually defined by its resting tension, clinically determined by resistance to passive movement.^{19–21} Muscle tone has two components: the contractile component, created by the low-frequency activation of a small number of motor units, and the viscoelastic component, which is independent of neural activity and reflects the passive physical properties of the elastic tension of the muscle fiber elements and the osmotic pressure of the cells.^{19, endnote 6}
 - a) Hypertonicity: an increase in muscle tone related to the contractile or viscoelastic components that can be associated with either elevated contractile activity and/or passive stiffness in the muscle.^{20,22} The terms neurogenic hypertonicity and non-neurogenic hypertonicity are recommended to describe the diagnosis and inform management.
 - b) Hypotonicity: a decrease in muscle tone related to the contractile or viscoelastic components that can be associated with either reduced contractile activity and/or passive stiffness in the muscle. The terms neurogenic hypotonicity and non-neurogenic hypotonicity are recommended to describe the diagnosis and inform management.^{endnote 7}
4. Stiffness: resistance to deformation.²³ Passive elastic stiffness is defined as the ratio of the change in the passive resistance or passive force (ΔF) to the change in the length displacement (ΔL) or $\Delta F/\Delta L$.²⁴ The term should only be used if stiffness is measured quantitatively, such as with the use of instruments such as dynamometry or myotonometry.
5. Tension: may have a similar meaning to tone and stiffness. Muscle tension can be increased or decreased because of exogenous factors such as the amount of pressure applied and endogenous factors such as thickness/cross-sectional area of the muscle itself, fluid present within the muscle (swelling, inflammation), position (e.g., standing versus sitting) or increased neural activity.
6. Spasm: persistent contraction of striated muscle that cannot be released voluntarily. If the contraction is painful, this is usually described as a cramp. Spasms occur at irregular intervals with variable frequency and extent,²⁵ and over days or weeks may lead to a contracture.
7. Contracture: an involuntary shortening of a muscle. Clinically, a muscle cramp and contracture may appear similar; however, contractures are electrically silent.²⁶
8. Cramp: a painful involuntary muscle contraction that occurs suddenly and can be temporarily debilitating. Pain is intense and localized. It tends to occur when the muscle

- is in the shortened position and contracting, is generated by motor units, and displays a high firing rate (20–150 Hz).^{26, endnote 8}
9. Fasciculation: a single, spontaneous, involuntary discharge of an individual motor unit. The source generator is the motor unit or its axon, before its terminal branches. Fasciculations display an irregular firing pattern of low frequency (0.1–10 Hz).^{5,26} Clinically, fasciculations are recognized as individual brief twitches. They may occur at rest or after muscle contraction and may last several minutes.
 10. Tender point: tenderness to palpation at soft-tissue body sites.¹⁹
 11. Trigger point (TrP): a tender, taut band of muscle that can be painful spontaneously or when stimulated.²⁷ The taut band is electrically silent.^{endnote 9}
 12. Pelvic floor muscle dyssynergia²: incoordination of the PFM and another muscle group during a functional activity, for example, the pelvic floor muscles may not relax appropriately during micturition or defecation.
 13. Nonfunctioning PFM (modified from Messelink et al.)²: a situation in which there is no PFM action measurable either on instruction to contract (inability) or as the absence of an automatic response to an increase in intra-abdominal pressure. This condition can be based on any pelvic floor symptom and on the sign of a noncontracting or nonrelaxing pelvic floor.
 14. Pelvic floor muscle injury (PFMI): on clinical palpation, PFMI is diagnosed when one or more of the following is present:
 - a) A discontinuity of the puborectalis muscle at its attachment to the inferior pubic ramus²⁸
 - b) A distance of >3.5 finger widths between the two sides of puborectalis muscle insertion^{29,30}
 - c) A gap in the continuity of the pubovisceral muscle between the pubic rami and the anorectum³¹
 15. Muscle action characteristics:
 - a) Maximal voluntary contraction (MVC): the attempt to recruit as many fibers in a muscle as possible for the purpose of developing force.³² MVC of the pelvic floor can be assessed by vaginal palpation, manometers, and dynamometers.^{endnote 10}
 - b) Muscle strength: force-generating capacity of a muscle.⁵ It is generally expressed as maximal voluntary contraction measurements and as the one-repetition maximum (1RM) for dynamic measurements.^{32–34}
 - c) Local muscle endurance: the ability to sustain near maximal or maximal force, assessed by the time a patient is able to maintain a maximal static or isometric contraction, or the ability to repeatedly develop near maximal or maximal force determined by assessing the maximum number of repetitions the patient can perform at a given percentage of 1RM.³⁵
 - d) Muscle power: the explosive aspect of strength; the product of strength and speed of movement (force × distance/time).³⁵
 - e) Co-ordination: property of movement characterized by the smooth and harmonious action of groups of muscles working together to produce a desired motion.⁵
 - f) Motor control: the ability of the nervous system to control or direct the muscles in purposeful movements and postural adjustment by selective allocation of muscle tension across appropriate joint segments.^{5,36}
 - g) Submaximal contraction: all contractions without maximal effort, expressed as a percentage of 1RM.
 - h) Synergistic contraction: the combination of several muscle actions that serve to optimally achieve a motor task.³⁷
 - i) Co-contraction: contraction of two or more muscles at the same time. Co-contraction of muscles can be synergistic (e.g., resulting in an augmentation of motor activity) or it could be counterproductive to normal function (e.g., contraction of antagonistic muscles resulting in abnormal movement or training other muscles instead of the targeted ones, e.g., training of gluteal muscles instead of the PFM).
 - j) Antagonistic contraction: contraction of muscle/ muscle groups with the opposite action to the desired action (activity that hinders the targeted muscle/ muscle group from contracting).
 16. Other:
 - a) Hypertrophy: the increase in size (volume) of the muscle fibers.³⁷
 - b) Atrophy: the decrease in size of muscle fibers as a result of inactivity, illness or aging.³⁸
 - c) Bulk: the absolute volume of a muscle measured using imaging techniques such as anatomical magnetic resonance imaging and ultrasound.³⁹
 - d) Anatomic cross-sectional area: for an individual muscle, the largest cross-sectional area along the length of that muscle and 90° on the muscle length.⁷
 - e) Physiological cross-sectional area: the total area of cross-section perpendicular to the muscle fibers.⁷
 - f) Flexibility: the ability of a muscle to lengthen and allow one joint (or more than one joint in a series) to move through a range of motion. Loss of flexibility is defined as a decrease in the ability of a muscle to deform.⁴⁰
 - g) Proprioception: sensory information from receptors of muscles, joints, capsules, and ligaments that provides information related to posture and movement.⁴¹

- h) Exteroception: sensory information from receptors in the skin registering touch, vibration, heat, and cold.⁴¹

INVESTIGATIONS AND IMAGING

All methods and devices used for assessments (e.g., palpation, manometers, dynamometers, EMG, urodynamics, ultrasound, and magnetic resonance imaging [MRI]) must be described in detail, and their responsiveness (ability to detect small changes), reliability and validity should be reported.⁴²

Existing (defined) investigations

Urodynamics

Urodynamics is the functional study of the lower urinary tract³:

1. Uroflowmetry³
2. Post-void residual (PVR) urine volume³
3. Cystometry³
4. Pressure flow study³
5. Assessment of urethral function³
 - a) Urethral pressure measurement³
 - b) Abdominal leak point pressure (ALPP)³

Frequency–volume chart

The frequency–volume chart (FVC) records the time of each micturition and the volume voided for at least 24 h, although 2 or 3 days of recording (not necessarily consecutive) generally provide more useful clinical data.³

1. Bladder diary: in addition to the FVC, a bladder diary includes fluid intake, pad usage, number incontinence episodes, and the degree of incontinence.³

Pad testing

Quantification of the amount of urine lost over the duration of testing, by measuring the increase in weight of the perineal pads used (weighed pre- and post-testing).³

Ultrasound imaging

1. PFMI: PFMI is diagnosed on ultrasound when at least one of the following is present:
 - a) Undetected puborectalis-to-ipsilateral sidewall attachment on any of the three central slices (full avulsion)

- b) Undetected puborectalis-to-ipsilateral sidewall attachment on at least one slice (partial avulsion)⁴³

- c) A levator–urethra gap (LUG) of greater than 2.5 cm⁴⁴

2. PFM position in the pelvis: can be measured in the sagittal plane in relation to defined landmarks, and may be related to PFM dysfunction (elevated or descended pelvic floor).
3. Hiatal dimension: is the cross-sectional area of the pelvic floor/levator hiatus, including anteroposterior and transverse distances (Fig. 1).

Radiological imaging

Videocystourethrography (VCU); intravenous urography (IVCU); micturating cystography (MCU); defecography; colpocystodefecography.

Magnetic resonance imaging

1. PFM injury: can represent a full spectrum, from disruption of a single fascicle, to complete disruption of the muscle origin. At present, there is no universally accepted system for the diagnosis and evaluation of the extent of the injury. Essentially, abnormalities are judged to have occurred

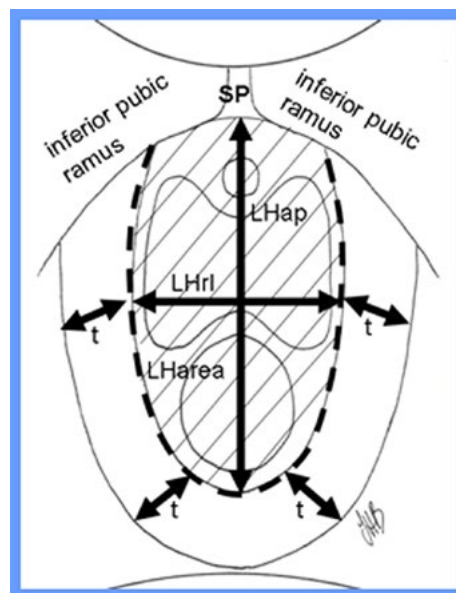


FIG. 1 Levator hiatal dimensions measured using transperineal ultrasound (reproduced with permission from Ingeborg Hoff Braekken). LHap levator hiatus antero-posterior, LHrl levator hiatus right-left, LHarea levator hiatus area, SP symphysis pubis, t pubovisceral muscle thickness

when the morphology of the pubococcygeal portion of the levator ani muscle deviates from what is seen in normal nulliparous women.⁴⁵ Several groups have studied and defined levator damage on MRI when one or more of the following is present: absence of pubococcygeal muscle fibers in at least one 4-mm section, or two or more adjacent 2-mm sections in both the axial and the coronal planes.⁴⁶ The degree of injury can be assessed based on the amount of muscle involved in the injury, with reasonable repeatability among different examiners in a single group.⁴⁷ More than half the expected muscle bulk is associated with the presence of POP.⁴⁸

2. PFM position in the pelvis: location of the PFM in the sagittal plane in relation to defined landmarks. They may be elevated or descended.

Palpation

The process of using fingers/hands as part of assessment, to gather information about the tissues. Digital palpation of the PFM is described by Messelink et al. (Fig. 2)².



FIG. 2 Digital palpation of the pelvic floor muscles (reproduced with permission from subjects in the photo and photographer Andreas Birger Johansen)

Manometer

A manometer is a device for measuring pressure.

Pelvic floor manometry

Measurement of resting pressure or pressure rise generated during contraction of the PFM using a manometer connected to a sensor, which is inserted into the urethra, vagina or rectum. Pelvic floor manometric tools measure pressure in mmHg, hPa or cmH₂O.^{42, endnote 11} Conversion of data to the international standard unit of measurement (hPa) is recommended (Figs. 3, 4).

1. Perineometer: the first PFM vaginal pressure device connected to a manometer developed by Kegel.^{49, endnote 12}

Dynamometer

A dynamometer is an instrument that measures power or force.⁸

Pelvic floor dynamometry

Measurement of PFM resting and contractile forces using strain gauges mounted on a speculum (a dynamometer), which is inserted into the vagina.⁵⁰ Dynamometry measures force in Newton units ($N = 1 \text{ kg} \times \text{m/s}^2$) (Figs. 5, 6).^{endnote 13}

Electromyography

Electromyography (EMG) is the recording of electrical potentials generated by the depolarization of muscle fibers.

Electromyographic diagnosis

Electromyographic diagnosis is made by evaluating the state of the muscle (muscle pathology) by recording and analyzing the electrical activity generated by the muscle.^{36, endnote 14}



FIG. 3 Peritron manometer (reproduced with permission from Laborie)

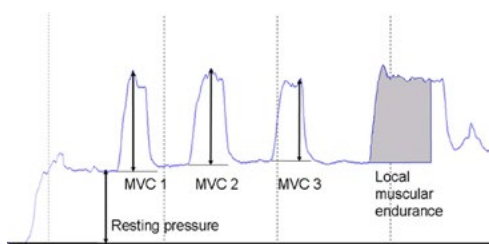


FIG. 4 Graphical illustration of pelvic floor muscle manometry readings (reproduced with permission from illustrator Ingeborg Hoff Braekken). *MVC* maximum voluntary contraction, 1/2/3 repetition 1/2/3

1. Intramuscular EMG: insertion of a wire or needle electrode into the muscle to record motor unit action potentials.^{endnote 15}
2. Surface electromyography: electrodes placed on the skin of the perineum or inside the urethra, vaginal or rectum (Fig. 7).^{endnote 16}

Pain assessment

Pain evaluation

Pain evaluation consists of baseline and ongoing regular evaluation of severity, quality of life, thoughts, emotions, and behavior associated with the pain (via direct consultation or questionnaires) and investigations to identify well-defined/confusable/non-pain syndromes.

1. Pain measurement: pain can only be measured subjectively. Patient-reported outcome measures include:
 - a) Numerical rating scale (NRS), from 0 (no pain) to 10 (extreme pain), with half-points marked.^{51,52}



FIG. 5 Ann Arbor, USA, dynamometer speculum. Note that the bills of the speculum are covered by a condom when in use (reproduced with permission from J.A. Ashton-Miller, R. Zielinski, J.O. DeLancey, J.M. Miller)



FIG. 6 Montreal, Canada, pelvic floor dynamometer (reproduced with permission from Chantale Dumoulin)

- b) Visual analog scale (VAS), a 10-cm line with the same labels at the ends
 - c) A simple verbal rating scale can be used, e.g., “none,” “mild,” “moderate,” “severe.”^{endnote 17}
2. Pain mapping: identifying pain generators through diagnostic procedures such as questionnaires, digital palpation, EMG, quantitative sensory threshold measurement, trigger point injections, nerve blocks, and imaging.
 - a) Questionnaires: several pain questionnaires can be used in the evaluation of musculoskeletal pain in the pelvis; the choice will be determined by which is most appropriate to the presenting pelvic floor dysfunction: McGill Pain Questionnaire,⁵³ Pelvic Floor Distress Inventory (PFDI),⁵⁴ Female Sexual Function Index,⁵⁵ Female Sexual Distress Scale,⁵⁶ Pelvic Pain and Urgency/Frequency Questionnaire.⁵⁷
 - b) Pain chart/body map: a simple line drawing of an outline of the front and back (or relevant body part) of the human body, onto which the patient sketches or ticks or marks areas of bodily pain to demonstrate the site and extent of perceived pain.⁵⁸
 - c) Pain checklist: a list of anatomical locations from which the patient selects sites that are relevant to his/her complaint.



FIG. 7 Verity Medical NeuroTrac MyoPlus Pro surface electromyography biofeedback apparatus (also incorporating electrical stimulation (reproduced with permission from Quintet, Norway)

- d) Measurement of muscle tone: there is no single tool that is able to measure all components of muscle tone. Some tools may be able to measure aspects of tone such as contractility, stiffness or elasticity. Instrumented methods may play a role in the valid and reliable evaluation of muscle tone, e.g., surface electromyography (sEMG), wire and concentric electromyography, dynamometry, real-time ultrasound, elastometry, myotonometry.
- e) TrP injection or needling: a diagnostic test to confirm if the identified TrP is a pain generator. The technique is the same as that used in TrP treatment.
- f) Imaging: tissue-specific evaluation to identify if morphological trauma or deficit is present, which may relate to the presenting pain. Types of imaging may include X-ray, ultrasound, and MRI.

DIAGNOSES

Diagnosis: the act or process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination, review of laboratory data, and the opinion derived from such an evaluation.⁵⁹

A diagnosis of female PFD is based on the information obtained from the patient's symptoms, signs, and any relevant diagnostic investigations. For the terminology of the six most common PFD diagnoses—urodynamic stress urinary incontinence, detrusor overactivity (DO), POP, voiding dysfunction, bladder oversensitivity, and recurrent UTI—the reader is directed to Haylen et al.³

Additional anorectal diagnosis

1. Local (fissures, hemorrhoids)¹⁸
2. Fecal incontinence¹⁸
3. Obstructed defecation syndrome¹⁸
4. Rectocele¹⁸
5. Enterocel/sigmoidocele¹⁸
6. Intussusception¹⁸
7. Internal mucosal prolapse¹⁸
8. Abscess/fistula¹⁸

Pain syndromes

1. Chronic pelvic pain syndrome (CPPS): persistent pain perceived in structures related to the pelvis, in the absence of proven infection or other obvious local pathology that may account for the pain. It is often associated with negative cognitive, behavioral, sexual or emotional consequences,

and with symptoms suggestive of lower urinary tract, sexual, bowel or gynecological dysfunction.¹⁴

2. Chronic PFM pain syndrome: the occurrence of persistent or recurrent, episodic, pain in the PFM, in the absence of a proven or well-defined local pathological condition. It is often associated with negative cognitive, behavioral, sexual or emotional consequences, and with symptoms suggestive of lower urinary tract, sexual, bowel or gynecological dysfunction.^{14, endnote 18}

Female sexual dysfunction

Any departure from normal sensation and/or function expressed by a woman during sexual activity.³

1. Dyspareunia³
2. Obstructed intercourse³
3. Vaginal laxity³

TREATMENTS

General terms

Behavioral

The way someone behaves, especially toward other people, and behavioral science is the study of human behavior.⁶⁰

1. Behavior therapy: a type of psychotherapy that attempts to modify observable maladjusted patterns of behavior by substituting a new response or set of responses to a given stimulus. The treatment techniques involve the methods, concepts, and procedures derived from experimental psychology; they include assertiveness training, aversion therapy, contingency management, flooding, modeling, operant conditioning, and systematic desensitization. It is also called behavior modification.^{12, endnote 19}
2. Cognitive therapy: any of the various methods of treating mental and emotional disorders that help a person to change their attitudes, perceptions, and patterns of thinking, from rational to realistic thoughts about the self and situations. The technique is often used in association with behavior therapy principles.¹²
3. Cognitive behavior therapy (CBT): Cognitive techniques are often used in association with behavior therapy principles; this is called cognitive behavior therapy (CBT).

Physiotherapy

Physiotherapy involves “using knowledge and skills unique to physiotherapists” and “is the service only provided

by, or under the direction and supervision of, a physiotherapist^{61, endnote 20}.

Adherence

Adherence is the extent to which a client/patient's behavior corresponds to the agreed treatment protocol and/or regime as recommended by their healthcare provider.⁶² It does not refer to the intervention itself; rather, the patient's commitment to undertaking the behavioral change to adhere to the intervention.^{endnote 21}

Compliance

Compliance is the extent to which a client/patient's behavior matches, or complies with, their healthcare provider's recommended treatment protocol and/or regime.^{63, endnote 22}

Combination therapy (also known as polytherapy, multimodal therapy or combined modality therapy)

Combination therapy is the use of more than one intervention concurrently to treat a single condition with one or multiple symptoms, for example, a combination of medication with PFM training (PFMT).

1. **Adjunctive therapies:** any treatment or modality used to augment or assist the main treatment. In conservative treatments, adjunctive therapies often refer to equipment or a secondary therapy used to supplement the effect of the primary therapy, e.g., biofeedback-assisted PFMT or neuromuscular electrical stimulation to augment PFMT.

Prevention

Prevention is the act of preventing or decreasing the risk of disease or disability. Activities that are directed toward slowing or stopping the occurrence of both mental and physical illness and disease, minimizing the effects of a disease or impairment on disability, or reducing the severity or duration of an illness.⁵

1. **Primary prevention:** prevention of the development of disease in a susceptible or potentially susceptible population through such specific measures as general health promotion efforts.⁵
2. **Secondary prevention:** efforts to decrease the duration of illness, reduce the severity of diseases, and limit the sequelae through early diagnosis and prompt intervention.⁵
3. **Tertiary prevention:** efforts to limit the degree of disability and promote rehabilitation and restoration of

function in patients/clients with chronic and irreversible diseases).⁵

Lifestyle

Lifestyle modification

Lifestyle modification is the application of interventions in the management of lifestyle-related health problems, e.g., change to a healthy diet and regular participation in physical activity and smoking cessation. The following lifestyle modifications may be applied to treat pelvic floor dysfunctions, either in combination with other therapies or as "stand-alone" treatments.

1. **Fluid consumption/restriction:** fluid consumption is the intake of fluid over 24 h. Fluid restriction is the limitation of fluid to a prescribed amount over a period of 24 h. These measures are often undertaken as part of a bladder training process.
2. **Dietary modification:** an alteration or adjustment of food to treat bowel disorders (e.g., constipation and fecal incontinence) or urinary disorders (e.g., incontinence or urgency), for example, increasing fiber to treat constipation. The specifics of the dietary changes should be described.
3. **Elimination diet:** a form of dietary modification. A diet designed to detect what ingredient in the food causes symptoms in the patient, food items to which the patient may be sensitive are withdrawn separately and successfully from the diet until the item that causes the symptoms is discovered. This is used frequently in patients with fecal incontinence, urinary urgency and urinary urgency incontinence (bladder diet).^{64,65}
4. **Physical activity:** any body movement produced by the skeletal muscles that results in a substantial increase above resting energy expenditure. Physical activity can be done at work, as transportation, as household and other chores, and as leisure time/sport and fitness activities.^{66, endnote 23}

Counseling

Counseling is the provision of professional assistance and guidance in resolving personal or psychological problems,⁷ and may be part of any clinician's management.

1. **Patient education:** providing patients with knowledge and understanding of their condition, thereby empowering them to play an active role in its management (Fig. 8).⁶⁷
2. **Motivational interviewing:** a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence. Compared with nondirective counseling, it is more focused and



FIG. 8 Patient education of pelvic floor muscle function (reproduced with permission from *Women's and Men's Health Physiotherapy*)

goal-directed. The examination and resolution of ambivalence is its central purpose, and the counselor/clinician is intentionally directive in pursuing this goal.⁶⁸

3. Coping strategies: intervention aimed at helping patients to live with the condition in the best way possible under the circumstances, to regain a feeling of being in control, to adjust their lifestyle where necessary, and to take a positive rather than a negative approach.⁶⁷
4. Self-care: the set of activities that comprise daily living, such as bed mobility, transfers, ambulation, dressing, grooming, bathing, eating, and toileting.⁵
5. Self-help: various methods by which individuals attempt to remedy their difficulties without making use of formal care providers.⁵
6. Self-efficacy: an individual's belief that he or she is capable of successfully performing a certain set of behaviors.⁶⁹

Scheduled voiding regimes

Toileting on a fixed schedule around the patient's normal voiding pattern, which includes a progressive voiding schedule using relaxation and distraction techniques for urgency suppression.⁷⁰ Scheduled voiding regimes have been categorized as: bladder training, timed voiding, habit training, and prompted voiding.⁷¹

Bladder training

In the past, bladder training has also been referred to as bladder drill, bladder discipline, bladder re-education, and bladder retraining. It consists of a program of patient education, along with a scheduled voiding regimen with gradually adjusted voiding intervals. Specific goals are to correct faulty habit patterns of frequent urination, improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes, and

restore patient confidence in controlling bladder function (modified from Moore et al.⁷¹),^{endnote 24}

Timed voiding

Timed voiding is a passive toileting assistance program, initiated and maintained by caregivers for patients who cannot participate in independent toileting. It is a fixed voiding schedule.⁷¹

Habit training

Habit training consists of a toileting schedule matched to the individual's voiding patterns based on their voiding diary. The toileting schedule is assigned to fit a time interval that is shorter than the person's normal voiding pattern and precedes the time period when incontinent episodes are expected.⁷¹

Prompted voiding

Prompted voiding is used to teach people to initiate their own toileting through requests for help and positive reinforcement from caregivers, often done in combination with a scheduled voiding regimen, typically every 2 h.⁷¹

Other techniques for bladder and bowel control

Other techniques consist of doing something that takes the patient's mind off the condition. Distraction techniques utilized in urgency may include (but are not limited to) counting backward from 100 in 7 s, reciting a poem, doing breathing exercises, reading or working.

Urgency suppression techniques

Urgency suppression techniques are methods/maneuvers that are used to decrease the feeling of urgency, which may include, but are not limited to: distraction, PFM contraction, perineal pressure such as sitting on a hard chair, relaxation and breathing, toe curling or plantar flexion of the ankle.

Double voiding

In double voiding, the patient is taught to urinate, relax, and attempt to urinate again.⁵⁹

Defecatory dynamics

Defecatory dynamics is a postural and respiratory technique to aid defecation. The mechanics involves co-ordination of the diaphragm, abdominal and PFM, with the intent to maintain rectal support whilst releasing the anal outlet with sufficient expulsion to be effective.^{72,73}

Bowel habit training

Bowel habit training is aimed at establishing a regular, predictable pattern of bowel evacuation by patient teaching and adherence to a routine to achieve a controlled response to bowel urgency (modified from NICE guideline).^{74, endnote 25}

Exercise/exercise training

Exercise is a form of leisure time activity that is usually performed on a repeated basis over an extended period of time (exercise training) with specific external objectives, such as improvement of fitness, physical performance, or health.⁶⁶ Exercise training includes: endurance training, strength training, flexibility training, and motor control (including balance), all of which may apply to the PFM.

Therapeutic exercise/exercise therapy

Therapeutic exercise consists of interventions directed toward maximizing functional capabilities. It includes a broad range of activities intended to improve strength, range of motion (including muscle length), cardiovascular fitness, flexibility, or to otherwise increase a person's functional capacity.⁵

1. Rehabilitation/re-education: help individuals to regain skills and abilities that have been lost as a result of illness, injury or disease, or incarceration, restoring a disabled individual to maximum independence commensurate with his or her limitations.

Mode of exercise training

The mode of exercise training is not only the type of activity to be performed (for instance, fast walking, jogging, or swimming, strength training), but also the temporal pattern of activity that is recommended (that is, continuous or intermittent activity), with a detailed specification of the duration of exercise and rest periods in the case of intermittent activity bouts.⁶⁶ Authors are encouraged to specifically describe all components of the mode of exercise and the dose provided.

1. Muscle training: exercise to increase muscle strength, endurance, power, flexibility or relaxation.
 - a) Strength training: training with high resistance (close to maximal contractions) and few repetitions with the aim of increasing muscle volume and neural adaptations.
 - b) Resistance: the amount of force opposing a movement.³⁹
 - c) Resistance devices: any object used to increase resistance to contraction, e.g., hand weights.
 - d) Vaginal resistance device: objects inserted into the vagina or rectum that are inflated or spring-loaded devices to increase resistance to contraction.

- e) Local muscle endurance training: training with a low load and a high number of repetitions or holding the contraction over time.
- f) Muscle power training: all training with the aim of generating power; can be close to maximal contraction training and/or rapid contractions.^{endnote 26}
- g) Overload: a situation in which the body is required to perform exercise beyond that to which the neuromuscular system is accustomed during routine activities. Training adaptation occurs in response to a progressive "overload".⁷⁵
- h) Progressive overload: the gradual increase in stress placed upon the body during exercise training.⁷⁶
- i) Detraining: cessation of training, but also planned or unplanned reduced volume or intensity of training.⁷⁷
- j) Maintenance training: a program designed to prevent loss of the previous level of functioning.
- k) Isometric/static contraction: a muscular action during which no change in the length of the total muscle or joint angle takes place.⁷⁷
- l) Isotonic contraction: a muscular action during which the tension developed by the muscle remains almost constant while the muscle shortens.⁷⁸
- m) Eccentric contraction: a muscular action in which the muscle lengthens in a controlled manner.^{77, endnote 27}
- n) Repetition: the completion of a whole cycle from the starting position, through the end of the movement, and back to the start,⁷⁵ e.g., one PFM contraction with relaxation.
- o) Set: the number of times the desired number of repetitions is performed,³³ e.g., three sets of 12 PFM contractions.
- p) PFMT: exercise to improve PFM strength, endurance, power, relaxation or a combination of these parameters.
- q) Kegels: a PFM contraction or PFM exercise. This term is named after Arnold Kegel, an American gynecologist who first described the clinical effect of PFMT in the late 1940s.⁴⁹ We recommend the use of the term PFMT (not the word Kegels) to refer to exercises that specifically target the PFM.
- r) Individualized PFMT: an individual PFM program aimed at improving the specific deficiencies in PFM structure or function based on assessment of the woman's ability to contract the PFM.
- s) Supervised PFMT: a PFMT program taught and monitored by a health professional/clinician/instructor.
- t) Group PFMT: PFMT conducted in an exercise class.⁷⁹ Class participation may occur with or without previous individualized PFM instruction.^{endnote 28}

- u) Home training/home PFM exercise program: an unsupervised PFMT program, which the individual performs at home.
 - v) Weighted vaginal cones: objects of different shapes, sizes, and weights, which are inserted into the vagina above the level of the PFM with the aim of providing sensory biofeedback and load on the PFM to increase muscle recruitment and strength.^{80, endnote 29}
3. Facilitation technique: any method of increasing recruitment/response of a nonresponding muscle. In the case of noncontractile or very weak PFMs, this may include a quick stretch of the PFM, with tapping or stretching the PFM digitally. An overflow effect from a strong contraction of a nearby synergistic muscle (e.g., external rotators) may also assist facilitation or recruitment of PFMs.

Dose–response issues related to exercise training

1. Dose–response: amount/volume of training and its effect on the speed and degree of the effect of the training program.
2. Frequency of exercise: the number of activity sessions per day, week, or month.³³
3. Duration of exercise: the unit of time (number of seconds/minutes) of activity in each repetition or session, e.g., a 10-s PFM contraction.³³ It also refers to the length of the whole training period (intervention), e.g., 3/6 months.
4. Intensity: the amount of resistance used or the effort associated with the physical activity.³³ For strength training, it is often expressed as a percentage of one repetition maximum: 1RM (the maximum load a person can lift once), e.g., 70 % of maximum.⁷⁵
5. Session/bout: the block of time devoted to the training, e.g., a 1-h session.⁷⁵

Relaxation training

1. Relaxation: the ability to control muscle activity such that muscles not specifically required for a task are quiet, and those that are required are fired at the minimal level needed to achieve the desired results.⁸¹ Relaxation “can be considered a motor skill in itself because the ability to reduce muscle firing is as important to control as the generation of firing”.⁴⁰
 - a) General relaxation technique: a technique that involves the whole body, with the aim of effecting a global relaxation, including a decrease in the skeletal and smooth muscles, a decrease in the heart rate and respiration rate, and an increase in parasympathetic activity. General relaxation techniques can also be used aimed at relaxing local muscles.

- b) Progressive muscular relaxation (also known as Jacobsen's technique): monitoring tension in each specific muscle group, by contracting, then relaxing the tension, with attention paid to the contrast between tension and relaxation.⁸² This type of relaxation is also termed “contract–relax.”
- c) Meditation: a practice of concentrated focus upon a sound, object, visualization, the breath, movement, or attention itself to increase awareness of the present moment, reduce stress, promote relaxation, and enhance personal and spiritual growth.⁸³
- d) Mindfulness: intentionally bringing one's attention to the internal and external experiences occurring in the present moment. Mindfulness is often taught through a variety of meditation exercises.⁸⁴
- e) EMG relaxation techniques: techniques to decrease EMG muscle activity or activation through a variety of methods, including a conscious effort to relax.

Stretching

1. Stretching (also referred to as flexibility training when the method is used on skeletal muscles where increased range of motion over the joints is the aim): the application of an external force to muscle and connective tissue to elongate it in the direction opposite to its shortened position. This can be done parallel or perpendicular to the muscle fiber direction. For the PFM this can be applied as a widening of the levator hiatus in the axial plane (laterolaterally) via a digit or use of a dilator, or a caudal movement (via a straining/bearing down maneuver) in the sagittal plane.
 - a) Dilator therapy: a conical or cylindrically shaped device (made of an inert material) inserted intra-vaginally or intra-anally, with the aim of increasing the flexibility or elasticity of the soft tissues via application of a prolonged elongation or stretch. Dilators may also be used as a desensitizer device, to reduce fear, anxiety or pain associated with vaginal touch and in conjunction with vaginismus or sexual pain. When combined with EMG, dilators can be used to train PFM relaxation during penetration. Dilators may also be used to increase the tolerance of skin to sliding when the dilator is moved in and out.

Functional training

Functional training consists of training for tasks of daily living and self-care activities, e.g., squatting to train quadriceps and gluteal muscles.

1. Functional PFM training: training and exercises that incorporate a correct PFM contraction into activities of

daily living such as lifting, transferring out of bed, or sneezing. A PFM contraction before a rise in intra-abdominal pressure, e.g., a cough (“the Knack”) is part of functional PFM training.

2. Coordination training: the ability to use different parts of the body together smoothly and efficiently.⁷ Related to PFM training, coordination training means PFM contraction with other muscles or other muscle groups, e.g., respiratory muscles.
3. Functional mobility training: an intervention directed at improving the physical ability to perform a daily task. For voiding/defecation, this may include: gait training, transfer training, stair training, and other mobility training to improve speed and safety in reaching the toilet.

Biofeedback training

Feedback

Feedback is sensory information that is available as the result of an activity that a person has performed. It can be provided by an intrinsic source (from within the individual), or an extrinsic source (from the clinician), and can occur concurrently with the activity or post-activity, e.g., verbal information from the clinician to the patient during or following PFM assessment.^{85, endnote 30}

Biofeedback

Biofeedback is the use of an external sensor to give an indication with regard to bodily processes, usually with the purpose of changing the measured quality.⁸⁶ It is an adjunctive therapy.^{endnote 31}

EMG biofeedback unit instrumentation

1. EMG signal amplitude: number of microvolts (μV) a muscle is generating.⁸⁷ EMG biofeedback units can deliver either the actual amount of EMG activity in μV or an average μV value.^{endnote 32}
2. Artifact: extraneous information nonrecognizable in the EMG signal from sources other than the target muscle such as the environment or other body functions.^{87, endnote 33}
3. Cross talk: muscle activity from nearby muscles that can artificially increase EMG amplitude; a type of artifact.^{87, endnote 34}
4. Dual-channel EMG: use of two channels to monitor two separate muscles or muscle groups at the same time, such as the PFM and abdominal muscles, with the goal of either promoting synergist activity or reducing EMG activity of one muscle while increasing the other.
5. Band pass: limits muscle fiber frequencies that are monitored and displayed in the EMG tracing.^{87, endnote 35}

EMG assessment of PFM

Electromyography assessment of PFM consists of the use and interpretation of the surface EMG recording of a muscle for rehabilitation purposes should be done cautiously, recognizing that the main goal is the qualitative description of the muscle activation pattern, and not a qualitative diagnosis.

1. Baseline muscle activity: amount of microvolts generated by the target muscle during rest.^{endnote 36}
2. Peak microvolts: the highest EMG amplitude achieved.
3. Slow recruitment: slow initiation of muscle activation contraction.^{endnote 37}
4. Slow de-recruitment or slow latency to return to baseline: slow relaxation of the muscle contraction.^{88, endnote 38}
5. Inconsistent resting baseline: variation of baseline between contractions, between sets, or between days may be related to a change in patient symptoms, e.g., hypertonic PFM.
6. Excessive accessory muscle contraction: increased amplitude in accessory muscles often resulting in cross talk and is indicative of poor isolation of target muscle contraction.

EMG training of PFM

1. Up-training: EMG biofeedback training to increase the EMG activity of a hypotonic muscle with low EMG activity.^{87, endnote 39}
2. Down-training: EMG biofeedback training to decrease EMG activity and relax muscles.^{87, endnote 40}

Manual therapy

Manual therapy is a clinical approach utilizing skilled, specific hands-on techniques, including but not limited to, massage, manipulation or mobilization.^{endnote 41}

Joint therapies

1. Mobilization: skilled passive movement of a skeletal joint including graded passive oscillations at the joint to improve joint mobility, e.g., movement of the coccyx.
2. Manipulation: a passive (for the patient) therapeutic movement, usually of small amplitude and high velocity, at the end of the available joint range.⁵ Manipulation is a sudden small thrust that is controlled by the clinician.^{endnote 42}

Soft-tissue therapies

1. Touch desensitization: use of finger/hand, vibration or device to reduce hypersensitivity of soft tissues to touch/contact.

2. Massage: the manipulation of the soft tissues of the body for the purpose of affecting the nervous, muscular, respiratory, and circulatory systems.⁵
3. Abdominal massage: therapist or self-directed massage of the abdominal wall with the aim of stimulating peristalsis and relieving the symptoms of constipation. Generally, the technique follows the ascending, transverse, and descending colon to aid emptying. The effect may be mechanical or sensory.⁸⁹
4. Myofascial release techniques: the use of deep friction and stroking of the fascia of the body to improve the ability of the fascia to deform and move within the body.⁵
5. Skin rolling: a manual technique in which skin is pulled away from the underlying structures and elongated in various directions.
6. Scar massage: a specific application of soft-tissue mobilization to an adherent scar.
7. Perineal massage: intravaginal massage by the woman, her partner or the clinician. Technique includes alternating downward and sideward pressure, using thumb and forefinger and a natural oil, with the aim of stretching and elongating the tissue in preparation for vaginal childbirth, or for treatment of adherent scarring in the perineum.⁹⁰
8. Transverse friction: the operator's fingertip is placed on the exact site of the lesion and rubbed firmly across the direction of the fibers of the affected tissue.⁹¹
9. Thiele's massage: per rectal digital massage of the levator ani, sweeping lengthwise along the muscle fibers. Massage is begun lightly, and pressure is increased as tenderness decreases.⁹²
10. TrP treatment: (sometimes called myofascial trigger point treatment): soft-tissue mobilization specifically targeting trigger points and may include ischemic pressure, massage, myofascial release, electrotherapy, ultrasound, laser, spray-and-stretch, injection (a variety of chemicals including local anesthetic, botox or steroids), dry needling (insertion of a solid needle into the TrP), and stretching.^{endnote 43}

Thermal modalities

Cold treatment/cryotherapy

Cold treatment is the application of ice for therapeutic purposes. It is used in the initial management of acute musculoskeletal injuries, to decrease edema through vasoconstriction and to reduce secondary hypoxic injury by lowering the metabolic demand of injured tissues.⁹³

Heat treatment (moist or dry)

Heat treatment consists of the application of heat to a body part, with the aim of relieving pain and/or stiffness. It is usually applied when an injury is older than 48 h.

Electrical therapy

Electrical therapy is the use of electric potential or currents to elicit therapeutic responses. Current may be directed at motor or sensory functions. It is not within the scope of this document to define all electrical stimulation terms. Readers are referred to more complete text books.⁹⁴

Electrical muscle stimulation (also known as neuromuscular electrical stimulation or electromyostimulation)

Electrical muscle stimulation (EMS) is the application of electric impulses directly to striated PFM (end-plate) to facilitate contraction. EMS is often referred to as “pelvic floor muscle electrical stimulation” (PFES) or “functional electrical stimulation.” PFES is the application of electrical current to the PFM.⁹⁵ All of these stimulations may (indirectly) cause inhibition of the detrusor contraction (Fig. 9).

Mode of application

1. Surface electrodes: non-invasive placement of electrodes, including intravaginal and intra-anal electrodes, in contrast to electrodes that pierce the skin, i.e., needle stimulation.
 - a) Non-invasive electrical nerve stimulation^{96,97} or transcutaneous electrical nerve stimulation (TENS): the application of electrical energy to stimulate cutaneous nerve and peripheral motor nerves, via suprapubic, perineal or sacral placement of electrodes, or other external sites, or intravaginal or intra-anal plug electrodes. Tibial nerve stimulation (TNS) is a form of peripheral neuromodulation targeting symptom relief of overactive bladder (OAB) and urinary urge incontinence. Indirect access to the sacral plexus is achieved by



FIG. 9 Enraf-Nonius Myomed pelvic floor machine, including electrical stimulation (reproduced with permission from Enraf-Nonius)

intermittent, electrical stimulation of the tibial nerve, which lies behind the medial malleolus, using skin surface electrodes applied to the medial malleolar area (transcutaneous TNS).⁹⁸ There are two main types of electrical stimulation with surface electrodes:

- i) Long-term or chronic electrical stimulation: is delivered below the sensory threshold. It is aimed at inhibiting detrusor activity by afferent pudendal nerve stimulation. The device is used 6–12 h per day for several months.⁹⁹
 - ii) Maximal neuromuscular electrical stimulation: applies a high-intensity stimulus, set just below the pain threshold. It is aimed at improving urethral closure, via striated muscle recruitment. Detrusor inhibition by afferent pudendal nerve stimulation has also been suggested as a mechanism of effect.⁹⁶ Maximal electrical stimulation (35–70 Hz) is applied over short period (15 to 30 min), is used several times per week (and up to 1–2 times daily), and may be provided via in-clinic application or via portable devices at home).^{100–102}
2. Percutaneous electrical nerve stimulation: a therapeutic modality that stimulates peripheral sensory nerves performed with a (few) needle electrode(s) that are placed in close proximity to the area to stimulate. Percutaneous neuromuscular electrical stimulation (e.g., posterior TNS) is a peripheral neuromodulation technique, in which the posterior tibial nerve is electrically stimulated three fingerbreadths above the medial malleolus, via insertion of a percutaneous needle electrode. This is coupled with an adhesive reference surface electrode placed near to the needle. This intervention is offered to patients with OAB.^{103–105}

Electrophysiological parameters

1. Electrical current: the flow (current) of electrons (electricity) from an electron source (stimulator) the wires and electrodes used to deliver such an electrical current to soft tissues.¹⁰⁶
- There are three types of current: direct, alternating, and pulsed. –
- a) Direct: the continuous, unidirectional flow of charged particles for 1 s or longer, the direction of which is determined by the polarity selected. Polarity refers to two oppositely charged poles, one positive and one negative. Polarity determines the direction in which current flows.¹⁰⁶
 - b) Alternating: the continuous, bidirectional flow of charged particles, for 1 s or longer, relative to the isoelectric baseline.¹⁰⁶
 - c) Pulsed: the noncontinuous, interrupted, and periodic flow of direct (DC) or alternating (AC) currents.¹⁰⁶

Currents used in therapy:

- a) Faradic current: an alternating and interrupted low-frequency current capable of stimulating (depolarizing) nerve fibers through the skin using surface-stimulating electrodes. It is used to stimulate innervated muscles, causing them to contract.¹⁰⁷
- b) TENS: an alternating and interrupted low-frequency current capable of stimulating (depolarizing) nerve fibers through the skin using surface-stimulating electrodes for pain modulation or pain relief.¹⁰⁶
- c) Interferential current: a medium frequency, amplitude-modulated electrical current that results from the interference (hence the word interferential) caused by crossing two or more medium-frequency alternating sine wave currents with different carrier frequencies. The carrier frequency of these medium, alternating sine wave currents ranges between 2,000 and 5,000 cycles per second.¹⁰⁶

Neuromuscular electrical stimulation parameters^{endnote 44}

1. Pulse frequency (or rate): the number of pulse cycles that are generated per unit of time (seconds). This is reported in hertz (Hz).¹⁰⁶
2. Pulse width: the determined period of time elapsing from the beginning to the end of one pulse cycle, usually expressed in microseconds or milliseconds.¹⁰⁶
3. Current amplitude: the magnitude of current relative to the isoelectric baseline, expressed in amperes (A). The current amplitude of therapeutic electrical stimulators ranges from micro- to milliamps.¹⁰⁶
4. Train: the continuous series of pulse cycles over time, usually lasting seconds. For example, a train of impulses may be the results of successive pulse cycles delivered at 50 Hz for a duration of 5 s.¹⁰⁶
5. Train ramp-up time and ramp-down time: ramp-up time is the time elapsed from the onset (or baseline) to the plateau current amplitude (or maximum) of the train, whereas ramp-down time is the time elapsed from the plateau current amplitude to zero baseline.^{106, endnote 45}
6. Duty cycle (D): the ratio of ON time to the summation of ON time + OFF time, expressed as a percentage (duty cycle = (ON)/(ON + OFF time) x 100, e.g., a duty cycle of 20 % is calculated when the ON and OFF times equal 10 and 40 s respectively).¹⁰⁶
7. Impedance (electric resistance): the opposition of our biological tissues to the flow of an electrical current. Measured in ohms and designated as Z.¹⁰⁶
8. Evoked potentials: electrical potentials recorded from the nervous system following a delivered stimulus.

Magnetic stimulation

Magnetic stimulation (or extracorporeal magnetic innervation): a pulsed magnetic technology developed for the transmission of nerve impulses that is aimed at causing PFM contraction. Patients receive therapy by sitting in a chair, which contains the device that produces the pulsing magnetic fields.

Mechanical devices

Intravaginal devices

Intravaginal devices are intended to provide some support to the bladder neck and possibly some compression to the urethra, to correct urinary stress incontinence. These can be traditional tampons, pessaries, and contraceptive diaphragms and devices designed specifically to support the bladder neck (removable, reusable intravaginal ring or single-use disposable devices).¹⁰⁸

Anal plugs

Anal plugs are containment devices aimed at blocking the loss of stool to control fecal incontinence. Plugs come in different designs, sizes, and compositions, such as polyurethane and polyvinyl-alcohol.^{109, endnote 46}

Rectal irrigation

Rectal irrigation is the use of liquid solutions given by enema to remove material from the rectum.¹¹⁰

Urethral plugs

Urethral plugs are containment products aimed at blocking urine leakage.¹¹¹

Pessaries

Pessaries are intravaginal devices used to try to restore the prolapsed organs to their normal position and hence to relieve symptoms. Vaginal pessaries can be broadly divided into two types: support pessaries (ring, ring with support, Gehrung, Hodge, shelf) and space-filling pessaries (donut, Gellhorn, cube, inflatable).^{111–113}

Hygiene

Bladder hygiene

Bladder hygiene prevents UTI by using techniques such as wiping the urethral meatus with clean wipes in an anterior-to-posterior direction after voiding, wearing clean

underwear, keeping the genital area clean, and emptying the bladder before and after sexual intercourse.^{114,115}

Vulval hygiene

Vulval hygiene involves maintaining a clean perineum by means of washing the area on a regular basis, and wearing cotton underwear. To avoid vulval irritation, shampoo, perfumed creams or soap should be avoided.¹¹⁶

Anal hygiene

Anal hygiene involves keeping the perianal region clean, which is especially important when fecal seepage is present. Advice includes using soft toilet paper or moist wipes (avoiding any with an alcohol base), always wiping from front to back, washing after a bowel movement, then gently patting dry.⁸⁹ To avoid irritation from products, the vulval hygiene advice above should be followed.

Vaginal lubricants

Vaginal lubricants are pharmacological preparations aimed at reducing friction during coital or any other sexual activity and thereby alleviating dyspareunia,¹¹⁷ or at reducing discomfort associated with a clinical (per vaginum or per rectum) examination. Pharmacological preparations and natural plant-based oils may be used.

Aids and appliances

Absorbent products

Absorbent products are those that have been specifically developed to help manage leakage or soiling, such as absorbent pads and pants, absorbent bed sheets and chair covers.^{108,118}

Catheters

Urinary catheters are small tubes inserted via the urethra or into the bladder suprapubically, to allow the drainage of urine. Catheters are made of plastic, latex, teflon or silicone, and may be impregnated with antiseptic or antibiotic solution.¹¹⁹

1. Self-catheterization: a procedure performed intermittently to empty the bladder by inserting a catheter into the urethra when normal voiding is not possible or if the bladder cannot be emptied completely. If a caregiver undertakes this procedure it is usually a sterile procedure; if a patient undertakes it, it is termed

“self-catheterization” and is generally a clean rather than a sterile procedure.^{120–122}

CONCLUSION

We trust that this consensus-based terminology report for the conservative management of female pelvic floor dysfunction will be a significant aid to clinical practice and a stimulus for research. Future updates will be required to reflect evolving knowledge and applications in this field.

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COMPLIANCE WITH ETHICAL STANDARDS

Disclaimer Any products/companies referred to in this document are not necessarily recommended or endorsed by the ICS.

CONFLICTS OF INTEREST

Elizabeth Shelly is a consultant to Analytica and Amanda Wells is a consultant to ARC Health Services. None of the other authors have any conflicts of interest.

ENDNOTES

- ^{endnote 1} Terminology for Female Anorectal Dysfunction.¹⁸
- ^{endnote 2} A comprehensive definition of these terms is covered by Doggweiler et al.¹²³
- ^{endnote 3} Symptoms of pelvic floor myalgia should be described in terms of location, quality, intensity, pattern, duration, frequency, moderating factors, and associated symptoms. Pain details may include: (a) Whether pain is present at rest or mechanical in nature (related to muscle contraction or relaxation or body posture) and/or altered with a change of posture (lying to sitting, sitting to standing) or movement (bending, walking, sexual activity) (b) Whether uni- or bilateral in nature (c) Whether accompanied by bladder or bowel dysfunction, vulvodynia or dyspareunia (superficial/deep)
- ^{endnote 4} The evidence for the existence of trigger points is debated.¹²⁴
- ^{endnote 5} Atrophy of the urogenital tract is normal at certain points in the life cycle, mainly caused by aging and hypoestrogenism.^{8,125}

^{endnote 6} Muscle tone is evaluated clinically as the resistance provided by a muscle when a pressure/deformation or a stretch is applied to it.^{19–21} Muscle tone may be altered in the presence or absence of pain. There is no single accepted or standardized way of measuring muscle tone, and there are no normative values.

^{endnote 7} The terms hyper- and hypotonicity are commonly used in neurology and muscle physiology. Messelink et al.² introduced the terms overactivity and underactivity related to PFM. These terms are not defined with cut-off points, nor are they based on comparison with normal populations. As activity can only relate to the active (i.e., contractile) portion of muscle tone, activity cannot be used interchangeably with muscle tone, unless it can be shown that the active component of the muscle is altered. If increased (over-) or decreased (under-) activity in the PFM can be demonstrated using electromyography (EMG) or another measure, then these terms may be used appropriately.

^{endnote 8} Muscle cramp either during or immediately after exercise is commonly referred to as “exercise-associated muscle cramping”⁹³; however, cramps are not specific to exercise.

^{endnote 9} Local or referred pain may be reproduced. An active TrP is said to have a characteristic “twitch” response when stimulated; however, the twitch response to palpation has been shown to be unreliable.¹²⁶ The most reliable sign of a TrP is sensitivity to applied pressure. Trigger points are implicated in myofascial pain; however, the validity of this theory is controversial and has recently been refuted.¹²⁴

^{endnote 10} Palpation is less reliable and responsive than manometers and dynamometers.⁴²

^{endnote 11} The pressure measured does not confirm its origin, and pressure measurement is only valid when used in combination with other methods, e.g., simultaneous observation of the inward movement of the perineum or device during PFM contraction.

^{endnote 12} The term perineometer is somewhat misleading as the pressure-sensitive region of the manometer probe is not placed at the perineum, but inside the vagina at the level of the levator ani. Vaginal pressure devices should be referred to as PFM manometers.^{42,49}

^{endnote 13} Today's dynamometers for the pelvic floor also detect resting and contractile contributions from muscles other than the PFM, contributing to the force recordings. As dynamometers can be opened at different muscle lengths to measure PFM force, the process of measurement should respect the maximum achievable vaginal aperture without inducing discomfort, so as not to influence the validity of the measurement.

^{endnote 14} EMG in this case usually means “concentric needle EMG,” but other EMG methods exist. EMG is typically distinguished as either intramuscular or surface. EMG diagnosis is often used as a synonym for “neurophysiological diagnosis of the peripheral neuromuscular system,” and that would also include the measurement of motor and sensory conduction, the recording of reflex responses, etc.³⁶ EMG does not directly measure muscle strength. The type of electrode being used should be specified.

^{endnote 15} This is not typically used in clinical assessment, but may be included in research or advanced examinations, for example, to diagnose striated muscle denervation/re-innervation.³⁶

^{endnote 16} Surface EMG is considered to be less specific than intramuscular EMG. The large surface area of the electrodes

- may result in cross-talk from adjacent muscles and other artifacts; therefore, technical expertise is required. EMG can reveal the pattern of activity of a particular muscle, as in the diagnosis of detrusor sphincter dyssynergia during urodynamics.^{2,36}
- endnote 17 Because pain is multidimensional, a single rating scale combines these dimensions in unknown quantities. One may separately assess pain intensity, pain distress, and interference of pain with activities of daily life.
- endnote 18 Other urological, gynecological, gastrointestinal and colorectal pain conditions without related PFM dysfunction, are well described in standard texts. Many pelvic floor pain-related conditions or syndromes (e.g., vulvodynia, interstitial cystitis/bladder pain syndrome, irritable bowel syndrome) are described in the Standard for Terminology in Chronic Pelvic Pain Syndromes (CPPS): A Report from the Ad Hoc Working Group of the International Continence Society Standardization Steering Committee (ICS-SSC) on Chronic Pelvic Pain, ICS Standardization of Terminology document on Chronic Pelvic Pain.¹²³ Several other systemic disorders (e.g., chronic fatigue syndrome, diabetes) may have an impact on the pelvic floor; however, PFD is not part of their recognized etiology.
- endnote 19 We recommend that “behavioral” be limited to studies that evaluate how people do or do not behave as desired, e.g., commencement or cessation of PFM training or change of a diet.
- endnote 20 We recommend that the specific treatment is described, e.g., PFM training, electrical stimulation, rather than the unspecific term physiotherapy, the latter also referring to a specific profession. Publications should report the actual professional who provided the intervention (e.g., physiotherapist, general practitioner, urogynecologist, urologist, midwife, nurse, fitness instructor), rather than using the vague term, “therapist”/“clinician”/“researcher.”
- endnote 21 Adherence is usually reported as the number or percentage of clinical visits attended and home exercises or regimen components followed or completed by the client/patient.
- endnote 22 The term “adherence” is generally preferred within health-care, as it acknowledges client/patient autonomy and implies a willingness on their part to participate and cooperate rather than the traditional view, inherent in “compliance,” of an expert clinician dictating to a naive patient.^{62,63} Simply, adherence is agreeing what to do; compliance is being told what to do.
- endnote 23 An increase in the physical activity level may affect UI positively via weight reduction in obese persons. Conversely, several studies have shown that there is a high prevalence of UI in physically active women during exercise (especially during high impact activity, defined as running and jumping). Strenuous exercise/work has been suggested to be a risk factor for the development of PFD.⁷¹ A well-functioning pelvic floor responds before and during an increase in intra-abdominal pressure.
- endnote 24 Ideally, the voiding intervals should be increased by 15–30 min each week, according to the patient’s tolerance to the schedule, until a voiding interval of 3–4 h is achieved. Use of a bladder diary is recommended for self-monitoring of progress.⁷⁰
- endnote 25 A bowel habit intervention may: encourage bowel emptying at a specific time of day, mainly after a meal (to utilize the gastrocolic response), encourage patients to adopt a sitting or squatting position where possible while emptying the bowel, teach patients techniques to facilitate bowel evacuation and stress the importance of avoiding straining.^{74,127,128}
- endnote 26 Speed changes little with training. Thus, power is increased almost exclusively by gaining strength.³⁵
- endnote 27 PFM training can be isometric, concentric or eccentric or a combination of any of these.
- endnote 28 Whether PFMT is performed with or without previous assessment of the ability to contract should be reported.
- endnote 29 The original shape was conical; however, different shapes are currently available. Maintenance of the weight in position can be challenged via different body positions and activities.
- endnote 30 PFM feedback can be provided by the therapist or patient during manual palpation internally or externally, or with a mirror. The purpose of feedback is to increase accuracy of contraction for maximum benefit.
- endnote 31 Biofeedback can be visual, auditory or both. Biofeedback is not a treatment on its own. It is an adjunct to training and can be used to help the patient be more aware of muscle function, and to enhance and motivate patient effort during training.¹²⁹ The correct terminology should be PFM strength training with biofeedback or relaxation training with biofeedback. Types of PFM biofeedback include: perianal, vaginal, and anal surface EMG, urethral, vaginal or anal manometry, vaginal dynamometry, real-time ultrasound.¹²⁹
- endnote 32 Clinicians are to be cautious with regard to the interpretation of the information, as many factors influence amplitude, including muscle activity, skin conductance, and artifact. “EMG amplitude does not equal force”.⁸⁷ More microvolt activity means more muscle activity, but does not always mean more strength.
- endnote 33 Artifact examples include movement or contact quality artifact, cross talk, heart rate, skin electrode shear, and electrode bridging.
- endnote 34 Minimizing cross talk is essential in research into quality EMG tracings.
- endnote 35 Recording with surface electrodes is prone to artifact and cross talk. The user should be trained appropriately and understand the limits of the EMG instrument and of the methodology. It is not within the scope of this document to define all EMG terms. Readers are referred to other texts for further terminology.^{87,88}
- endnote 36 Baseline EMG reading can be influenced by many factors and therapists must take into account the patient’s symptoms, digital palpation results, overall tension of the patient, the possibility of artifacts, and other factors in determining the meaning of the baseline muscle activity.
- endnote 37 Slow recruitment can be symptomatic of leakage during coughing and sneezing when a quick muscle contraction is needed to counteract increased intra-abdominal pressure.
- endnote 38 Slow de-recruitment can be indicative of a hypertonic PFM.
- endnote 39 The general principles of strength training are the same with and without biofeedback. (See the sections “Mode of exercise training” and “Dose–response issues related to exercise training”)

- endnote ⁴⁰ The general principles of relaxation training are the same with and without biofeedback.
- endnote ⁴¹ Manual therapy is used to treat soft tissues and joint structures for the purpose of modulating pain; increasing the range of motion; reducing soft tissue edema; inducing relaxation; improving contractile and noncontractile tissue extensibility, and/or stability; facilitating movement; and improving function. This broad group of skilled hands-on treatments can be divided into two groups: joint therapies and soft-tissue therapies.
- endnote ⁴² Neither mobilization nor manipulation should be used when referring to muscle.
- endnote ⁴³ The notion of trigger points causing myofascial pain is controversial.¹²⁴
- endnote ⁴⁴ Depending on the particular device being used, the type of electrical current, the specific health problem and condition being treated, and the individual's needs and circumstances, many electrical stimulation parameters may be adjusted by the therapist administering the treatment.
- endnote ⁴⁵ The slower the current intensity rises to the preset amplitude or threshold level, the more comfortable the stimulation may feel. Conversely, the faster the ramp, or the more vertical the ramping up signal, the more discomfort may be felt.
- endnote ⁴⁶ Terminology for female anorectal dysfunction.¹⁸

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An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Reporting Outcomes of Surgical Procedures for Pelvic Organ Prolapse

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Introduction and Hypothesis: Standardized terminology has yet to be developed for reporting the outcomes for surgery for pelvic organ prolapse (POP). **Methods:** This report combines the input of the Terminology and Standardization Committees of the International Urogynecological Association (IUGA) and the International Continence Society (ICS) and a joint Working Group on this topic, as well as expert external referees. The aim was to present a standardized terminology for the definitions of surgery and propose a structure for reporting the outcomes of surgical procedures for POP. An extensive drafting and review process was undertaken, as well as open review on both IUGA and ICS websites. **Results:** A terminology report was developed outlining the recommended structure for reporting outcomes of surgical trials involving POP. This document does not define success and failure. The report includes patient-reported subjective and objective outcomes to enable researchers to report on their results and compare them with other studies. **Conclusions:** A consensus-based method for standardizing terminology for reporting outcome measures of POP surgery was developed to aid clinicians working in this area of research. *NeuroUrol. Urodynam.* 31:415–421, 2012. © 2012 Wiley Periodicals, Inc.

Key words: terminology; outcomes; surgical procedures; pelvic organ prolapse; female pelvic floor dysfunction

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INTRODUCTION

Whereas recommendations for reporting outcomes of surgery for stress urinary incontinence have been reported^{1,2} few exist for surgery of pelvic organ prolapse (POP). In addition, there has been ambiguity in reporting of “prolapse surgery outcomes,” particularly with regards to success/failure and further surgery/re-operation. Within the literature, there is limitation in the methodology as evidenced by the recent Food and Drug Administration (FDA) report^{3,4} and other reviews.⁵ For example, information is often incomplete or limited relative to the inclusion and exclusion criteria and study design. In addition, the power calculation is often poorly described. Issues such as detection bias (lack of blinding), conflict of interest and reporting of adverse events are problematic

Christopher Chapple led the peer-review process as the Associate Editor responsible for the paper.

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and make it difficult to interpret the information. In addition, many studies include both primary and repeat prolapse repairs, as well as additional procedures including other prolapse and/or stress incontinence surgery. Long-term follow-up past 2 years is infrequent. As a result, it is difficult to draw conclusions from these studies relative to other studies or populations in order to provide guidance for patient care. Standardized information is required to help answer the important questions regarding efficacy and safety of traditional and new POP procedures. The aim of this report, therefore, is to present a standardized terminology for the definitions of POP surgery and propose a structure for reporting the outcomes of surgical procedures. Consistency in reporting has the potential to help produce meta-analyses and reliable clinical guidelines.

The document does not define success and failure, but outlines the recommended structure for reporting outcomes of surgical trials involving POP. It complements published IUGA-ICS Joint Standardization Reports on (i) Terminology for Female Pelvic Floor Dysfunction⁶ and (ii) Terminology and Classification of Complications related directly to the insertion of prostheses and grafts in female pelvic floor surgery⁷ and (iii) concomitantly published terminology and classification of complications related to native tissue female pelvic floor surgery.⁸

BACKGROUND

The perceived ambiguity in the reporting of POP surgery outcomes might have arisen from two studies assessing success/failure and further surgery/re-operation.^{9,10} The former study by Olsen et al.⁹ suggested that the lifetime risk of requiring incontinence and/or prolapse surgery was 11% (for prolapse surgery alone, the figure was 6.7%) and 29.2% of patients required repeat surgery/re-operation. The definition of repeat surgery was any operation for prolapse or urinary incontinence following an index (first) procedure, often some years previously. While the 29.2% re-operation rate is still commonly quoted and often interpreted similarly to that stated by the authors (i.e., that this implies a high rate of surgical failure), the failure to adjust for both time and variation in operative site reduces the usefulness of the conclusions and might be misleading with regards to the true failure rate of POP surgery. This observation is borne out when the same cohort was reviewed 10 years later with the authors quoting a 17% re-operation rate.¹¹ On further analysis of the same compartment recurrence (i.e., repeat anterior repair), the re-operation rate was significantly lower at 4.6%.¹² More recently, several investigators have looked specifically at the issue of site-specific recurrence, with re-operation rates ranging from 2.8% to 9.7%.^{13–15} A recent Cochrane review¹⁶ looking at vault suspension suggested that re-operation rates after POP surgery, which includes suspension of the vaginal vault/apex, are 1.3–3.9% at 17–32 months respectively, depending upon the type of vault suspension. These data become more useful in terms of site and timescales.

The second study¹⁰ reported a 58–70% anatomical failure rate for anterior colporrhaphy. This study has recently been subject to further analysis, as the definitions of objective success and failure were based on POP quantification (POPQ) changes of small magnitude. When more clinically relevant criteria for success are used (anatomic recurrence beyond the hymen, symptomatic recurrence and re-operation), the outcome is considerably better with only 10% of subjects developing anatomic recurrence beyond the hymen, and 5% developing symptomatic recurrence and re-operations in <1% (at 23 months follow-up).¹⁷

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The lack of subjective/patient-reported outcomes was highlighted in a systematic review on mesh repairs commissioned by the National Institute for Clinical Excellence (NICE) in the UK.^{18,19} As a consequence of this and the uncertainty following further consideration of the studies mentioned above, there is a need for clear definitions and standardization for reporting of outcomes for POP surgery.

NEW DEFINITIONS

It is understood that there is close interaction among three commonly defined compartments: apical/vaginal vault, anterior, and posterior, when discussing pelvic organ support or prolapse. However, for ease of use, the definitions are limited to “primary” or “recurrence at specific sites” defined as apical/vaginal vault, anterior and posterior. As our understanding of how these compartments interact improves, the definitions of “primary prolapse surgery/different site” and “repeat surgery/same site” will evolve.

The following standardized terminology is proposed for surgical trials and clinical audit:

- A. **Primary Surgery:** This indicates the first procedure required for the treatment of POP in any compartment.
- B. **Further Surgery:** Provides a global term for the number of subsequent procedures the patient undergoes, directly or indirectly, relating to the primary surgery. Further surgery per se should not be interpreted as a measure of failure as the definitions of success and failure will be defined within the context of the individual study. Further surgery is subdivided into:
 - I. *Primary prolapse surgery/different site:* a prolapse procedure in a new site/compartment following previous surgery (e.g., anterior repair following previous posterior repair).
 - II. *Repeat surgery:* a repeat operation for prolapse arising from the same site. Where combinations of procedures arise, such as new anterior repair plus further posterior repair, these should be reported separately as primary anterior repair and repeat posterior repair.
 - III. *Surgery for complications:* mesh exposure or extrusion, pain, or patient compromise such as hemorrhage (see Complications section).
 - IV. *Surgery for non-POP related conditions:* subsequent surgery for stress urinary incontinence or fecal incontinence.

STANDARDIZATION OF REPORTING OUTCOMES—OVERVIEW

One of the major difficulties in reporting the results of prolapse surgery is that, unlike most surgeries, there is a range of outcomes which are not reported in a consistent manner; this makes uniform assessment of procedures difficult.

The International Consultation on Incontinence (ICI) has already suggested that POP and urinary incontinence surgery should report subjective, objective, and quality of life outcomes.³ This is significant in that there are a number of measures that can be used to generate useful information to benchmark practice for and against a particular procedure, as well as inform patients about potential outcomes. Therefore, it is recommended that in clinical research studies, entry criteria, design, methodology, power, and absence of bias are addressed to allow the reader to assess the reliability of findings which have the potential to influence clinical practice.

Conflict of interest should be reported due to the potential for positive reporting bias and this declaration should be at the start of the paper.

- I. Chronic cough,
- J. Chronic constipation,
- K. Smoking.

REPORTING OF METHODOLOGICAL DATA

General Criteria

The following should be defined:

- A. Inclusion criteria.
- B. Exclusion criteria.
- C. Recruitment time span.
- D. Flow diagram including²⁰
 - (i) Number of patients evaluated.
 - (ii) Number suitable for inclusion.
 - (iii) Number agreed to participate.
 - (iv) Clear documentation accounting for all patients' progress throughout the study period.

Comparative Studies

- A. Clear explanation of patient allocation to treatment groups.
- B. Allocation concealment from surgeon and/or patient.
- C. Randomized trials: explanation of randomization process.
- D. Stratification of associated issues utilized such as concomitant continence surgery or hysterectomy.

Interventions

- A. Clear documentation of interventions performed, experience level of surgeons and number of interventions performed prior to study commencement.
- B. Criteria for performing concomitant surgery.

Evaluation Process

- A. Who performed the evaluation and the training received.
- B. Were reviewers and/or participants blinded.
- C. Evaluation tools: were validated, patient-completed assessments standardized.
- D. Evaluation timeline:
 - i. Very early (up to 3 months).
 - ii. Early (up to 1 year).
 - iii. Intermediate (12–36 months).
 - iv. Late (3–5 years).
 - v. Very late (>5 years).

Power Analysis

Details of the assumptions made in the Power calculation, estimate of the type 1 error and sample size should be reported.

REPORTING DEMOGRAPHICS IN POP SURGICAL RESULTS

The reporting of minimum demographics in POP surgery should include:

- A. Age,
- B. Parity,
- C. Body mass index (BMI),
- D. Menopause status,
- E. Hormone replacement therapy (HRT) usage,
- F. Prior hysterectomy,
- G. Prior POP surgery,
- H. Prior continence surgery,

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REPORTING OF RANDOMIZED CONTROLLED TRIALS (RCTs)

There are already accepted standards for reporting RCTs such as the CONSORT (Consolidated Standards of Reporting Trials)²⁰ which requires detailed information provided by authors to reviewers with a checklist added as an appendix. However, many studies fail to provide complete descriptions of critical information.

REPORTING OF SYSTEMATIC REVIEWS AND META-ANALYSES

Due to the lack of consistent descriptions of critical information reported from RCTs, a new instrument, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA),²¹ has been introduced to evaluate systematic reviews and meta-analyses. The aim of the PRISMA statement is to give authors an evidence-based minimum set of items to improve the reporting of systematic reviews and meta-analyses in POP issues. Other standards include the Standards for the Reporting of Diagnostic (STARD) accuracy studies,²² and STROBE (STrengthening the Reporting of OBServational studies in Epidemiology).²³ Researchers should quote which standard they adopt and reference accordingly.

REPORTING OF PATIENTS' PRE-OPERATIVE GOALS AND EXPECTATIONS

To date, few studies have provided data on patients' preoperative goals and expectations.^{24–27} These might have advantages over objective measures of outcome. With this in mind, goals should be reported using SMART criteria.²⁸ The aim of the SMART criteria is to help clinicians review and confirm the utility of the chosen endpoint and how it will relate to other studies and reports. Criteria comprise:

Specific	Defining goal (for POP: absence of bulge)
Measurable	Validated symptom scale or objective measure such as the POPO
Appropriate	Relevant to improving patient lifestyle
Realistic	Achievable by treatment
Timely	For example at 6 months/2 years

The following is an example of good and poor reporting of patient expectations and outcomes, using the SMART Schema:

Good example: "The absence of bother from a vaginal bulge as measured using a defined tool at 2 years." This statement has Specific, Measurable, Appropriate, Realistic, and Timely attributes.

Poor example: "Feeling perfect" when followed-up. "Perfect" is not specific (OB compared with absence of bulge), is less measurable (because it is difficult to define), has no defined timepoint and is not appropriate or relevant to the surgery as many factors define "perfect."

Definitions relating to the SMART criteria should be derived from the symptoms the researchers feel are important. When designing a study, the symptoms should be listed and then SMART should be applied. Authors should use this as a *checklist* to ensure that the methodology is sound and relevant.

REPORTING OF OUTCOMES FOLLOWING SURGICAL TREATMENT OF POP

Perioperative Data

Perioperative data includes blood loss (ml) and/or hemoglobin change, operating time, length of hospital stay, return to normal daily activities and complications.

Patient Reported Outcomes

The primary patient reported outcome should be subjective and would usually be the absence of a bulge.²⁹ This can be regarded as a “subjective cure”²⁹ and can be recorded as part of a symptom scale. Details of validated questionnaires for patient reported outcomes can be found on ICI’s website.³⁰ To adhere with the SMART criteria, patient/subjective outcomes should be defined at a specific time interval and classified on a 7-point Likert scale (i.e., very much better, moderately better, a little better, no change, slightly worse, moderately worse, very much worse) such as the Patient Global Impression of Improvement (PGI-I) scale.³¹

Patient Satisfaction

Patient satisfaction can be measured using qualitative measures, such as a patient-defined measure or a validated instrument (PGI-I scale).³¹ Qualitative assessment can include Expectations, Goal setting, Goal achievement and Satisfaction (EGGS).³² Again these should be in accordance with the SMART acronym. The number of pre-specified goals and the number achieved post-operatively should be recorded and reported for responsiveness and reliability of goal achievement.²⁴

Quality of Life

Appropriate and fully validated quality of life instruments should be used to cover prolapse, urinary, bowel and sexual function.³⁰

New questionnaires can be included when they have demonstrated good psychometric properties (i.e., validity, reliability and responsiveness) in women with POP. It is important to verify that the questionnaire has been validated in the language of the trial investigator(s).

Objective Outcomes

Objective outcomes (e.g., POPQ³³) should be tabulated with percentages achieving each level to allow studies to compare results, as definitions of success will vary among studies (see below). This report does not attempt to provide a definition for success and failure, as these are unknown. However, authors should report data on the leading edge of the prolapse for each site (e.g., patients who achieve points -1 and 0 post-operatively having had prolapse greater than -1 or 0 before surgery). These data, which may help identify the level of anatomical restoration that leads to improvement in symptoms, should be reported separately.

When possible, raw data should be provided for POPQ, quality of life measures and all primary symptoms. These should be reported in separate tables, which can be published as supplementary material in the electronic (online) version rather than the printed version.

Reoperation or Further Surgery

See Further Surgery in “New Definitions” above.

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Timelines

Timelines should be described chronologically, as outlined below, using the classification above. Of note, these timescales are different to those described in the classifications of complications reports related to female pelvic floor surgery using either prostheses and meshes⁷ or native tissue.⁸

- I. Very early (up to 3 months).
- II. Early (up to 1 year).
- III. Intermediate (12–36 months).
- IV. Late (3–5 years).
- V. Very late (>5 years).

Economic Evaluation/Cost Analysis

Despite considerable cost, sparse cost-effectiveness data exists related to POP surgery. Investigators are encouraged to include economic analyses in their studies whenever possible. Further details are below in the section Reporting on Economic Evaluation/Cost Analysis.

COMPLICATIONS

Complications specifically related to prostheses and grafts⁷ and native tissues⁸ should be reported as per the IUGA-ICS classifications of complications directly related to the insertion of prostheses and grafts or the use of native tissue in female pelvic floor surgery.^{5,6} These classifications both use the CTS Classification System:

- (C) Category of complication.
- (T) Time the complication was diagnosed in relation to primary surgery.
- (S) Site of the complication.

There are seven Categories with subdivisions of (A–D). For the majority of complications, this would mean:

- (A) Asymptomatic,
- (B) Symptomatic,
- (C) Infection,
- (D) Abscess.

For complications involving bowel or bladder injury or patient compromise, variations in the pattern of the increasing index of severity exist: e.g., Category 5: rectal or bowel injury (both classifications—^{7,8}) (A) Small intraoperative defect; (B) rectal injury or compromise; (C) small or large bowel injury or compromise; (D) abscess.

Studies, in particular of a specific surgical procedure, should have a procedure-specific list of complications using the CTS Classification Systems^{7,8} as part of the reporting. Only in this way can the nature and chronology of possible complications be determined (in relation to time of surgery) and at which sites they might most commonly occur.

Note is also made of the generic Clavien-Dindo complication classification³⁴ which consists of four severity grades of complications. This has been modified to include a fifth category:³⁵

Grade I	Requires no treatment
Grade II	Requires drug therapy
Grade III	Requires a procedure or intervention (a: in local; b: general anesthesia)

Grade IV	IC/ICU organ or system dysfunction (a: single organ; b: multi-organ dysfunction)
Grade V	Death

POSTOPERATIVE PAIN

Pain associated with surgical complications is addressed separately in the IUGA-ICS classifications of complications of female pelvic floor surgery (7,8). The addition of a letter (a to e), as part of a subclassification to the CTS Classification System, specifies the presence of pain as part or all of the abnormal finding or complication and the grade in terms of the presence and severity of symptoms.

- (a) Asymptomatic or no pain.
- (b) Provoked pain only (during vaginal examination).
- (c) Pain during sexual intercourse.
- (d) Pain during physical activities.
- (e) Spontaneous pain.

Additional information on pain may include “permanent or temporary” and “severity” as measured by impact on quality of life and treatment required (e.g., simple oral analgesia, compound analgesia, opiates, referral and management by pain team or further surgery).

REPORTING OF SECONDARY OUTCOMES

Secondary outcomes to be reported include an assessment of other symptoms known to be associated with prolapse:

Lower urinary tract symptoms (LUTS): Overactive bladder, stress urinary incontinence (either pre-existing or de-novo) and voiding dysfunction.

Bowel dysfunction: Obstructed defecation, feeling of incomplete emptying, constipation and digitation.

Sexual dysfunction: Dyspareunia, loss of libido, abstinence due to prolapse symptoms and change in sexual satisfaction. Authors should report numbers of all patients who are sexually active with and without pain, pre and post-intervention.

Figure 1 has been developed to illustrate the reporting of these data. All participants in trials should be accounted for pre- and post-intervention.

De novo/new onset symptoms (if not previously reported): LUTS, sexual dysfunction, pain and bowel dysfunction.

Backache: Backache is a common presenting symptom, the resolution of this may be an important outcome.

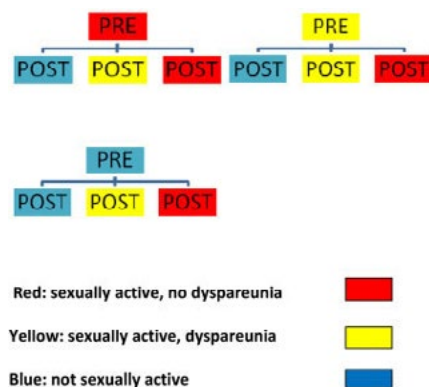


Fig. 1. Reporting of sexual function.

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REPORTING ON ECONOMIC EVALUATION AND COST ANALYSIS

Economic evaluation techniques provide systematic methods of comparing the costs and consequences of clinical and other health sector interventions. Cost-utility analysis (CUA), a form of cost-effectiveness analysis (CEA), is by far the most commonly used and requires quantifying the effects of interventions on both morbidity and mortality.

In a CUA, benefits are measured in units of health gain (or loss), most commonly using quality-adjusted life-years (QALYs) and combined with estimates of cost to create a ratio of incremental costs to incremental consequences (e.g., “incremental cost per QALY”). QALYs are usually calculated using a generic health status measure, such as Short Form (SF)36 or EuroQOL/EQ-5D, which can be used with a standard set of health state values or by other measures of utility, such as the standard gamble or time-trade off technique. These incremental cost effectiveness ratios (ICERs) enable comparison of competing interventions on the basis of the cost at which they create improvements in health-related quality-of-life.

In economic evaluations, it is important to consider the perspective (e.g., patients, hospital, third-party payer, government and society) of the evaluation, as this will have significant influence on which costs should be included in the analysis. For example, the perspective of the analysis will influence whether it should include both direct and indirect costs. Direct medical costs typically relate to the intervention and the immediate impact of the intervention on the health system: e.g., personnel costs/time (physician, nurse, technician), diagnostic and laboratory tests, hospital costs, treatment costs (drugs, operating room time, etc.), treatment of side effects and outpatient visits. Indirect costs will be of more relevance to a patient and/or societal perspective (e.g., loss of productivity, time lost from work, loss of service to family and community and premature mortality) and are often more difficult to quantify and to put a monetary value on.

DISCUSSION

This document was born from the recognition that contemporary practice lacks sufficient reproducible evidence to help clinicians translate published literature into clinical practice and enable patients to be aware of likely outcomes.

For example, the assessment of prolapse surgery has been subject to a number of limitations. First, and perhaps most important, is the quality of the studies. The majority are case series, with very few well-constructed and sufficiently powered RCT. As a result, the quality of the available evidence is questionable.^{3,4} The emphasis then lies within systematic reviews and meta-analyses, which may be less robust due to the lack of good quality data.

New surgical procedures for POP reconstructive surgery have evolved dramatically in recent years, suggesting that the perceived dissatisfaction with conventional/traditional surgery as expressed by White³⁶ at the turn of the twentieth century persists. This perception is based on clinical experience and reports of anatomical failure and re-operation.^{9,10} As the findings of these studies^{9,10} have been questioned by more recent studies,^{12,13,17} this highlights the need for a standardized method of reporting surgical outcomes so that appropriate recommendations for patient care can be provided from meta-analyses and systematic reviews. This report sets out to provide a framework through which researchers and clinicians can standardize reporting and allow results to become more transferable.

TABLE 1. Recommendations for Reporting in Audit of Clinical Practice and Surgical Trials

	Audit	Research trial
Type of surgery	R	R
Primary outcome including patient satisfaction	R	R
Secondary outcomes	O	R
Timelines	O	R
Cost analysis	N	O ^a
Complications	R	R
Commitment to longer term follow-up	O	R
Audit database	R	O

R, routine; O, optional; N, not required.

^aIt is recognized that this is ideal and not all researchers will be able to do this, but it is recommended.

History has taught that surgical complications (particularly in the case of implants) may be long-term and researchers should be encouraged to revisit early results (e.g., 1 year) and include long-term data of 5–10 years.

The Austrian and Finnish experiences with mid-urethral slings have demonstrated that, in addition to properly constructed prospective trials, there is a moral and ethical responsibility for users of advanced techniques, such as those employing implants, to contribute to clinical governance and audit through local, regional or national databases.

SUMMARY OF RECOMMENDATIONS FOR POP SURGICAL OUTCOMES

In all surgical trials of POP surgery, authors should clearly report their Methodology. These should follow CONSORT/STROBE and type of surgery (primary or further using the agreed definitions, see above) should be stated. Table 1 outlines what should be reported in both clinical audit and surgical trials. In addition, researchers should give a commitment in the original trial design and at publication of early results, to publish longer term data at a minimum of 5 years.

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An International Urogynecological Association (IUGA)/ International Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertion of Prostheses (Meshes, Implants, Tapes) and Grafts in Female Pelvic Floor Surgery

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Introduction and hypothesis: A terminology and standardized classification has yet to be developed for those complications arising directly from the insertion of synthetic (prostheses) and biological (grafts) materials in female pelvic floor surgery. **Methods:** This report on the above terminology and classification combines the input of members of the Standardization and Terminology Committees of two International Organizations, the International Urogynecological Association (IUGA) and the International Continence Society (ICS) and a Joint IUGA/ICS Working Group on Complications Terminology, assisted at intervals by many expert external referees. An extensive process of 11 rounds of internal and external review took place with exhaustive examination of each aspect of the terminology and classification. Decision-making was by collective opinion (consensus). **Results:** A terminology and classification of complications related directly to the insertion of prostheses and grafts in female pelvic floor surgery has been developed, with the classification based on category (C), time (T) and site (S) classes and divisions, that should encompass all conceivable scenarios for describing insertion complications and healing abnormalities. The CTS code for each complication, involving three (or four) letters and three numerals, is likely to be very suitable for any surgical audit or registry, particularly one that is procedure-specific. Users of the classification have been assisted by case examples, colour charts and online aids (www.icsoffice.org/complication). **Conclusion:** A consensus-based terminology and classification report for prosthesis and grafts complications in female pelvic floor surgery has been produced, aimed at being a significant aid to clinical practice and research. *NeuroUrol. Urodynam.* 30:2–12, 2011. © 2010 Wiley-Liss, Inc.

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Conflicts of interest: BT Haylen: Assistance from Boston Scientific to attend London June 2008 Meeting of the Authors of the IUGA-ICS Report on Terminology for Female Pelvic Floor Dysfunction; RM Freeman: Educational meetings: Astellas and Pfizer. All income from commercial trials and some of the honoraria go to his research fund. Locality lead for the NIHR Peninsula Collaboration for Leadership in Applied Health Research and Care (PenCLAHRC).

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PREFACE

The Standardization and Terminology Committees of the International Urogynecological Association (IUGA) and the International Continence Society (ICS) and the Joint IUGA/ICS Working Group on Complications Terminology seek to provide a terminology and a standardized classification for those complications arising directly from the insertion of prostheses and grafts in female pelvic floor surgery. This document would then be, amongst its various other possible applications such as medical records and surgical audits (often procedure-specific), the basis for a registry of such complications. As the first aim is to standardize the terminology used in this classification, the terms used in the title need to be initially defined.

- **Classification:** A systematic arrangement into classes or groups based on perceived common characteristics.¹ N.B. *Division:* A separation into two or more parts.
- **Complication:** A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery ("surgery" replacing "disease" in the definition; "course" includes postoperative of whatever duration).¹
- **Directly:** Without an intermediary or intervening factor.²
- **Related:** Connected.²
- **Insertion:** Putting in.¹
- **Prosthesis:** A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure.¹
- **Mesh:** A (prosthetic) network fabric or structure; open spaces or interstices between the strands of the net.² The use of this term would be for *prolapse surgery with synthetic materials*.
- **Implant:** A surgically inserted or embedded prosthesis.¹ (*Explant:* a surgically excised prosthesis).
- **Tape (Sling):** A flat strip of synthetic material.¹ The use of this term would be for *incontinence surgery with synthetic materials*.
- **Graft:** Any tissue or organ for transplantation.^{1,2} This term will be used to refer to *biological materials inserted*³:
 - (a) *Autologous grafts:* From patient's own tissues, for example, dura mater, rectus sheath, or fascia lata.
 - (b) *Allografts:* From post-mortem tissue banks.
 - (c) *Xenografts:* From other species, for example, modified porcine dermis, porcine small intestine, and bovine pericardium.
 Terminology for grafts has not been separated into the different applications for prolapse and continence surgery.
- **Trocar:** A surgical instrument with either a pyramidal, conical, or needle-type cutting or dissecting point.

INTRODUCTION

A significant increase in the use of an ever-widening array of prostheses and grafts has occurred in female pelvic floor surgery over the last 30 years. In the 1980s, silastic slings and artificial urinary sphincters⁴ were used for urodynamic stress incontinence (USI). McGuire repopularized the rectus sheath fascial sling (an autologous graft) described originally by Aldridge.⁵ In the early 1990s, variations on the Stamey-type⁶ needle suspension procedures were used involving permanent sutures and modified needles or bone anchors.

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In the mid to late 1990s, suburethral synthetic slings for USI using mesh were introduced, the tension-free vaginal tape (polypropylene mesh) being the most notable.⁷ Trocars were used both retropubically and, over the last 8–10 years, laterally passing the obturator membrane and the insertion of the obturator internus muscle.⁸ These trocars have the potential for causing trocar insertion-related complications in addition to complications due to the use of the prostheses or grafts themselves.

The prosthetic materials used to date have, in retrospect, been of different surgical propriety, not appreciated at the time of their introduction. Amid⁹ has presented a classification for different types of meshes for repair of abdominal wall herniae (the behavior of meshes around the vagina may differ) based on pore size and fiber type used and the likelihood of complications according to these factors. This has been extremely useful in directing clinicians and the mesh and/or device manufacturers to more appropriate mesh types and designs. The consensus today is that the least morbidity will be achieved by using a low weight, inert, large pore, monofilament prosthesis, with an elasticity between 20% and 35%.^{10,11}

Deprest et al.¹¹ have presented an excellent analysis of the biology behind the use of prostheses (synthetic) and grafts (biological) in pelvic organ prolapse repair. The classification to be outlined will cover insertion issues as well as infection, healing abnormalities, and other signs of poor integration of these materials, though not the materials themselves.

In terms of prolapse surgery, there has been at times a quest to achieve a prolapse repair with as close to 100% efficacy (anatomical success) and reduce the 29% long-term risk for a woman to undergo a subsequent prolapse surgery after prior prolapse or continence surgery.¹² Anatomical benefits have not been necessarily matched by subjective benefits, that is, functional acceptability for the patient. "Kits" (defined as a set of articles or equipment needed for a specific purpose²) have been introduced for all types of prolapse repairs, again involving the use of different materials with different fixation devices or trocars. Papers on such procedures meeting the scientific criteria for randomized prospective trials have been relatively slow to emerge. In addition to "kits," the same materials have also been independently laid in place or fixed with surgical sutures. The use of prostheses or grafts has progressed questionably in some areas from an indication for recurrent prolapse to that of using them in primary procedures.¹³

Historically, discontinuation of a surgical procedure occurs generally due to either (i) a lack of efficacy or (ii) the nature or frequency of complications. Native [patient's own, not an autologous (transplanted) graft] tissue repairs are also not without complications. Prostheses or grafts potentially add to the complication profile the aspects of (i) trauma of insertion; (ii) reaction of the body to the prosthesis in terms of inflammation or infection; (iii) the stability of the prosthesis over time; (iv) morbidity at the donor site from harvesting an autologous graft.

One key precept in the Hippocratic oath, often quoted in Latin, is *primum non-nocere* (first, to do no harm). Surgeons need to know the possible complications that their surgeries might cause and when and where they might occur. In respect of the use of prostheses and grafts, such information might be

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generated from a table of complications (personal, institutional, or multi-center), classified according to three aspects: category, time, and site (defined below). In addition, there have been examples of personal, multi-center, national, and industry-coordinated registries. It is a simultaneous aim, with the production of this document, to initiate the development of a user-friendly, online accessible joint ICS-IUGA web-based registry of the complications referred in this document. With the information from a codified table of procedure-specific complications, possibly involving a registry (at whatever level): (i) a surgeon might better know the value and risk of a certain procedure; (ii) informed counseling might be provided before a woman embarks on that procedure; (iii) if the procedure involves a prosthesis supported by industry, then that group would have detailed feedback on the complications of that procedure. Should the overview in terms of complications be sufficiently adverse, the procedure and/or the prosthesis or graft should be abandoned.

In drawing up such a classification of complications based on category, time, and site, the bias would be towards optimizing sensitivity, clarity, and interpretability. Increasing sensitivity comes with the natural risk of the classification appearing overly complex. It is hoped that the following outline and explanatory notes, user-friendly tables, case examples, and some online aids (to be introduced in conjunction with the publication of this document – see abstract and discussion for web reference) might alleviate any such concern. It would be of greater concern if the classification did not cover all the different complication scenarios, such that previously undefined additional terminology might be needed.

PROPOSED NEW DEFINITIONS

Complications involving the use of meshes, tapes, and grafts in female pelvic floor surgery need to involve the following viewpoints of (i) local complications; (ii) complications to surrounding organs; and (iii) systemic complications. The generic term of “erosion” (medically defined as the “state of being worn away, as by friction or pressure”¹), does not necessarily suit the clinical scenarios encountered. Its use is best avoided, to be replaced by terms with greater physical specificity and clarity.

The additional terms to be used are (see also Table 1):

- **Contraction:** Shrinkage or reduction in size.¹
- **Prominence:** Parts that protrude beyond the surface¹ (e.g., due to wrinkling or folding with no epithelial separation).
- **Separation:** Physically disconnected,² for example, vaginal epithelium.
- **Exposure:** A condition of displaying, revealing, exhibiting, or making accessible¹ (e.g., vaginal mesh visualized through separated vaginal epithelium; Fig. 4).
- **Extrusion:** Passage gradually out of a body structure or tissue¹ (e.g., a loop of tape protruding into the vaginal cavity; Fig. 5).
- **Compromise:** Bring into danger.²
- **Perforation:** Abnormal opening into a hollow organ or viscus.¹
- **Dehiscence:** A bursting open, splitting, or gaping along natural or sutured lines.¹
- **Sinus tract formation:** (Localized) formation of a fistulous tract towards vagina or skin, where there is no visible implant material in the vaginal lumen or overlying skin.

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CATEGORY, TIME, AND SITE (CTS) CLASSIFICATION

The overall aim of the classification is to summarize any of a large range of possible clinical scenarios into a code (“a numeric system for ordering and classifying information”¹) using as few as three numerals and three (or four) letters. No additional verbal description, possibly involving undefined terminology, should be necessary (see Table 2).

SELECTION OF CATEGORIES

The selection of category (C) has used the principal that the least severe complication would involve the prosthesis remaining within the anatomical site into which it was inserted. More severe complications would involve (i) increasing exposure in surrounding anatomical structures; (ii) opening into surrounding organs; and (iii) systemic compromise. The following seven categories (by number) have been formed:

1. **Vaginal complication—no epithelial separation:** This incorporates the terms prominence (e.g., due to wrinkling or folding) or contraction (shrinkage). Also incorporated here is the palpation of mesh fibers.
2. **Vaginal complication—(smaller) exposure:** A smaller (1 cm or less) degree of vaginal epithelial separation is involved.
3. **Vaginal complication—(larger) exposure or extrusion:** A larger degree (>1 cm) of vaginal epithelial separation or prosthesis or graft extrusion is involved.

Categories 1–3 have been separated into the following divisions:

1A–3A: Asymptomatic—abnormal mesh finding: These are generally physician-diagnosed at any episode of clinical care. It can be argued that the “abnormal prosthesis or graft finding” aspects of category **1A**, in particular, aren’t really complications as the patient isn’t bothered by the potential problem. It may be, however, that the woman may not have engaged in an activity that is likely to provoke symptoms for herself, for example, pain or bleeding during sexual intercourse (or for her partner), which would convert these complications to category **1B**.

1Aa–3Aa: Asymptomatic—abnormal mesh finding—no pain: The addition of an “a” specifies that the patient experiences no pain in association with the abnormal finding.

1B–3B: Symptomatic—unusual discomfort or pain; dyspareunia (for either partner): Bleeding or discharge may be possible symptoms.

1Bb–3Bb: Symptomatic—provoked pain only (during vaginal examination): The addition of a “b” to the category code specifies that pain, provoked only during vaginal examination, is associated with the abnormal finding.

1Bc–3Bc: Symptomatic—pain during sexual intercourse: The addition of a c to the category code specifies that pain, provoked during sexual intercourse (patient only), is associated with the abnormal finding.

1Bd–3Bd: Symptomatic—pain during physical activities: The addition of a d to the category code specifies that pain, provoked during physical activities, is associated with the abnormal finding.

1Be–3Be: Symptomatic—spontaneous pain: The addition of an e to the category code specifies that pain, spontaneously

TABLE 1. Terminology Involved in the Classification

TERMS USED	DEFINITION
PROSTHESIS	A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure
A: Mesh	A (prosthetic) network fabric or structure
B: Implant	A surgically inserted or embedded prosthesis
C: Tape (Sling)	A flat strip of synthetic material
GRAFT	Any tissue or organ for transplantation. This term will refer to biological materials inserted
A: Autologous Grafts	From the woman's own tissues e.g. dura mater, rectus sheath or fascia lata
B: Allografts	From post-mortem tissue banks
C: Xenografts	From other species e.g. modified porcine dermis, porcine small intestine, bovine pericardium
COMPLICATION	A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery
CONTRACTION	Shrinkage or reduction in size
PROMINENCE	Parts that protrude beyond the surface (e.g. due to wrinkling or folding with no epithelial separation)
SEPARATION	Physically disconnected (e.g. vaginal epithelium)
EXPOSURE	A condition of displaying, revealing, exhibiting or making accessible e.g. vaginal mesh visualized through separated vaginal epithelium
EXTRUSION	Passage gradually out of a body structure or tissue
COMPROMISE	Bring into danger
PERFORATION	Abnormal opening into a hollow organ or viscus
DEHISCENCE	A bursting open or gaping along natural or sutured line

present (i.e., without physical activity), is associated with the abnormal finding.

1C–3C: Clinical infection: This is always a possibility with a synthetic prosthesis or graft. Signs of local tenderness are suggestive with the combination of redness and a purulent discharge being more conclusive.

1C–3C (b–e): Infection–pain. The addition of the letters *b* through to *e* specifies that pain (as defined in Table 4) is part or all of the infected abnormal finding.

1D–3D: Abscess formation: This is a more serious possibility with a synthetic prosthesis or graft.

1D–3D (b–e): Infection–pain. The addition of the letters *b* through to *e* specifies that pain (as defined in Table 3) is

part of the abnormal finding associated with abscess formation.

Category 4: Urinary tract compromise or perforation. This category class has been subdivided into:

4A: Small intraoperative defect: For example, bladder perforation. Such a complication does not generally create longer-term compromise for the bladder if recognized, prosthesis (graft) removed as indicated, defect oversewn (if necessary), and some minor precautions are taken, for example, short-term bladder drainage, with suitable antibiotics commenced.

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TABLE 2. A Classification of Complications Related Directly to the Insertion of Prostheses (Meshes, Implants, Tapes) or Grafts in Female Pelvic Floor Surgery

	CATEGORY			
	A (Asymptomatic)	B (Symptomatic)	C (infection)	D (Abscess)
1 General Description Vaginal: no epithelial separation include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)	1A: Abnormal prosthesis or graft finding on clinical examination	1B: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	1C: Infection (suspected or actual)	1D = Abscess
2 Vaginal: smaller \leq 1cm exposure	2A: Asymptomatic	2B: Symptomatic	2C: Infection	2D = Abscess
3 Vaginal: larger >1cm exposure, or any extrusion	3A: Asymptomatic 1-3Aa if no prosthesis or graft related pain	3B: Symptomatic 1-3B (b-e) if prosthesis or graft related pain	3C: Infection 1-3C /1-3D (b-e) if prosthesis or graft related pain	3D = Abscess
4 Urinary Tract: compromise or perforation including prosthesis (graft) perforation, fistula and calculus	4A: Small intraoperative defect e.g. bladder perforation	4B: Other lower urinary tract complication or urinary retention	4C: Ureteric or upper urinary tract complication	
5 Rectal or Bowel: compromise or perforation including prosthesis (graft) perforation and fistula	5A: Small intraoperative defect (rectal or bowel)	5B: Rectal injury or compromise	5C: Small or Large bowel injury or compromise	5D = Abscess
6 Skin and / or musculoskeletal: complications including discharge pain lump or sinus tract formation	6A: Asymptomatic, abnormal finding on clinical examination	6B: Symptomatic e.g. discharge, pain or lump	6C: Infection e.g. sinus tract formation	6D = Abscess
7 Patient: compromise including hematoma or systemic compromise	7A: Bleeding complication including haematoma	7B: Major degree of resuscitation or intensive care*	7C: Mortality* *(additional complication - no site applicable - S 0)	
TIME (clinically diagnosed)				
T1: Intraoperative to 48 hours	T2: 48 hours to 2 months	T3: 2 months to 12 months	T4: over 12 months	
SITE				
S1: Vaginal: area of suture line	S2: Vaginal: away from area of suture line	S3: Trocar passage Exception: Intra-abdominal (S5)	S4: other skin or musculoskeletal site	S5: Intra-abdominal
<p>N.B.</p> <p>1. Multiple complications may occur in the same patient. There may be early and late complications in the same patient. I.e. All complications to be listed. Tables of complications may often be procedure specific.</p> <p>2. The highest final category for any single complication should be used if there is a change over time. (patient 888)</p> <p>3. Urinary tract infections and functional issues (apart from 4B) have not been included.</p>				
<p style="text-align: center;">CODE <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p style="text-align: center;">- T - S</p>				

TABLE 3. Subclassification of Complication Categories to Specify the Presence of Pain (by the Patient only, not the Partner) Associated with the Abnormal Finding and the Grade in Terms of the Presence and Severity of Symptoms

GRADE OF PAIN	SYMPTOMS
a	Asymptomatic or no pain
b	Provoked pain only (during vaginal examination)
c	Pain during intercourse
d	Pain during physical activities
e	Spontaneous pain

4B: *Other lower urinary tract (bladder or urethral) complication or compromise*: This division would incorporate injuries causing longer-term bladder issues, for example, ongoing prosthesis or graft perforation, fistula, calculus around the prosthesis, or graft. This category also incorporates urinary retention directly related to the procedure requiring subsequent surgical intervention (apart from any form of bladder drainage). The time and site divisions relates to those for the surgical intervention.

4C: *Ureteric or upper tract complication or compromise*: This division is self-explanatory.

Category 5: Rectal or Bowel compromise or perforation. This category class has been subdivided into:

5A: *Small intraoperative defect*: Such a complication may not generally be expected to cause compromise if the defect is recognized, prosthesis (graft) removed as indicated, defect oversewn (as necessary) with appropriate precautions taken, for example, short-term bowel rest is instituted with suitable antibiotics commenced.

5B: *Rectal injury or compromise*: This division would incorporate injuries causing longer-term rectal issues, for example, ongoing prosthesis (graft) perforation, fistula.

5C: *Small or large bowel injury or compromise*: This division would incorporate injuries causing longer-term bowel issues, for example, ongoing prosthesis (graft) perforation, fistula, obstruction.

5D: *Abscess formation from bowel injury/compromise*.

Category 6: Skin and/or musculoskeletal complications:

6A: *Asymptomatic*: Physician-diagnosed complication at any episode of care.

6B: *Symptomatic*: For example, discharge, pain, lump.

6C: *Infection from skin or musculoskeletal complication*: Including sinus tract formation.

6D: *Abscess formation from skin or musculoskeletal complication*.

Category 7: Patient compromise. This category recognizes that the patient might be brought into systemic danger with some of the complications in addition to any localized issue.

7A: *Bleeding complication including hematoma*: This division refers to any clinically diagnosed hematoma as well as those where blood transfusion or surgical intervention is a consideration.

7B: *Major degree of resuscitation or intensive care*: This division refers to significant hemodynamic or cardiopulmonary resuscitation directly related to the procedure, and/or patient transfer for management in intensive care facilities.

7C: *Mortality*: The insertion of the prosthesis, whilst not necessarily fatal at the time, has set in train further morbid events leading to mortality.

N.B. Because of their systemic nature, 7B and 7C will not have a specific site division. They will be denoted 50.

SELECTION OF TIME (T) DIVISIONS

The time (T) for the complication is when it is *clinically diagnosed*. This section incorporates four time periods, all of the possible episodes where clinical care might be given by the physician or sought by the patient. It might not always be possible to predict with any prosthesis or graft when complications might be more frequently seen. This would depend on the results of a procedure-specific surgical audit using the classification. The earliest time division (T1) might involve more insertion issues, whilst later divisions (T2–T4) might be biased towards healing abnormality issues.

T1: *Intraoperative—48 hr*: Insertion complications more likely.



Fig. 1. 52-year-old female underwent a transobturator tape. At 6 weeks, she was cured of her USI and reported no vaginal discharge. Vaginal examination revealed a smaller mesh exposure away from vaginal suture line. **Classification:** 2A T2 S2.



Fig. 3. 65-year old with urinary incontinence, underwent a multifilament transobturator sling. At 14 months follow up, she experienced severe pelvic pain and vaginal discharge. Clinical examination revealed hyperthermia to 40°C, (i) sling exposure at right vaginal sulcus and (ii) severe cellulitis in the genito-crural fold. **Classification:** (i) 3C T4 S2; (ii) 6C T4 S3.

T2: 48 hr–2 months: Healing or infection complications more likely.

T3: 2–12 months: Later healing abnormalities more likely.

T4: Over 12 months: Late healing abnormalities and other mesh complications more likely.



Fig. 2. 55-year-old female had a retropubic tape. At 2 years follow up, she reported vaginal discharge. Examination revealed a palpable but unseen lateral mesh exposure, together with a cutaneous fistula with local purulent discharge. **Classification:** (i) 2B T4 S2; (ii) 6C T4 S4.

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SELECTION OF SITE (S) DIVISIONS

The selection of these divisions incorporates the current sites where prosthesis or graft complications have been noted:

S0: Systemic complications (no specific site): As mentioned earlier, category divisions 7B and 7C which are systemic complications will be denoted S0.

S1: Vaginal: area of suture line: Perhaps the commonest site for prosthesis and graft complications from vaginal surgery is close to the vaginal suture line.

S2: Vaginal: away from the vaginal suture line: As most suture lines would be midline, this would generally be lateral in the vagina.

S3: Trocar passage: The passage of any sharp surgical instrument can cause damage along the path of insertion. This division incorporates any extraperitoneal, bladder, or rectal complication, but not intra-abdominal complications which are S5.

S4: Other skin or musculoskeletal site: This division is relevant to any skin or musculoskeletal complications away from the sites of trocar entry or exit. Included might be cutaneous sinus or fistula formation.

S5: Intra-abdominal: Included in this section would be bowel perforation or obstruction.

CTS Classification: (Complete code):

- Example of complete CTS code: 3B/T2/S3 (for simplicity, there is no “C” in front of the category class and division). The letters *a–e* may be added to the category code, for example, 3Bc/T2/S3 to indicate that pain is part of the abnormality (*c*—pain with intercourse).

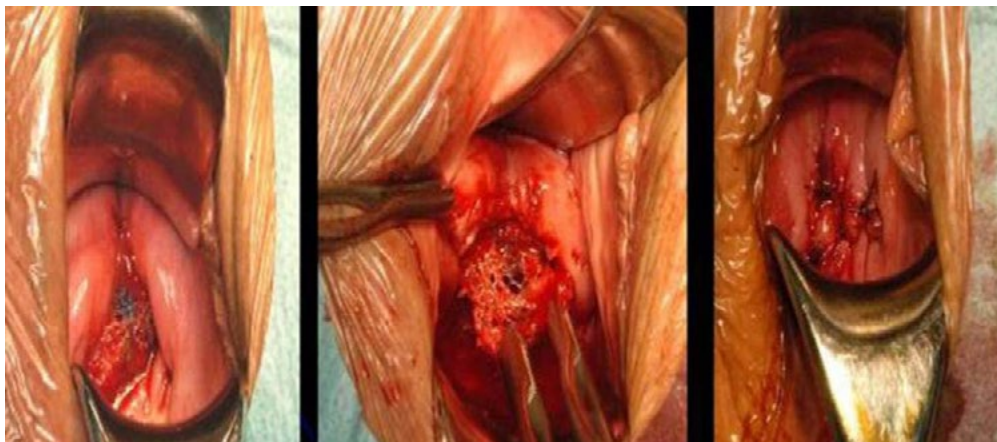


Fig. 4. A 67 year old woman had undergone a vaginal prolapse repair with hysterectomy. She subsequently had a transvaginal mesh repair for a large recurrent cystocele. At 5 months follow up, she complained of dyspareunia. Vaginal examination revealed a mesh exposure of 20 mm by 15 mm at anterior vaginal wall and vaginal cuff. **Classification: 3Bc T3 S1.**

CLASSIFICATION GUIDELINES

The following should be noted:

- *Multiple complications may occur in the same patient:* These should be reported separately as noted in Table 3.
- *There may be early and late complications in the same patient:* again, these should be reported separately.
- *All complications should be listed.*
- *If there is progression of a particular complication over time, the highest final category is to be used:* progression of a

vaginal tape exposure from asymptomatic to symptomatic; an exposure progresses from smaller to larger.

CLASSIFICATION LIMITATIONS

- *The classification does not note the specific type of mesh:* Use of prostheses other than those with the least morbidity (as described in the Introduction Section) might be further reflected in an increased rate of the healing abnormalities.



Fig. 5. A 47-year-old woman underwent a transoburator tape for USL. At 5 months follow-up, she reported vaginal discharge. Clinically she was febrile at 38°C with a large sling extrusion as depicted. **Classification: 3C T3 S1.**

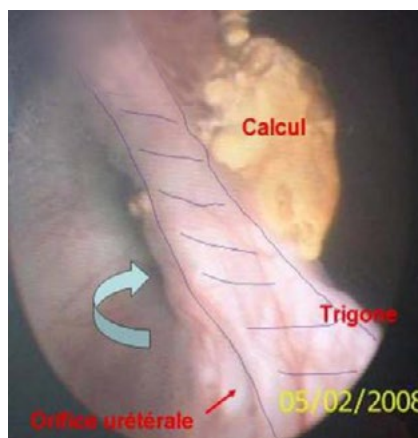


Fig. 6. A 65-year-old woman underwent a transvaginal mesh repair for a grade 3 prolapse. At 32 months, she had recurrent urinary tract infections, urgency and urge incontinence, pelvic pain and deep dyspareunia, bladder pain, and lumbar pain. Radiology: right hydronephrosis and ureteral obstruction. (i) Cystoscopy: mesh extrusion (<0.5 cm) with stone. No right ureteric patency. (ii) Vaginal examination: severe anterior mesh shrinkage and pain during anterior vaginal wall palpation. **Classification: (i) 4C T4 S3; (ii) 1Bc T4 S1.**

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Fig. 7. A 56-year-old woman underwent a posterior vaginal mesh procedure using a trocar. At 3 months, clinical examination confirmed an (i) infected midline 15 mm vaginal mesh exposure together with (ii) a recto-vaginal fistula. There had been mesh penetration of the rectum. **Classification:** (i) 3C T3 S1; (ii) 5B T3 S3.

- **Functional issues** (e.g., voiding dysfunction) are not included: Voiding dysfunction can be defined as abnormally slow (assessed by urine flow rate data) and/or incomplete (assessed by postvoid residual) micturition.¹⁴ Surgical intervention for severe voiding dysfunction, namely urinary retention is included in Section 4B.



Fig. 8. A 62-year-old woman underwent a transobturator anterior vaginal mesh procedure. At 24 months follow up, she reported no vaginal discharge. Clinical examination revealed skin erosion with local inflammation and some discomfort at (trocar) exit point. **Classification:** 6B T4 S3.

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- **Urinary tract infections** have not been included.
- The small risk (about 1 in 2 million) of prion or viral infection associated with a xenograft¹⁵ is not included.
- **Recurrences:** It is claimed that meshes are used to prevent recurrence of pelvic organ prolapse. However, a mesh procedure might fail resulting in a recurrence. This can be either by degradation or local release of sutures, the clinical result being the same. Sometimes local complications can lead to the removal of the mesh, which could further increase the risk for recurrence. However, it should be emphasized that recurrence is not a complication.
- **Intraperitoneal adhesions:** Some procedures involve the use of implant material into the abdomen. As a consequence, intraperitoneal adhesions can arise either on the implant or remotely.
- **Bulking agents:** Complications related to bulking agents including migration are not included.

DISCUSSION

The present classification has been developed to be sensitive to all possible physical complications involving the use of a prosthesis or graft in a female pelvic floor surgical procedure. Both insertion complications (e.g., trocar related) and healing abnormalities are covered. Whilst this creates a large number of possible complication scenarios, appropriate organization has still been possible by category, time and site. The end-point is a code of three letters (4 if *a–e* are used) and three numerals. The addition of the pain subclassification reflects the recognition of the authors that chronic pain, especially if in the higher subclasses (*c–e*), can be amongst the most disabling surgical outcomes from the use of prostheses or grafts in female pelvic floor surgery.

A key advantage of a standardized classification is that all parties involved in female pelvic floor surgery including surgeons, physicians, nurses, allied health professionals, and industry will be referring to the same clinical issue. It is anticipated that a (CTS) codified table of complications will be a necessary part of reports of surgical procedures relevant to this document. Many countries already have national databases for new surgical devices. It is inevitable that there will be more regulation over time for their introduction. With a standardized classification in place, quicker assessment of adverse events will be achieved together with uniform reporting of prosthetic-related complications. Any procedure showing a consistently high rate of complications in a surgical audit would need closer scrutiny and/or possible abandonment. As result of the use of such a classification, in terms of patient care, the principle from the Hippocratic oath, “first, to do no harm” is more likely to be observed.

It is acknowledged that to optimize the coverage of complications, the classification might still appear complex and not immediately mastered. However, as noted in the Introduction Section, we anticipate that the case examples provided below, the color charts and the online ICS-IUGA Complication Classification Calculator (www.icsoffice.org/complication) will ameliorate any initial concerns.

It has been a consensus view of the authors that a formal academic terminology and classification should be completed prior to attempts at further simplification. This otherwise might run the risk of compromising coverage of complications.

TABLE 4. An Example of a *Non-Procedure Specific* Table of Complications Related Directly to the Insertion of Prosthese (Meshes, Implants, Tapes) or Grafts in Female Pelvic Floor Surgery using the Category (C), Time (T) and Site (S) system. The CTS Classification Code is Placed Adjacent to the Description of the Complication. One Might Expect these Tables to be Often Procedure-Specific.

Patient Number	Description of complications	Code	Code
000	Retropubic haematoma following a tape procedure (first 24 hours)	7A/T1/ S3	
111	Persistent thigh pain six weeks after an obturator tape	6B/T2/ S4	
222	Bowel obstruction and 2cm vaginal vault exposure with bleeding 6 months after a mesh sacrocolpopexy	5C/T3/ S5	3B /T3/ S1
333	Mesh fibre exposure (lateral vaginal) in a woman at a 6 week postop review whose partner is describing discomfort with intercourse	1B/T2/ S2	
444	A midline vaginal exposure of mesh (< 1cm) with redness, dyspareunia, discharge 15 months after an anterior colporrhaphy using mesh.	2Cc/T4/S1	
555	Lateral vaginal extrusion with malodorous discharge and a midline rectovaginal fistula 8 months after a posterior vaginal tape	3C/T3/ S2	5B /T3/ S1
666	Intraoperative obturator vessel injury during a transobturator tape procedure requiring major resuscitation	7B/T1/ S3	
777	Persistent intravesical tape / calculus formation / haematuria 2 years after a retropubic tape procedure	4B/T4/ S3	
888	Pelvic abscess presenting 8 days after a mesh sacrocolpopexy complicated by an intraoperative bowel defect (final category). Initial code was 5A/T1/S5	5D/T2/S5	
999	Tender prominent mesh contraction noted 9 months after an anterior mesh repair (no symptoms, husband unwell)	1Bb/T3/S1	
XXX	Persistent postvoid residual of 150mls with recurrent UTI requiring posterior division of suburethral tape 4 months after insertion	4B/T3/S1	

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Developing Evidence-Based Standards for Diagnosis and Management of Lower Urinary Tract or Pelvic Floor Dysfunction

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The International Continence Society (ICS) has a key role in standardizing terminology related to lower urinary tract and pelvic organ dysfunction. The ICS Standardization Steering Committee (SSC) presents the new structure and process by which future ICS Standards will be developed. The new processes aim to meet present-day evidence-based practice requirements, and to foster unbiased, inclusive, and transparent development. For each new ICS Standard, the SSC will oversee a dedicated ad hoc Working Group (WG). Applications to chair or contribute to a WG will be invited from the ICS membership. The SSC will select the Chairperson, and work with him or her to select the WG composition, balanced to represent key disciplines, stakeholders, and regions. Consultants can be invited to contribute to the WG where specific need arises. Every WG will review current knowledge, adhering to evidence-based medicine requirements. Progress reports will be reviewed by the SSC, and amendments recommended, culminating in a first draft. The draft will be offered to the ICS membership and additional relevant experts for comment. Further revision, if needed, will result in a document, which the SSC will submit to the ICS Trustees, as arbiters of whether the document should be adopted as an ICS Standard. The SCC will then coordinate with the WG to ensure that the new ICS Standard is published and disseminated. Implementation strategies, such as education, audit, accreditation, and research initiatives will be linked to the Standards where appropriate. Revisions of ICS Standards will be undertaken to maintain contemporaneous relevance. *NeuroUrol. Urodynam.* 31:621–624, 2012. © 2012 Wiley Periodicals, Inc.

Key words: standards; evidence-based medicine

INTRODUCTION

One of the most recognized activities of the International Continence Society (ICS) has been the publication of standardizations of terminology for diagnosis and testing in functional urology. This work started in 1976, with subsequent updates. The 1988¹ and the 2002² reports, with $\pm 1,000$ and $\pm 2,500$ citations, respectively, are amongst the most widely quoted publications in urology.

There have been two particularly important categories of publication. The first is the standardization of terminology, such as the “Standardization of Terminology of Lower Urinary Tract Function”.² Standardized definitions of key medical terms with international consensus are increasingly needed as analysis and registration in healthcare become ever more automated and communication increasingly global. The establishment of the International Health Terminology Standards Development Organization (IHTSDO; <http://www.ihtsdo.org/index.php?id=502>) signifies the increasing weight attached to the agreed definitions of terminology to describe conditions at a fundamental level in medicine. The second category deals with the provision of guidelines for quality control and improvement of standards, which serve as a benchmark for professional activity, exemplified by the “Good Urodynamic Practice” document.³

ICS standards and standardization have led the way and have been widely accepted. The process by which they have been produced has been based on intensive expert discussion

and consensus with input from the ICS membership, but without inclusion of the published evidence in a systematically weighed and transparent manner. The most recent report, a joint report with the International Urogynecological Association,^{4,5} was developed in a similar manner. Ease of modern electronic communication has allowed more experts to monitor the content of draft editions of newer documents. This has meant that expert opinions were included in a “numerically” more balanced manner. However, no “methods” paragraph was given to explain explicitly how decisions on topics to include were made, nor how evidence and expert opinion were prioritized, included or excluded beyond acknowledgement of the commenting experts in a final paragraph.

Ideally, only “genuine evidence” is included in standards and guidelines. Where genuine evidence is lacking or conflicting, it is preferable that expert opinion is separately added to

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Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

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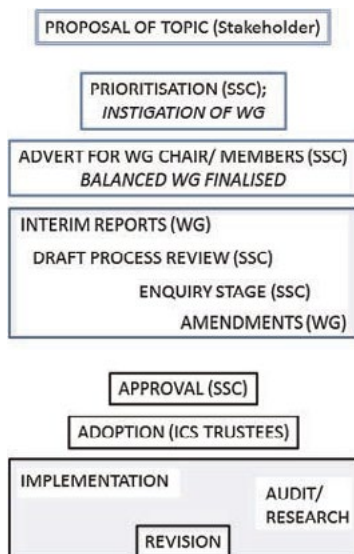


Fig. 1. Summary diagram of the key stages in development of an ICS standard. (SSC, Standardization Steering Committee; WG, Working Group).

recommendations in a transparent and explicit manner. In the mid-eighties a group around David Sackett, a key figure in evidence-based medicine (EBM),⁶ developed a systematic approach to evaluate published evidence, after he analyzed the problem of “observer error” in the interpretation of medical literature.⁷ “EBM is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research”.⁸ Standards to produce evidence-based clinical practice guidelines have been developed,⁹ with guidance manuals.¹⁰

EBM as a strategy to improve healthcare is not disputed, but the implications in a rapidly expanding field of knowledge are

substantial.¹¹ In the modern era of information technology, transparency, accountability, and complex multidisciplinary responsibilities cannot be ignored; expert opinion is only acceptable where evidence is lacking and must be clearly marked and explained as being expert opinion.

The ICS Standardization Committee recognized the importance of adhering to EBM principles. In 2010, a reorganization took place from which the renamed Standardization Steering Committee (SSC) emerged. A key difference between the new SSC and the old Standardization Committee is that the SSC does not itself deliver standardization documents; instead it oversees ad hoc Working Groups (WGs) (see below) which deliver the documents, aiming to ensure transparency, balance, and adherence to the methods and principles of EBM. The SSC Chairman is elected from the ICS membership according to the ICS articles and bylaws. The Chairman and the SSC members serve for a term of 3 years, once renewable.

The ICS SSC aims to ensure ongoing development of high quality terminology and/or practice standards, for guidance of professionals dealing with the basic scientific investigation, diagnosis, and management of lower urinary tract, pelvic floor, genital, and anal function and dysfunction. Developing these standards requires transparency and integrity; the SSC’s process and expectations for modern-day development of some of the most important ICS documents are described below and illustrated in Figure 1.

PROCESS OF DEVELOPING AN ICS STANDARD

Topics selected by the SSC for development or revision of standardization reports will be based on areas of priority need, whether identified by the SSC itself, or in response to stakeholder suggestions. The delivery of a standardization document on a selected topic will be the remit of a specifically created ad hoc WG, which will focus on that specific subject (see Table I). The SSC’s role is to agree the scope of the WG’s activity, instigating and steering activity, checking compliance with suitable working practices, monitoring progress, ensuring adequate stakeholder input and evaluating the end result.

Once the need for a new or revised standard has been identified, the SSC will invite applications from ICS members wishing to chair the relevant WG. The person selected will have submitted the proposal with the best strategy for developing the document in the opinion of the majority of SSC members.

TABLE I. Structure and Function of Standardization Document WG

<p>The composition needs to be multidisciplinary and multinational, representing the most important stakeholders (including, e.g., patient representatives, health economists, and others as appropriate)</p> <p>Non-ICS members can be part of the WG as experts or representatives of specific stakeholders</p> <p>The WG should generally not include more than 15 people</p> <p>Selection of WG members should follow a transparent process, which is recorded and publicly available</p> <p>Additional contributions to a WG’s deliberations can be received from outside individuals</p> <p>The WG should not receive any sponsorship from industry and the members should disclose all relationships</p> <p>All members of the WG will be responsible for the entire content of the document as a group.</p> <p>The WG has a chairman who:</p> <ul style="list-style-type: none"> will propose the key question or topics of discussion to the SSC, together with a strategic plan. will keep a digital working log of the WG activities will make sure that the composition of the WG is well balanced and that the process of standardization is transparent will use web-based and e-mail exchange of information and monitor the execution of assignments within the assigned timeline will adhere to EBM principles, where appropriate will report to the SSC will be responsible for production of a first draft of the report within a stipulated time frame (generally 18 months) will be responsible for submission for publication and dissemination. <p>After publication of the standard, the WG will be dissolved.</p> <p>A typical lifespan for an ad hoc WG will maximally be 36 months. If the WG fails to be productive, the SSC dissolves the WG.</p> <p>The ICS or ICS SSC will not provide financial budget for face-to-face meetings of any ad hoc WG.</p>
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TABLE II. SSC Criteria for Assessing WG Proposals

Title of the project
Name of applicant
Description of the topic: The arguments for creating the WG are: (Explain why one or more of the following arguments is relevant)
area of clinical uncertainty or "debate" exists
evidence of better treatment is available
evidence for renewal of the existing standard is available
evidence of practice variation is available
other clinical or scientific relevance
there is significant controversy in practice or literature
there is conflicting or incomplete evidence
there are cultural differences in practices or viewpoints
there is socio-economic relevance
List of proposed names (with CVs):
confirmation that individuals have agreed to contribute
evidence of multinational and interdisciplinary balance
opportunity for ICS members to apply to join the WG and transparent, documented process for selection
process to register contributions from individuals or groups not in the WG
Description of the methodology and how it will be used:
web-based approach
e-mail
conference calls or webcasts
face-to-face meeting (mainly during ICS international meetings)
proposed timeline
Description of topic, proposed WG composition, likelihood of implementation, likelihood of publication, innovation of approach, realistic timeline, use of electronic tools.

The SSC will evaluate proposals according to key criteria (Table II).

WG Composition

The selected Chairperson will establish a WG of interested and knowledgeable individuals from a multinational and interdisciplinary background, representing all key stakeholder groups. Technical expertise relevant to the WG's remit will be taken into consideration in the selection of members. The WG will also be permitted or asked by the SSC to invite input from outside consultants where this is needed. This will typically be applicable in specialist contexts that are not widely represented within the ICS, such as engineering, computer sciences, or data handling. It may also be relevant in other fields, such as consumer perspectives, or economic issues, for example.

TABLE III. Development of an ICS Standard

	Timescale (months)	WG	SSC
Proposal stage	-6 to 0	Applications for Chairmanship or membership.	Call for applications. Review subject, Chair, Group, criteria, timeline and starting date.
Preparatory stage	0 to 18	WG constituted. Development of draft.	Evaluate progress. Appoint mentor. Evaluation (at least every 6 months).
Committee stage	18 to 21	Draft submitted to SSC.	Review of the process and document against criteria. Approval by consensus.
Enquiry stage	21 to 24	Draft on ICS website.	Internal and external review. Comments by ICS members and stakeholders.
Approval stage	24 to 27	Submit final document to SSC.	Process review. Submission to ICS Board of Trustees.
Publication	27 to 36	Final text to ICS office for web publication. Journal submissions.	Official ICS document. WG dissolved.
Implementation stage	>36		Support implementation. Education (with ICS Education Committee). Register of comments. Identify research needs. Support health technology and economic assessment.
Revision stage		Submit proposal to SSC.	Start new process.

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The SSC will ensure a transparent process for selection of WG members, and will evaluate and adapt the composition to ensure a balance between different viewpoints (professional, patient, and other stakeholders' perspectives). Once agreed, the proposal and the names of the WG's members will be published on the ICS website. If a member of the SSC is also a member of a WG, he/she will not be included in SSC decisions related to that particular WG. All (potential) conflicts of interest will be published on the ICS website.

Stages of a Standard

Stages through which a standardization document will progress are summarized in Table III. These will be listed in the project management-working log of the WG and the Chairperson of the WG should report progress to the SSC. The SSC will provide a mentor for the WG, who will evaluate the progress at least every 6 months and be available if any problems arise. The mentor will keep a log of these contacts.

Preparation of a Draft Report

The WG will prepare successive working drafts, circulating the drafts, and amending according to comments, until the group is satisfied that it has developed the best solution for the subject being addressed. Standards should adhere to EBM principles, where appropriate and possible. At an early stage, therefore, the WG has to devise a strategy for a comprehensive review of published literature and use an inclusive and transparent approach to derivation of expert opinion. It might sometimes be necessary to use the Delphi method.^{1,2} Each WG will ensure a strategy for capturing and assimilating the views of all groups of stakeholders and criteria for inclusion or exclusion of these views in the finished document.

Throughout, the WG's Chairperson is responsible for:

- keeping a digital log of the WG's activities
- documenting the methods that were used to produce the draft document
- promoting web-based and e-mail exchange of information and monitoring the execution of assignments within the agreed timeline
- reporting to the SSC
- producing a first draft of the report within 18 months.

Committee Stage (Assessing the Process of Standardization)

As soon as a draft is available, the Chairperson of the SSC will forward it to all the members of the SSC for internal process review. The process by which the draft standard was created will be evaluated according to preset criteria. The document requires SSC approval prior to progressing to the next stage of development. The SSC may require revisions or amendments which will need to be undertaken by the WG in a defined time frame. A document that fails to meet the objectives or was not developed in accordance with the appropriate approach will be rejected, and the WG will be dissolved.

Enquiry Stage (Wider Assessment of the Content of the Document)

The actual assessment of the content of the document will be undertaken by internal and external experts (invited by the SSC) and the ICS membership. The draft standard will be circulated to all members by website publication for commenting over a period of 3 months.

Approval Stage

The WG should resubmit the final version based on the comments received. Explicit criteria for the inclusion or exclusion of comments should be developed and each comment should be accompanied by a narrative explaining the reason why it was either included in or excluded from the final version. All comments and accompanying narrative will be published on the relevant document web forum. The revised version should be resubmitted to the SSC for process review and assessment of the amendments. If approved, the document and the log of the development process will be sent to the ICS Board of Trustees for confirmation and adoption.

Publication

Once the Board has confirmed and adopted the document and the process, the final text will be published on the ICS website and will then be referred to as the new ICS Standard, superseding previous Standards. Thus, the new report must outline where it differs from previous reports. The WG will be encouraged to submit the document as an ICS Standard to *Neurourology and Urodynamics*, and the SSC will advise in this process. Co-publication with other journals can be considered if relevant, within copyright regulations. Publication of the respective ICS Standard will conclude the WG's activities.

Implementation Stage

The ICS SSC will promote implementation of the standards by publication, dissemination and education, and the proposing of new standards to its affiliate and collaborating societies and organizations. Additionally, the SSC will monitor the undertaking of clinical audit based on the ICS Standards' recommendations as a key aspect of successful introduction of the documents into mainstream practice,¹³ and the undertaking of the research and development necessary for ongoing development of the evidence base.

Standards will be written in UK English. Translation into other languages will be supported; for terminology standards, this will require that appropriate linguistic validation procedures are followed (for an example of the application of linguistic validation in the context of translation of symptom assessment tools, see Acquadro et al., 2006).

Revision of Standards

The ICS SSC will also keep track of comments that are received for consideration during a future revision of the standard text, as well as identifying future research needs. A revision or update can be proposed by the SSC or any ICS member or group of ICS members when there is a perceived need, and the timescale for anticipated revision of a standard will be specified at the time of adoption—subject to future developments in the field. The SSC can discuss not to revise outdated documents and declare them obsolete.

CONCLUSIONS

In developing evidence-based standardization documents, the ICS SSC aims to ensure inclusiveness, responsiveness, transparency, accessibility, flexibility, and evolution. The ICS SSC presents a structured process for ad hoc WGs to develop ICS standards, and a strategy to guide that process. Consequently, each WG will be responsible for several stages of development, each clearly documented, until a high quality document has been approved as an ICS standard.

The presented structure and strategy place emphasis on the principles of EBM and transparency in the development of ICS standards. They also provide the flexibility necessary for the varied nature of the initiatives established by the ICS, where multiple stakeholders are generally present, and also circumstances in which the evidence base may be limited. ICS standards will continue to be adopted and promoted as the basis for good professional practice, suitable for the demands of the modern era of EBM.

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2. FUNDAMENTALS

The Fundamentals of Assessment articles are commissioned by the ICS Board of Trustees, setting out the core knowledge for any practitioner needing to assess lower urinary tract dysfunction (LUTD) in their clinical work. The documents aim to give a solid knowledge basis for several different aspects of LUTD, suitable for trainees, allied health professionals, and people working in related disciplines like neurology, primary care, and care of the elderly. They describe what any practitioner really must know for everyday practice, and provide examples, covering;

- Urinary symptoms in general.
- Specific patient groups: nocturia; neurological disease; chronic pelvic pain
- Pelvic organ prolapse quantification
- Urodynamic tests: flow rate testing; urodynamics; videourodynamics
- The relevance of Standardisation

As well as a knowledge base, the Fundamentals are a starting point for the ICS Standardisations, which are the basis of specialist practice in LUTD in substantial detail.



Marcus Drake
ICS Trustee

Neurourology AND Urodynamics

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T A B L E O F C O N T E N T S

EDITORIAL COMMENT

S6 Editorial Comment

Sherif Mourad, Roger Dmochowski, and Marcus Drake

SOUNDING BOARD

S7 A Commentary on Expectations of Healthcare Professionals When Applying the International Continence Society Standards to Basic Assessment of Lower Urinary Tract Function

Marcus J. Drake and Paul Abrams

S13 Fundamentals of Terminology in Lower Urinary Tract Function

Marcus J. Drake

S20 Basic Concepts in Nocturia, Based on International Continence Society Standards in Nocturnal Lower Urinary Tract Function

Hashim Hashim and Marcus J. Drake

S25 Neurological Lower Urinary Tract Dysfunction Essential Terminology

Jerzy B. Gajewski and Marcus J. Drake

S32 The Fundamentals of Chronic Pelvic Pain Assessment, Based on International Continence Society Recommendations

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S39 How to Use the Pelvic Organ Prolapse Quantification (POP-Q) System?

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Andrew Gammie and Marcus J. Drake

S50 Fundamentals of Urodynamic Practice, Based on International Continence Society Good Urodynamic Practices Recommendations

Marcus J. Drake, Stergios K. Doumouchtsis, Hashim Hashim, and Andrew Gammie

S61 Basics of Videourodynamics for Adult Patients With Lower Urinary Tract Dysfunction

Michel Wyndaele and Peter F. W. M. Rosier

T A B L E O F C O N T E N T S

EDITORIAL COMMENT

S67 Why ICS Standardization of Lower Urinary Tract Symptoms Matters

Dirk De Ridder and Marcus Drake

SOUNDING BOARD

S69 Critical Steps in Developing Professional Standards for the International Continence Society

Peter F. W. M. Rosier

The International Continence Society (ICS) Board of Trustees is glad to present a special supplement of *Neurourology and Urodynamics* which sets out the core knowledge for any practitioner needing to assess lower urinary tract dysfunction (LUTD) in their clinical work. The material will be useful to trainees, allied health professionals, and people working in related disciplines like neurology, primary care, and care of the elderly. The documents are written in a simplified way to offer a helpful source of education and knowledge of several different aspects of LUTD.

A significant motivation for this effort is the need to be concise, explicit, and definitionally correct when using a common lexicon, as with the ICS Standardization documents, that govern the manner in which professionals in our field define their research and report results thereof. A sequence of documents is included which covers;

- Urinary symptoms in general, and in specific patient groups (nocturia; neurological disease; chronic pelvic pain)
- Pelvic organ prolapse quantification
- Urodynamic tests (flow rate testing; filling cystometry with pressure flow studies; videourodynamics)
- The importance of standardization and how the ICS Standards are developed

The knowledge base is drawn from the ICS Standards, which constitute the basis of specialist practice in LUTD, supplemented by practical application. The authors were

asked to write succinct and approachable documents, describing what they feel any practitioner really must know for everyday practice, and providing examples. Thus, these documents are derivatives of the many reports and publications that represent the ICS Standards but are not in themselves ICS Standardization documents. Inevitably, the choice of content is subjective, but each document seeks to offer simplicity and clarity. For those working to become specialists in the area, this supplement is a starting point for getting to grips with the comprehensive repository of detailed professional consensus documents established by the ICS over the course of several decades and available on the ICS website (<https://www.ics.org/folder/189>).

A significant aspect of the knowledge transfer is the education of those who are students or early career clinicians and investigators. Thus, the supplement aims to facilitate clarity, accuracy, and specificity of reports in the fields of urodynamics, neurourology, pelvic floor disorders, and urogenital reconstruction. Health care practitioners and clinicians will benefit from these documents, which give a brief review of those subjects related to LUT dysfunction, and as their knowledge grows, we hope they will feel enthused to engage with the full ICS Standards.

Sherif Mourad
Roger Dmochowski
Marcus Drake

A commentary on expectations of healthcare professionals when applying the international continence society standards to basic assessment of lower urinary tract function

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The Continence Society (ICS) has sustained a drive to improve the clinical assessment of lower urinary tract function for many years. Increasingly, healthcare professionals (HCPs) engage with the guidance, and patients benefit from the precision that results when their carers apply a sensible and logical approach to assessment. The current supplementary issue of *Neurourology and Urodynamics* (NAU) summarizes the fundamentals derived from major ICS initiatives, emphasizing what HCPs must know when dealing with these patients, regardless of the medical discipline in which they work. It also introduces the basics of urodynamics testing to trainees and HCPs who may refer patients for testing. In this editorial review we draw out some additional points of consideration. We emphasize the need to avoid using terms in a clinical context that could imply causative mechanism, until the mechanism has actually been identified. We caution against the use of severity thresholds, until there is proper data to justify their application for any given patient group. Finally, we provide a description of the philosophical basis of urodynamics testing, including videourodynamics. This commentary should be read in the context of the other articles provided in the NAU supplement.

KEY WORDS

LUTS, overactive bladder, standardization, urodynamics

1 | INTRODUCTION

LUTD is encountered in some form by a wide range of healthcare practitioners (HCPs), notably medical, nursing, and allied professionals working in Primary Care, Gerontology and Neurology. For these, awareness of a fundamental knowledge base should include the correct use of the terminology for lower urinary tract symptoms (LUTS), and the relevant signs and urodynamic observations. Likewise, residents in urology and gynaecology need to appreciate the fundamentals of LUTS and lower urinary tract dysfunction (LUTD), as a stepping stone for the more

detailed knowledge used in specialist practice. The International Continence Society (ICS) has developed standards which set the specialist terminology and diagnostic methodology in great precision for the full scope of practice in LUTD with considerable detail as needed by specialists in the area. These documents produced by the Standardization Steering Committee and other ICS Committees meet the needs of specialists, and professionals who have mastered the fundamentals and who are strongly encouraged to engage with the full standards.

The ICS approach is founded on the importance of logical and clear-thinking clinical diagnosis and therapy selection,

Dr. Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

making sure that treatment options are specifically matched to the individual patient. Well-worded terminology has steadily evolved over the years to make sure that it is suited to the potential presentations. Standards for testing in Urodynamics have been refined to give practitioners the best chance to identify abnormalities in their patients and interpret the features appropriately. This supplement of Neurourology and Urodynamics was commissioned by the Trustees of the ICS to introduce a new generation of residents and recently appointed consultants to the important work of standardization in functional urology. It aims to set out and exemplify the fundamentals as a starting point to engaging with the ICS Standards. Experts have been asked to extract pertinent aspects from some of the most widely used Standards, to facilitate awareness of key points in LUTS, nocturia, neuro-urology, chronic pelvic pain, pelvic organ prolapse quantification, flow rate testing, urodynamics, and videourodynamics.

2 | LOWER URINARY TRACT FUNCTION

The description of lower urinary tract function breaks it down into symptoms, signs, and urodynamic observations. The terminology is phrased to ensure that patients and doctors can align their discussions appropriately. A key requirement is to ensure that the words HCPs use do not imply a mechanism without good justification. In male patients, words or phrases like “obstructive,” “prostatism,” or “prostate symptom score” insinuate that the mechanism of symptoms is already known, and caused by the prostate. Yet it is wrong to imply this at the start of the patient’s assessment; it innately biases the doctor (and sometimes the patient) to expect therapy aimed at relieving obstruction and dealing with the prostate. That may come later, but only once other causes which can lead to very similar symptoms have been excluded. Weak or slow stream may be due to the prostate and the possibility of an underactive detrusor being the cause must also be considered. Likewise, “irritative” is not appropriate, given that there is generally no evidence for irritation in the context of storage LUTS. Fundamentally, the potential to misrepresent mechanism by careless use of terminology needs to be avoided.

Two areas where clinicians can get a little bit muddled by terminology are frequency and overactivity. “Frequency” indicates how often a person passes urine in a given time period, so it is a sign. “Increased daytime frequency” indicates that the patient feels he or she voids too often by day, so it is the correct phrase to describe a symptom reported by a patient. The word “Overactivity” is used in two terms: firstly, it is used in the context of overactive bladder (OAB), which is a symptom syndrome, and by its definition, everyone with OAB experiences urinary urgency. Secondly, detrusor overactivity (DO), is a urodynamic observation of a bladder contraction during filling, which is usually, but not always,

associated with urgency. Therefore, DO and OAB are not interchangeable terms.

The categorization of LUTS relates the timing of the symptom to the micturition cycle, hence storage LUTS, voiding LUTS, and LUTS happening straight after voiding has finished (post-micturition symptoms). Many individuals present with several LUTS, and these can be grouped into symptom syndromes. OAB is one, in which storage LUTS are principal features. Underactive bladder (UAB) is another, in which voiding LUTS are prominent. Because OAB and UAB occur mainly in the storage and voiding phases, respectively, it is perfectly possible for one person to have both overactive and underactive symptoms, that may or may not be shown by urodynamics to be due to DO and detrusor underactivity (DU).

3 | SEVERITY THRESHOLDS

The HCPs need to be careful in setting thresholds to “qualify” someone as having symptoms (eg, not counting someone as having nocturia because they only get up once per night to pass urine). Unfortunately, there is only limited robust evidence to warrant thresholds. Furthermore, quantifying the significance of symptoms can be difficult as symptoms are subjective, and may vary a lot from day to day, so even a 3 day observation period of a bladder diary may not capture the full story. Furthermore there is considerable variation from person to person, so values are difficult to compare. Thus the ICS emphasises the need to distinguish a symptom’s frequency from the impact on quality of life and bother it brings, as they are not necessarily correlated. For example, many men report a relatively severe level of slow stream, but do not describe themselves as particularly bothered by it. In contrast, symptoms like urgency and post micturition dribble can be highly bothersome even if severity appears relatively mild to the impartial observer. For nocturia, people who generally experience a single episode on average each night should be cataloged as having nocturia; it will be non-bothersome for many patients, but that does not mean nocturia is absent.

In practice, it seems reasonable to suggest;

- A symptom is important if the patient says it is bothersome. For example, the symptom of increased daytime frequency (the complaint by the patient who considers that he/she voids too often by day¹) is very much dependent on the patient’s attitude, and there is a large variation in what patients consider intrusive.
- A symptom or sign is important if it can explain mechanism or identify disease. For example, nocturia (**symptom**: the complaint that the individual has to wake at night one or more times to void; **sign**: the number of times an individual passes urine during their main sleep period¹) may be non-bothersome to the patient if they only void once per night,

but it might identify the early stages of a systemic medical condition, such as chronic kidney disease, needing diagnosis and therapy.²

- All urodynamic observations should be noted, as they may explain symptoms or signs, and guide treatment selection. The urodynamic observation of detrusor overactivity (involuntary detrusor contractions during the filling phase) should be noted, even if the contraction is only very low amplitude.

4 | FUNDAMENTALS OF URODYNAMIC PRACTICE

Practitioners must show due consideration to their patients. It is important that staff recognize that somebody attending to do a flow rate test may be a patient experiencing urgency in their day to day life, so it is not appropriate to demand of them that they must pass a minimum voided volume of 150 mL, if they say that they are desperate to go! Furthermore, it is not appropriate to load somebody with very large volumes of liquid in an attempt to try to make them pass urine a bit more quickly for the convenience of the flow rate clinic. This is an unrealistic expectation, and is often detrimental to reliable voiding behavior. For filling cystometry and pressure flow studies, patients are apprehensive about undertaking a test in which their urethra and anus are going to be cannulated. People may feel the whole process is very undignified and compassionate handling by staff is essential. Patients are much more satisfied after urodynamics if they received an information leaflet before they come for their tests.

In flow rate testing, some key points are;

- Calibrate the equipment for reliable results.

- Ask the patient to complete a 3 day bladder diary in advance.
- Provide a suitable environment for testing (a place to wait, rapid access to the meter when needing to pass urine, privacy, a hygienic setting).
- Validate that the voided volume is representative, by comparing with the bladder diary.
- Check that bladder volume at the start of voiding (derived by adding voided volume and post void residual) is in a suitable range (150-500 mL).
- Identify key artefacts; knock, squeeze, and release, to ensure the values reported are indicative of the patient rather than an artefact.

Some basic principles are important for urodynamic units;

1. A urodynamic unit must follow the appropriate instructions given by the equipment manufacturers, and practitioners should calibrate and check their equipment regularly. All staff must be trained and properly supported by experienced clinicians.
2. Before a test, each patient's symptoms should be fully understood, with a symptom score and bladder diary completed. Ideally, potential treatment options should be considered before the test by the referring clinician, who has already discussed them with the patient. Thereby, the test can be done so as to help select the treatment, based on chance of success and identification of potential adverse outcome.
3. When running a test, the pressure traces should be scrutinized throughout the study to be confident recordings are genuinely picking up the pressures. This requires looking to see that the bladder and abdominal pressure lines detect breathing and movement similarly, and that

TABLE 1 Contents of a urodynamics report proposed in the UK continence society (UKCS) minimum standards for urodynamics³

UKCS recommendation	Possible urodynamic observations
Record of the urodynamic findings during filling, whether normal or abnormal	
Detrusor function during filling	Normal/detrusor overactivity
Urethral function during filling	Competent/incompetent
Bladder and urethral sensation	<ul style="list-style-type: none"> • At what volume did the patient report FSF, NDV and SDV? • Did they experience urgency?
Bladder capacity	Report volume
Record of the urodynamic findings during voiding, whether normal or abnormal	
Detrusor function during voiding	Normal/underactive or acontractile
Urethral function during voiding	Normal/obstructed
Post void residual	Report volume
Statement on whether the patient's everyday symptoms were reproduced ^a	

FSF: first sensation of filling; NDV: normal desire to void; SDV: strong desire to void?

^aThe report should document whether the patient's everyday symptoms were fully reproduced/ partly reproduced/ not reproduced.

coughs are done throughout filling, plus before and after voiding to monitor trace quality.

- a) Regular labels must be applied during the study; these annotations will help anyone not present at the study to interpret the findings later on.
- b) The “zero” button is a software button which drops the vesical and abdominal pressure lines onto zero. This must only be clicked when recording from atmosphere, not when the transducers are connected to the patient—this is a common mistake.

4. After the test, the trace must be scrutinized to make sure that crucial pressure and flow values are genuinely indicative of the patient's urinary tract function. High pressures caused by knocking the equipment, or low pressures because a tube got blocked, must be identified, corrected if possible, and interpreted accordingly. Urodynamic machines and software are not reliably able to identify artefacts with current technology. Key parameters such as maximum flow rate, bladder outlet obstruction (BOO) index or bladder contractility index

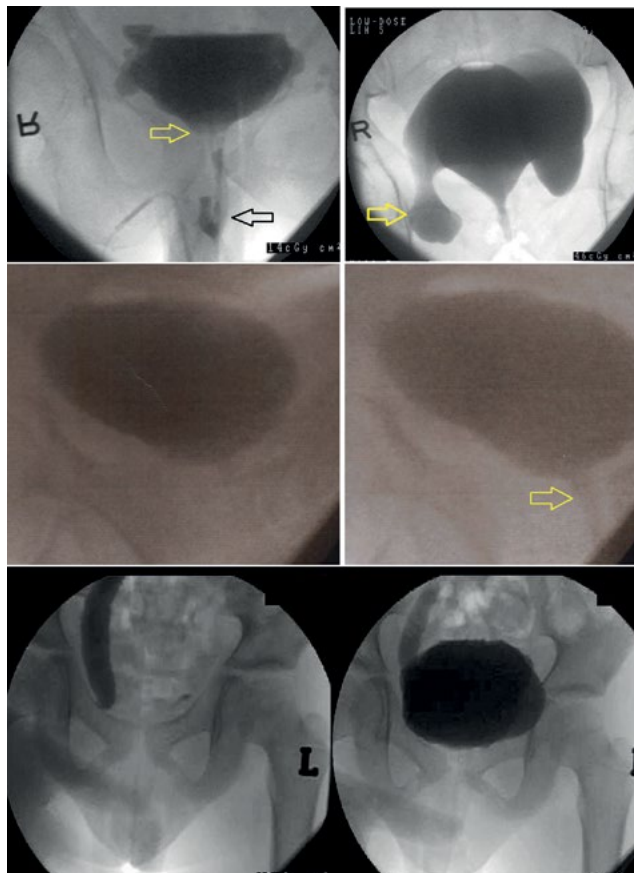


FIGURE 1 Additional information with radiological imaging during urodynamics. Top left; identifying the site of BOO in a man with Parkinson's disease. In this case, the obstruction is at the bladder neck (yellow upper arrow). This man also had significant pooling in the bulbar urethra (black lower arrow), which caused post micturition dribble. Top right; a man with large bladder diverticula, the one on the right entering an inguinal hernia (arrow). These diverticula made it very difficult to measure bladder pressure. Middle pictures; a man with prior transurethral resection of the prostate (TURP) whose presenting complaint was urgency. He did not have detrusor overactivity. During filling cystometry, contrast was not present in the proximal urethra to begin with (middle left image), but it was seen to enter the urethra (arrow, middle right) synchronous with the patient's report of urgency, which was the typical sensation of his presentation. Lower pictures; images taken at the end of voiding in a boy with vesico-ureteric reflux. The left hand image confirmed bladder emptying was complete. The right hand image was taken 30 s later, and a lot of contrast had re-entered the bladder— a “pseudo-residual.” If this patient had been studied with a bladder scanner instead of videourodynamics, a post void residual might wrongly have been presumed

may be reported by a urodynamic machine, but practitioners must check the source traces for plausibility, noting any spikes which the machine may inappropriately have used for deriving those parameters, and moving the cursors to instruct the machine where the values can be taken.

The final report must be carefully phrased, describing whether symptoms reported by the patient were actually encountered during the test, and what was the urodynamic observation at that time (Table 1). Of course, certain symptoms simply cannot be reproduced during a urodynamic test—obvious examples being nocturia, nocturnal enuresis, and coital incontinence. For these symptoms, observations made during urodynamics must not be claimed as the cause of the symptom. The “only report what you see” approach is crucial for safer consideration to making treatment recommendations.

5 | VIDEOURODYNAMICS

Conventional urodynamic tests principally can be used if there is a relatively evident underlying mechanism. The main situations are;

- Post-obstetric stress incontinence in a healthy woman, where urethral hypermobility has been identified on physical examination.
- Voiding LUTS in a man in the right age range, where benign prostate enlargement is identified on rectal examination.

For these individuals, the underlying mechanism can be assumed with reasonable confidence. Thus, if stress urinary incontinence is seen in the first situation, the hypermobility is probably the cause. In the second, if BOO is seen, the prostate enlargement is probably the cause. However, many other presentations throw up more complex possibilities and a range of causes should be considered. Using X-ray contrast as the urodynamic filling medium, and taking images at key moments during the tests (“videourodynamics”) allows greater confidence when deciding what mechanism(s) are present, and potentially linking them to symptoms. The additional information that X-ray screening can achieve includes;

1. Instantaneous detection of leakage.
 - a) If there is delay for the leakage reaching the flow meter, for example, in men with post prostatectomy incontinence due to sphincter damage.
 - b) When evaluating leak point pressures in a patient with neurological disease.

This precision on identifying timing of leakage allows the urodynamicist to know the detrusor pressure at the precise moment when it matters.

2. Identifying the exact location of bladder outlet obstruction; bladder neck (Figure 1a), prostate, urethral sphincter/pelvic floor, stricture. This can be very valuable for establishing the cause of BOO, and hence deciding on treatment.
3. Detecting muscle function deficits in patients with neurological disease.
 - a) An open bladder neck may indicate a deficit in sympathetic innervation.
 - b) A poorly supported bladder base and proximal urethra, which can be seen to descend on straining, may be due to pelvic floor weakness and may reflect muscle denervation in men, or women with no obstetric history.
4. Explaining difficulty in detecting expected increased pressure change, due to dispersal into a low pressure region.
 - a) A large bladder diverticulum (Figure 1b).
 - b) Significant vesico-ureteric reflux (VUR).
5. Identifying VUR in its early stages; potentially it may be possible to treat early VUR with a bulking injection of the ureteric orifice.
6. Correlating a patient's reported urgency sensation with urine entering the proximal urethra (Figure 1c); this might help explain why some people with urgency do not gain benefit from medical therapy of OAB.
7. Demonstrating whether the bladder empties fully; a well-timed X-ray taken at the exact end of voiding confirms whether the bladder has emptied fully. This is more accurate than bladder scanning, since the scanner takes a while to get in position, during which time people with VUR may have had enough liquid come back in to the bladder to show up on a scanner— a “pseudo-residual” (Figure 1d).
8. Identifying pooling in patients with post micturition dribbling.
 - a) Pooling in the male urethral bulb (Figure 1a).
 - b) Vaginal pooling.

6 | CONCLUSIONS

The ICS has pushed a logical and systematic approach to terminology and assessment in lower urinary tract function. In the current review we emphasize the importance of being specific with the language used, the need to justify severity thresholds, the philosophy underlying urodynamic testing and the potential benefits of videourodynamics in patients whose underlying pathophysiology is potentially complex.

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Fundamentals of terminology in lower urinary tract function

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Aims: To summarize basic definitions in the International Continence Society (ICS) Standardization of Terminology in lower urinary tract (LUT) function and their application.

Methods: Fundamental terminology in the ICS Standardization of Terminology LUT Function was identified and summarized.

Results: Evaluation of LUT requires appreciation of symptoms, signs and urodynamic observations. Symptoms are categorized according to their occurrence during the micturition cycle into storage symptoms (eg, increased daytime frequency [IDF], urgency, nocturia, or incontinence) or voiding and post-voiding symptoms (eg, slow stream or post micturition dribbling). Several problems may be present, giving rise to symptom syndromes, notably overactive bladder (during the storage phase) or underactive bladder (during the voiding phase). Signs may be derived from a bladder diary or may be elicited on physical examination. Urodynamic observations may be made by assessing flow rate, and this is combined with pressure measurement when undertaking filling cystometry and pressure flow studies. Key elements of flow and pressure measurement are described.

Conclusions: The review provides a succinct summary of symptoms, signs, and urodynamic observations as set out in the ICS Standard on LUT Function.

KEY WORDS

LUTS, overactive bladder, standardization, urodynamics

1 | INTRODUCTION

The International Continence Society (ICS) has for many years led the development of standardized definitions of the symptoms, signs, urodynamic observations, and conditions associated with lower urinary tract dysfunction (LUTD). The current document is a summary of core terminology related to LUTD for use in a general medical context. For example, LUTD is commonly encountered by healthcare professionals working in gerontology, neurology, and nephrology. The terminology is also useful for residents in urology or gynaecology preparing for examinations. This document is not intended for subspecialists working in functional urology,

urogynaecology, and neuro-urology, for whom the ICS has developed a range of standardizations (see www.ics.org). These cover the full scope terms in different contexts and patient groups for use in subspecialty research and clinical practice, which are beyond the scope of the current review.

2 | METHODS

Recommendations in the ICS Standard on LUTD¹ were reviewed and summarized, this document being selected as the terminology is applicable to all patients regardless of gender. Definitions of nocturia,² underactive bladder,³ and pelvic organ

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

prolapse (POP)⁴ are those given in subsequent context-specific ICS consultations or documents. Definitions and key terms are generally transcribed verbatim. In the original document, many of the definitions are accompanied by explanatory or exemplary footnotes. The footnotes have been adapted (non-verbatim) in certain cases for the current review, or have been excluded for the sake of brevity, and additional explanatory text is included. Readers should note that in urogynaecology practice, some terms have been updated in the International Urogynecology Association/ICS joint report on the terminology for female pelvic floor dysfunction,⁴ where there is some divergence from the reported definitions in the current review. Accordingly, users are advised to specify the source of the definitions they employ when publishing in the area.

3 | LOWER URINARY TRACT SYMPTOMS

Normal lower urinary tract (LUT) function relies on the facility for storage of urine in the bladder, and the ability to pass urine (voiding) at a time to suit the individual. The alternation between these two modes of storage and voiding is known as the micturition cycle (Figure 1). Lower urinary tract symptoms (LUTS) are categorized according to the time at which they are experienced in relation to the micturition cycle;

1. Storage symptoms

- a) Increased daytime frequency (IDF) is the complaint by the patient who considers that he/she voids too often by day.¹ There is no minimum voiding frequency serving as a threshold for the symptom, since it is highly subjective, and there is a wide overlap between normal and symptomatic.



FIGURE 1 The micturition cycle as anchor for categorizing LUTS. Each individual person stores urine until they make an active decision to switch to voiding in response to a sensation or a social reason (eg, anticipation that toilets will be difficult to access in the foreseeable future as a result of a meeting or journey, or when going to bed for sleep). Once voiding is complete, storage mode is re-established. Voiding occupies only a very small part of the cycle (eg, if frequency is six times daily, and duration of each void is 20 s, then only 2 min of 24 h may be in voiding mode). NDV, normal desire to void; SDV, strong desire to void

- b) Nocturia is waking at night to pass urine.² If a person typically passes urine once per night, they should be documented as having nocturia even if it does not cause them impairment of quality of life.

“Day” and “night” for IDF and nocturia refer to the patient’s sleeping pattern, not environmental daylight and night-time.

These symptoms are strongly influenced by fluid intake, and healthcare practitioners need to factor in whether the symptom reflects LUTD, or rather a physiological mechanism dealing with excessive intake of free water or salt, or a pathological consequence of a systemic medical condition (eg, chronic kidney disease).⁵

- c) Urgency is the complaint of a sudden compelling desire to pass urine which is difficult to defer.¹
- d) Urinary incontinence is the complaint of any involuntary leakage of urine.¹

Incontinence is subclassified according to the circumstances most typically eliciting the problem

- (i) Urgency urinary incontinence is the complaint of involuntary leakage accompanied by or immediately preceded by urgency.
- (ii) Stress urinary incontinence is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.
- (iii) Mixed urinary incontinence is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing.

2. Voiding and post-voiding symptoms

Voiding symptoms

- a) Hesitancy is the term used when an individual describes difficulty in initiating micturition resulting in a delay in the onset of voiding after the individual is ready to pass urine.¹
- b) Slow stream is reported by the individual as his or her perception of reduced urine flow, usually compared to previous performance or in comparison to others.¹
- c) Intermittency is the term used when the individual describes urine flow which stops and starts, on one or more occasions, during micturition.¹

In addition, a person may report splitting of the stream, or spraying. They may also describe straining to void, which is muscular effort used to either initiate, maintain, or improve the urinary stream.

Post-voiding symptoms are experienced immediately after voiding.

- d) Feeling of incomplete emptying is experienced by the individual after passing urine.¹

- e) Post-micturition dribble describes the involuntary loss of urine immediately after an individual has finished passing urine.¹

All these symptoms may vary considerably over time, even fluctuating on successive days. The healthcare professional needs to take into account this variability, and clarify with the patient how often each symptom may be experienced to try to build a representative picture. Likewise, the presence of a symptom (severity) does not always lead to impact on quality of life (bother), and healthcare professionals should consider both severity and bother for a complete evaluation of LUTS.

3.1 | Symptom syndromes

Initial management may rely on empirical diagnoses applied after clinical assessment of a patient's LUTS, combined with basic investigations, such as urinalysis. These may be used for the purposes of applying initial conservative management, and do not rely on invasive urodynamic observations.

1. Overactive bladder syndrome (OAB) is characterized by urinary urgency, with or without urgency urinary incontinence, usually with IDF and nocturia, if there is no proven infection or other obvious pathology.⁶
2. Underactive bladder syndrome (UAB) is characterized by a slow urinary stream, hesitancy, and straining to void, with or without a feeling of incomplete bladder emptying sometimes with storage symptoms.³

OAB is applicable during the storage phase of the micturition cycle, and UAB during the voiding phase, so it is possible for one individual to manifest both symptom syndromes.

4 | SIGNS SUGGESTIVE OF LOWER URINARY TRACT DYSFUNCTION

4.1 | Voiding frequency

Frequency refers to the number of voids observed in a defined time period¹; it is not a symptom (ie, it should not be confused with IDF). The frequency of voiding is generally identified by asking the patient to complete a record;

1. A micturition time chart, which records only the times of micturitions for at least 24 h.
2. A frequency volume chart (FVC), which also records the volumes voided, as well as the time of each micturition, day and night, for at least 24 h.
3. A bladder diary: this records the times of micturitions and voided volumes (VV), and additional information

appropriate for the individual being evaluated. It could include incontinence episodes, pad usage, fluid intake, the degree of urgency, and the degree of incontinence.

Three-day recordings are generally used in clinical practice. Any of these charts make it possible to identify 24-h frequency of voiding; provided the waking and sleeping times are marked, this can be broken down into the daytime frequency and nocturia (Figure 2). The sign of nocturia is the number of times an individual passes urine during their main sleep period.² Polyuria is the measured production of more than 2.8 L of urine in 24 h in adults.¹ Nocturnal polyuria is present when an increased proportion of the 24-h output occurs at night. If polyuria or nocturnal polyuria is present, the observation of a high voiding frequency may reflect a cause other than LUTD (eg, systemic illness or behavioral factors such as a high fluid intake).

A diary that includes fluid intake and urine output measurement generally shows the former exceeds the latter each day, but on some days there can be a discrepancy (as seen on the totals for the second day in Figure 2). Such discrepancies generally even out if the diary is completed over a longer time. Alternatively, they may suggest inaccurate completion of the diary, or inability to measure the liquid content of the person's food intake.

4.2 | Physical examination

In LUTD, examination should cover abdominal, pelvic, and perineal examination. In general, a focused neurological examination is needed, and this will be more extensive for patients with possible neurogenic LUTD.⁷

1. Urinary incontinence (the sign) is urine leakage seen during examination.¹
 - a) Stress urinary incontinence is the observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing
 - b) Extra-urethral incontinence is the observation of urine leakage through channels other than the urethra.
2. POP is the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix), or the apex of the vagina (vaginal vault or cuff scar after hysterectomy).⁴ The presence of any such sign should be correlated with relevant POP symptoms. More commonly, this correlation would occur at the level of the hymen or beyond.⁴
3. Pelvic floor muscle function can be qualitatively evaluated according to the tone at rest, and the strength of a voluntary or reflex contraction.¹ Strength, duration, displacement, and repeatability should be considered. It may be reported qualitatively as strong, weak, or absent, and there are validated grading systems.

DAY 1 DATE					DAY 2 DATE					DAY 3 DATE				
Time	Drinks	Urine output (ml)	Bladder sensation	Pads	Time	Drinks	Urine output (ml)	Bladder sensation	Pads	Time	Drinks	Urine output (ml)	Bladder sensation	Pads
	Amount	Type				Amount	Type				Amount	Type		
6am	Woke	250 tea	400	1	6am	Woke	250 tea	450	1	6am	Woke	250 tea		
8am		300 water			8am		200 water			8am		400	1	
9am					9am					9am				
10am					10am					10am	250 coffee			
11am		300 water			11am					11am	300 water			
Midday					Midday					Midday		300	2	
1pm		400	1		1pm		300 water			1pm				
2pm					2pm					2pm				
3pm					3pm		400	1		3pm		300 water		
4pm					4pm					4pm		350	1	
5pm		400 water			5pm		250 coffee			5pm				
6pm					6pm		350	1		6pm		250 tea		
7pm					7pm					7pm		400	1	
8pm		500 juice			8pm		300 wine			8pm		300 water		
9pm			400	1	9pm					9pm				
10pm					10pm		150 wine			10pm		200 water		
11pm	Sleep	100 water	200	0	11pm	Sleep	200 water	200	0	11pm	Sleep	300	0	
Midnight					Midnight					Midnight				
1am					1am					1am				
2am					2am					2am				
3am					3am					3am				
4am					4am		450	1		4am				
5am					5am					5am				
TOTAL		1850	1450		TOTAL		1650	1800		TOTAL		1850		

Bladder sensation codes
0- No sensation of needing to pass urine, passed urine for "social reasons"
1- Normal desire to pass urine and no urgency
2- Urgency, but it had passed away before you went to the toilet
3- Urgency, but managed to get to toilet, still with urgency, but did not leak urine
4- Urgency and could not get to the toilet in time so you leaked urine

Frequency: 4, 4, 5

Nocturia: 0, 1
NUV: 450 850
NPI: 0.31 0.47
(450/1450) (850/1800)

Maximum voided volume 450

FIGURE 2 Information abstracted from a bladder diary,¹⁰ showing some commonplace features. "Woke" indicates the start of each day, "sleep" for the start of each night. Daytime frequency is the number of voids recorded during waking hours and includes the last void before sleep and the first void after waking and rising in the morning. Frequency was 4-5 over the three complete days of the study period. Twenty-four hour production is measured by collecting all urine for 24 h. This is usually commenced after the first void produced after rising in the morning and is completed by including the first void on rising the following morning. The range in the current example was 1450-1800 mL for the two complete 24 h using this definition. Nocturia (nocturnal frequency) is the number of voids recorded during a night's sleep: each void is preceded and followed by sleep. It was 0-1 over the two complete nights of the study period. Nocturnal urine volume (NUV) is the total volume of urine passed between the time the individual goes to bed with the intention of sleeping and the time of waking with the intention of rising; it excludes the last void before going to bed but includes the first void after waking. NUV was high on the second night, perhaps due to alcohol consumption in the preceding evening. This also is associated with a high nocturnal polyuria index (NPI, calculated from $NPI = NUV/24 \text{ h volume}$) at 0.47. The maximum VV was normal (450 mL). Bladder sensation was generally 1 or 0; the only 2 was on day 3, and followed a couple of caffeine drinks

4. Pad testing may be used to quantify the amount of urine lost during incontinence episodes and methods range from a short provocative test to a 24-h pad test.²

5 | URODYNAMIC OBSERVATIONS

Bladder and bladder outlet function both need to be considered for a full understanding of a person's LUT. Urodynamics is a general term for tests that assess bladder and urethra function during the micturition cycle, and includes tests such as uroflowmetry, ambulatory urodynamics and videourodynamics. Urodynamics is also commonly used more specifically to indicate filling cystometry and pressure flow studies (PFS).

5.1 | Measurement of urine flow

Flow rate is defined as the volume of fluid expelled via the urethra per unit time (in mL/s) (Figure 3). "Free flow rate"

means that no tube is present for recording bladder pressure. Urine flow is either continuous or intermittent, depending on whether any interruptions happen during flow. A continuous flow curve may be a smooth arc-shaped curve, or it may be fluctuating, when there are multiple peaks during a period of continuous urine flow. Maximum flow rate (Q_{\max}) is the maximum measured value of the flow rate after correction for artefacts. VV is the total volume expelled via the urethra. Post void residual (PVR) is the volume of urine left in the bladder at the end of micturition.¹ If, after repeated voiding, no residual urine is demonstrated, then the finding of a PVR should be considered an artifact, due to the circumstances of the test.

5.2 | Measurement of bladder pressure

Both vesical pressure in the bladder (p_{ves}) and abdominal pressure (P_{abd}) are measured together, since the bladder is an abdominal organ. P_{abd} is generally estimated from rectal or vaginal recordings. Detrusor pressure (P_{det}) is that component of intravesical pressure that is created by forces

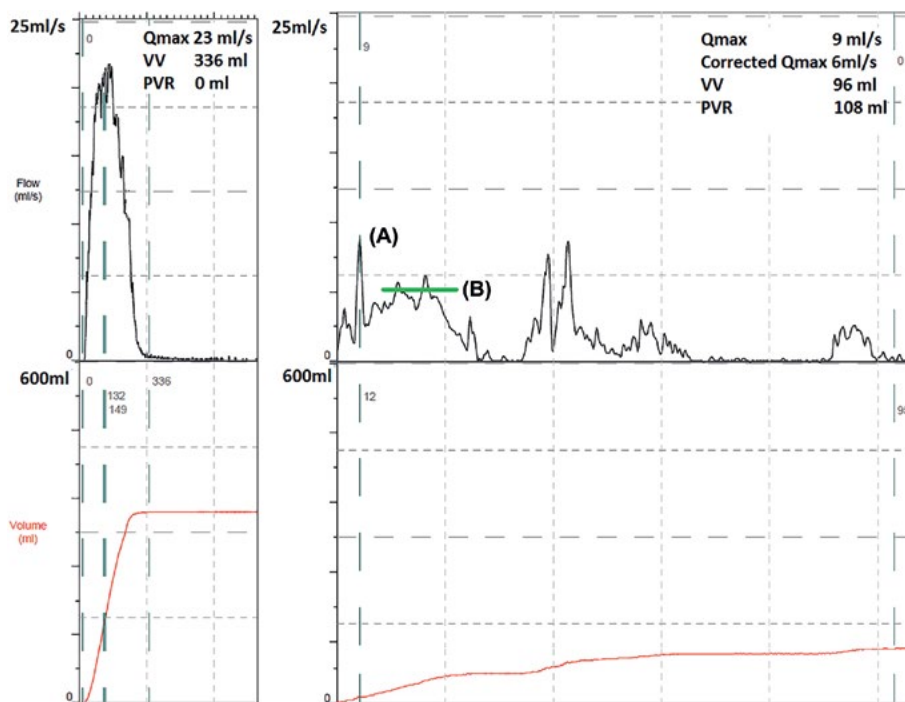


FIGURE 3 Uroflowmetry (free flow rate testing). On the left is a normal flow rate test for a women. It shows a continuous flow, with a good maximum flow rate (Qmax) and complete emptying, with a suitable VV. The pattern of flow is interrupted. The Qmax reported by the machine was 9 mL/s, but inspection of the trace shows the machine interpreted a spike (A) as the maximum flow, which will not be indicative of the patient's own urinary tract function, but rather is likely to be an artefact (eg, an aberration of flow delivery to the meter, a strain by the patient, or the patient moving on the commode). By definition, Qmax must be corrected to exclude artefacts.¹ Correcting the Qmax to a part of the curve (B) that is likely to be properly representative of urinary tract function gives a lower Qmax of 6 mL/s. The VV was low, but when the PVR of 108 mL is factored in, the bladder volume can be considered adequate when the flow test was done (96 + 108 = 204 mL)

in the bladder wall (passive and active), and it is calculated by subtracting P_{abd} from P_{ves} .¹ P_{det} is computed throughout filling cystometry and PFS, and is plotted alongside the two measured pressures (P_{ves} and P_{abd}) and flow (Q) (Figure 4).

Filling cystometry assesses the storage phase of the patient's micturition cycle. Filling cystometry should be described according to bladder sensation, detrusor activity, bladder compliance, and bladder capacity. Bladder compliance describes the relationship between change in bladder volume and change in detrusor pressure, and is calculated by dividing the volume change by the change in p_{det} during that change in bladder volume¹ (Figure 4). The standards points are (i) p_{det} at the start of bladder filling and the corresponding bladder volume (usually zero) and (ii) the p_{det} and bladder volume at cystometric capacity or immediately before the start of any detrusor contraction that causes significant leakage.

Both points are measured excluding any detrusor contraction. Detrusor overactivity (DO) is a urodynamic observation characterized by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked. Provocative maneuvers are techniques used during urodynamics in an effort to provoke DO, for example, rapid filling, use of cooled medium, postural changes, and hand washing.¹

Cystometric capacity is the bladder volume at the end of the filling cystometrogram. It is the volume voided, plus any PVR. The PFS starts when "permission to void" is given (Figure 4), or when uncontrollable voiding begins, and ends when the patient considers voiding has finished. PFS is a model of the patient's voiding phase and combines synchronous flowmetry with measurement of p_{ves} . Thus, flow rate testing in PFS differs from free flowmetry by the presence of a fine tube to enable pressure measurement. Normal voiding is achieved by a voluntarily initiated

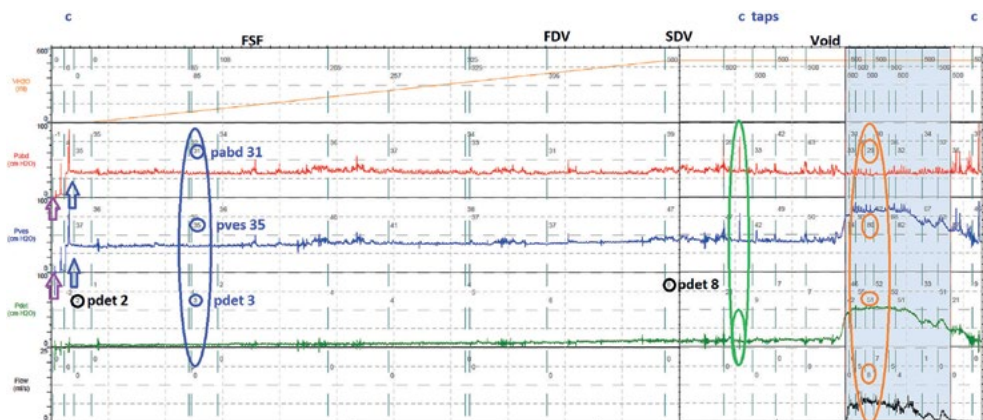


FIGURE 4 Pressure measurement. The record shows continuous tracings of two measured pressures; the abdominal pressure p_{abd} in red, and the vesical bladder pressure p_{ves} in blue. These are continuously subtracted ($p_{ves}-p_{abd}$) to give the detrusor p_{det} in green. Also shown are the volume instilled in orange, and flow rate in black. Filling cystometry precedes permission to void (indicated with “void”), and the pressure flow study (PFS) follows it. The zero reference point is atmospheric pressure (purple arrows), so when the transducers are connected to the patient (blue arrows), there is an obvious rise in p_{abd} and p_{ves} , referred to as “resting pressures”—the blue oval indicates the resting pressures for this patient at one timepoint. Coughs (indicated with “c”) are used to check that p_{abd} and p_{ves} detect a short spike of pressure (larger green oval), and that the p_{det} has a deflection which is equal above and below the line, the biphasic artefact (smaller green oval). It is important to check pressure recording with a cough at the start of filling, and on each side of the PFS. Normal detrusor function allows bladder filling with little or no change in pressure, and there should be no involuntary phasic contractions despite provocation.¹ In this study, the p_{det} was 2 cmH₂O at the beginning of the filling cystometry, and eight at the end; since filled volume was 500 mL, the compliance (change in volume/change in pressure = 100/[8-2]) was 17 mL/cmH₂O. Sensations are reported by the patient and annotated on the trace. First sensation of bladder filling (FSF) is the feeling the patient has, during filling cystometry, when he/ she first becomes aware of the bladder filling. First desire to void (FDV) is the feeling that would lead the patient to pass urine at the next convenient moment, but voiding can be delayed if necessary. Strong desire to void (SDV) is a persistent desire to void without the fear of leakage.¹ A provocation was applied to try to elicit DO by making the sound of running water “taps”; no change in p_{ves} or p_{det} was seen, so this patient had a stable detrusor. In the PFS, the key parameters derive from the time of maximum flow rate (Q_{max}). The current patient had a Q_{max} of 8 mL/s and detrusor pressure at Q_{max} of 51 cmH₂O, so his BOO Index was 35 and Bladder Contractility Index was 91. p_{abd} did not change at that time, so no allowance has to be made for the effect on p_{det} .

continuous detrusor contraction that leads to complete bladder emptying within a normal time span, and in the absence of obstruction. Detrusor underactivity (DUA) is a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete emptying within a normal time span. Bladder outlet obstruction (BOO) is the generic term for obstruction during voiding and is characterized by increased detrusor pressure and reduced urine flow rate.¹ For male patients, BOO and DUA can be quantified using the BOO Index and the Bladder Contractility Index.⁸ They rely on measuring Q_{max} and detrusor pressure at maximum flow, which is the lowest pressure recorded at maximum measured flow rate (see ⁹).

6 | CONCLUSIONS

The ICS Standardization provides a logical framework and definitions to describe symptoms, signs, and urodynamic observations in relationship to the micturition cycle.

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Basic concepts in nocturia, based on international continence society standards in nocturnal lower urinary tract function

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Email: h.hashim@gmail.com**Aims:** To review the recommendations on nocturia in the International Continence Society (ICS) Standardization documents, setting out key definitions and parameters for use in clinical practice.**Methods:** Definitions and evaluations described in the ICS Standards on Nocturia and Terminology for Lower Urinary Tract Function were identified and summarized.**Results:** The terms have been divided into signs and symptoms. Nocturia as a symptom is waking at night to pass urine and as a sign is the number of times an individual passes urine during their main sleep period. Nocturnal polyuria as a symptom is passing large volumes of urine at night and as a sign is the excessive production of urine during the individual's main sleep period. These should be quantified using a 3-day bladder diary, thereby facilitating identification of 24-h polyuria, nocturnal polyuria, lower urinary tract dysfunction, or sleep disorder.**Conclusions:** The summary reflects the multifactorial influences in nocturia and provides a pragmatic insight into bladder diary analysis for deriving key parameters relevant to clinical therapy.**KEYWORDS**

enuresis, International Continence Society, nocturia, nocturnal polyuria, terminology

1 | INTRODUCTION

Nocturia is a significant problem affecting a large proportion of the population, especially in older age groups.^{1,2} Increasing recognition of its prevalence and potential health impact for individual patients and for population health has led to recognition of the need to establish the specific underlying mechanisms relevant for anyone presenting with the symptom. Crucially, a range of observations need to be properly understood by any clinician responsible for caring for these patients.

In 2002, the International Continence Society (ICS) defined nocturia as the complaint that the individual has to

wake at night one or more times to void.³ In 2014, a new ICS Nocturia working group was set up to review the terminology related to that document and will be reporting in 2018. The current review sets out the principles underlying the fundamental nocturia terminology, and describes how they are applied in an example bladder diary to help direct healthcare professionals toward the most logical approach to investigation and therapy. The aim is for this to be a practical and pragmatic guide for use in both clinical and research settings.

2 | METHODS

Recommendations in the ICS standards on Nocturia⁴ and Lower Urinary Tract Function,⁵ and the 2018 ICS consultation on nocturia terminology, were reviewed and

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

summarized. From these, definitions and key terms are generally transcribed verbatim. Additional explanatory text is included for context. Explanatory or exemplary footnotes from the original documents have been adapted or excluded for the sake of brevity. Users are advised to refer to the source documents and specify the source of the definitions they employ when citing definitions.

The terminology is broken into symptoms, that is, as reported by the patient, and signs. Lower urinary tract symptoms (LUTS) are broken down into storage, voiding and post-voiding symptoms, depending on their timing in relation to the micturition cycle. Nocturia is categorized as a storage symptom, based on the fact that a person is in the storage phase of the micturition cycle when asleep. For nocturia, the key signs are the voiding frequency and the voided volumes during the main sleep period; these are usually captured from a frequency/volume chart (FVC) or bladder diary.

“Night-time” for the purposes of the nocturia terminology refers to the individual’s sleep cycle, rather than the solar cycle (from sunset to sunrise). For this reason, a shift worker sleeping between shifts may experience nocturia during daylight hours.

3 | URINE OUTPUT

The production of urine by the kidneys is a continuous process of filtration in the glomeruli, and reabsorption (water and soluble nutrients) in the tubules. Urine production serves to balance water, salt, and acid levels according to the homeostatic needs of the person, and this is principally a result of adjustments to the tubular reabsorption. Surplus water increases urine production (diuresis), and surplus salt also increases urine production (natriuresis). Making urine also serves to dispose of toxins and by-products.

The rate of urine production increases if there is;

- Diuresis
- Natriuresis
- Products in the glomerular filtrate in such large quantities that the tubules cannot reabsorb it all (poorly controlled diabetes mellitus can cause this, due to glucosuria)
- Dysfunction of the renal tubules

Tubular dysfunction can occur in chronic kidney disease. If associated with disease affecting the glomeruli, estimated glomerular filtration rate (eGFR), and creatinine levels will be abnormal. If it is a selective tubular dysfunction, eGFR and creatinine levels may be normal.

The continuous production of urine is the task of the upper urinary tract (UUT). Expelling the urine at appropriate times, and storing at other times, is the task of the lower urinary tract (LUT). The “micturition cycle” is a concept describing how

the LUT serves these two contrasting tasks of urine storage and voiding. Voiding generally can be initiated by someone at any time that suits them, but the main driver prompting people to take active steps to pass urine is when they feel their bladder is “full.”

The number of times someone has to pass urine over a specified time period reflects;

1. How fast the UUT is producing urine
2. The bladder volume at which the LUT signals “fullness”

Renal regulation tends to see the rate of urine production reduced when the person is asleep. In young people living a healthy lifestyle, rate of UUT urine production is low and LUT storage volume is high, so nocturia is uncommon.

3.1 | Voiding frequency

The symptom of nocturia is present if the patient reports waking at night to pass urine. Nocturia is also a sign indicated by the number of times an individual passes urine during their main sleep period.

3.2 | Volume of voiding

In order to decide whether the presence of nocturia reflects production of large quantities of urine from the UUT, an estimate of urine output is needed. 24-h voided volume is the total volume of urine passed during a 24-h period excluding the first morning void of the period. A 24-h polyuria indicates that 24-h urine output is more than 40 mL/kg, in men and women. The general increase in urine output will elevate the voiding frequency in the daytime and night-time, outstripping even normal bladder capacity. The symptom of nocturnal polyuria is present if the patient reports passing large volumes of urine at night. Nocturnal polyuria is also a sign indicated by excessive production of urine during the individual’s main sleep period. It is often expressed as a proportion of the 24-h voided volume. The nocturnal polyuria index is the nocturnal urine volume/24-h voided volume, expressed as a percentage. NP is said to be present if the NPi is more than 33% in the elderly (eg, aged more than 65), and more than 20% in younger individuals.

4 | CAPTURING THE SYMPTOMS

The ICS emphasises the need to distinguish a symptom’s severity from the bother it brings, as they are not necessarily correlated. In nocturia, there are various symptom scores which can assess both the severity and associated bother of nocturia and other LUTS, such as the International Consultation on Incontinence Questionnaires (ICIQ).⁶ There

is a specific score for quality of life in nocturia (ICIQ-NQoL⁷). Practitioners need to be clear that waking once per night to pass urine, on average, means nocturia is present. Research shows that a single episode of nocturia is generally of relatively low bother to the patient (assuming they return to sleep satisfactorily). However, even if causing low bother, it still constitutes nocturia. Future research is needed to identify whether nocturia once per night might actually be medically significant (eg, the start of a medical problem for which early identification and treatment might avoid future progression).

Direct questioning is needed to establish the symptom of NP. Some discussion is also needed to review “reason for waking”; the symptom of nocturia implies that the need to pass urine was the reason for waking. This is distinct from the situation that sleep disturbance may actually have been for some other reason, but the person went to pass urine because they happened to be awake.

5 | ASSESSING THE SIGNS

The fundamental tools for assessing signs in LUTS are the physical examination and the bladder diary. Examination can

identify whether the person has risk factors for NP (eg, a physical body habitus suggesting risk of obstructive sleep apnoea or the presence of peripheral oedema), or whether they have chronic urinary retention.

A well-completed FVC or bladder diary⁸ recorded for three days⁹ is invaluable. The time of going to bed and the time of waking up from sleep must be clearly marked by the patient (it is rather common for patients to overlook noting these, rendering the diary uninterpretable for analyzing nocturia). From the chart or diary the following can be calculated (Figure 1):

- The daytime and night-time voiding frequency
- 24-h voided volume: the total volume of urine passed during a 24-h period excluding the first morning void of the period.
- Nocturnal urine volume: the total volume of urine produced during the individual's main sleep period.
- Nocturnal polyuria index: the nocturnal urine volume/24-h voided volume.
- Maximum voided volume, average voided volume, and bladder sensation scores

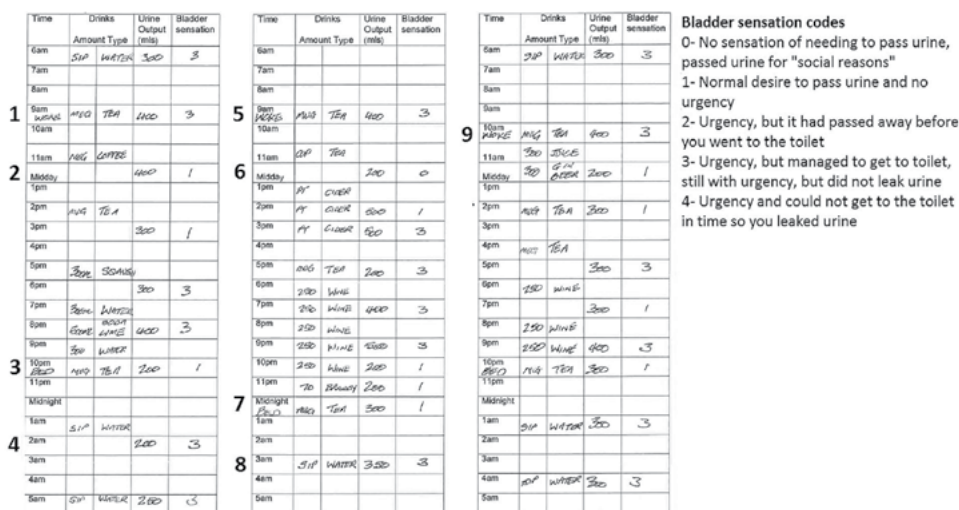


FIGURE 1 Analysis of a 3-day bladder diary. On the first day, the person woke at 9 am (1), went to bed at 10 pm (3), and woke the following morning at 9 am (5). To calculate the first complete 24-h voided volume, we need to exclude the first morning void of Day 1 as that is part of the previous night's volume. Thus, the first 24 h voided volume includes the voids between points 2 and 5 (400 + 300 + 300 + 400 + 200 + 250 + 400 [1st morning void from Day 2]) = 2450 mL. The contribution of night-time voided volume is from point 4 to 5 (200 + 250 + 400) = 850. The nocturnal polyuria index (NPI) was 850/2450 = 35%. Nocturia is the voids between points 3 and 5 but excludes the voids at points 3 and 5 (so the voids at 2 am and 5 am), that is, nocturia was twice. For the second complete 24-h period, the voided volume should be taken from points 6 to 9, and totals 4050 mL. The nocturnal voided volume is from points 8 to 9, totaling 1050 mL. The NPI was 26% (1050/4050), and nocturia was twice (3 am and 6 am). This patient was 32 years old, so they had nocturnal polyuria (NPI >20% in a patient below the age of 65). Their body weight was 60 kg, so they also had 24-h polyuria (>40 mL/kg/24 h). A 3-day diary contains two complete 24-h periods and two complete nights, since there is no information to complete the third night (unless the patient keeps recording up until they wake on Day 4)

6 | EXPLAINING THE PROBLEMS

For anyone with nocturia, a basic interpretation of the bladder diary can be used to categorise likely contributory factors,¹⁰ and thereby guide subsequent evaluation and treatment.^{11,12}

- 24-h polyuria; caused by a range of medical problems, such as diabetes insipidus, salt loss, or poorly controlled diabetes mellitus. These people often report constant thirstiness.
- NP; caused by problems such as obstructive sleep apnoea or peripheral oedema.
- LUTD; generally associated with storage LUTS, and with increased bladder sensation scores on the bladder diary.
- Sleep disturbance; should be considered if the patient describes anxiety, restless legs, nightmares, and sleep-walking.

Simple behavioral tendencies should be considered, for example identification of a high fluid intake in someone who does not experience constant thirst. LUTD is actually a relatively uncommon explanation for nocturia in the wider population, so urologists or urogynecologists should identify the other possible situations and avoid urological or gynecological interventions, where not specifically indicated.

7 | ENURESIS

Enuresis is a symptom in which the patient complains of intermittent incontinence that occurs during periods of sleep. It is also a sign of “wetting” while asleep. This is not the same as waking with urinary urgency and having insufficient time to reach the toilet, which is urgency urinary incontinence.

Enuresis may have more in common with voiding dysregulation (urination in situations which are generally regarded as socially inappropriate) or involuntary voiding (sporadic bladder emptying when awake)¹³ than nocturia. Thus, they must be clearly distinguished when both nocturia and enuresis are reported by a patient.

8 | CONCLUSION

The symptom of nocturia is present if the patient reports waking at night to pass urine and nocturia is also a sign indicated by the number of times an individual passes urine during their main sleep period. NP is present if the patient reports passing large volumes of urine at night, and this can be quantified with the nocturnal polyuria index. The bladder diary is an important diagnostic tool, helping identify 24-h polyuria, NP, LUTD, and sleep disturbance. Enuresis is distinguished from nocturia, as the patient fails to wake up for passing urine.

CONFLICT OF INTEREST

Dr. Hashim reports personal fees and non-financial support from Ferring, personal fees from Astellas, personal fees from Medtronic, personal fees from Boston, personal fees and non-financial support from Allergan, outside the submitted work. Dr. Drake reports grants, personal fees and non-financial support from Ferring, during the conduct of the study; grants, personal fees and non-financial support from Astellas, grants, personal fees and non-financial support from Allergan, outside the submitted work.

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Neurological lower urinary tract dysfunction essential terminology

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Aims: To introduce basic concepts and definitions in the International Continence Society (ICS) Standardisation of Terminology in adult Neurogenic Lower Urinary Tract Dysfunction (NLUTD).

Methods: Fundamental terminology in the ICS Standardisation of Terminology of Adult NLUTD was identified and summarized.

Results: NLUTD is often associated with impairment of cognitive, motor, sensory, and/or autonomic functions. Lesions are categorized into suprapontine, pontine/suprasacral spinal, sacral spinal, cauda equina/peripheral nerve, or mixed lesions. People affected with neurological disease are also at risk of the conditions seen in the general population, such as benign prostate enlargement. Symptoms of NLUTD include alterations in bladder or urethral sensation and incontinence. Loss of urine can result from incontinence, involuntary passing of urine and factors that impair toilet use, incorporating problems such as impaired cognition urinary incontinence, impaired mobility urinary incontinence, and voiding dysregulation. Signs may be discerned by physical examination and recording of a frequency volume chart or bladder diary. Urodynamic observations during filling cystometry may include altered sensations, neurogenic detrusor overactivity, and reduced bladder compliance. During pressure flow studies, there may be detrusor underactivity or bladder outlet obstruction (BOO). BOO may be caused by various forms poorly co-ordinated muscle activity in the bladder outlet. Symptoms, signs, and urodynamic observations may be useful in diagnosing the presence and specific location of neurological impairment.

Conclusion: The review provides a succinct summary of symptoms, signs, and urodynamic observations as set out in the ICS Standard on Adult NLUTD.

KEY WORDS

incontinence, LUTS, neurological disease, standardization

1 | INTRODUCTION

Adult neurogenic lower urinary tract dysfunction (NLUTD) refers to abnormal or difficult function of the bladder, urethra

(and/or prostate in men) in mature individuals in the context of clinically confirmed relevant neurologic disorder. NLUTD is a key subgroup of the broad range of lower urinary tract symptoms (LUTS), due to the severity of the symptoms, and the implications of urinary dysfunction for wider health. The International Continence Society (ICS) categorizes symptoms, signs, urodynamic observations, and conditions

Alan Wein led the peer-review process as the Associate Editor responsible for the paper.

associated with lower urinary tract dysfunction (LUTD) in relationship to the storage and voiding phases of the micturition cycle. Neurological disease brings additional dimensions to the LUTD as experienced in the lives of affected individuals. The current document is a summary of core terminology in NLUTD for use in the wider context of LUTS in people known to have a neurological disease, or suspected of potentially having one which has not yet been diagnosed.

2 | METHODS

Recommendations in the ICS Standard on Adult Neurogenic Lower Urinary Tract Dysfunction¹ were reviewed and summarized. Definitions and key terms are generally transcribed verbatim and highlighted in bold. In the original document, many of the definitions are accompanied by explanatory or exemplary footnotes which have been adapted or excluded for the current review for the sake of brevity. Readers requiring more detailed information are referred to the full ICS Standard, and other documents produced by the ICS Standardisation Steering Committee.

3 | NEUROLOGICAL CONTROL

The nervous system controls many facets that are essential for the normal micturition cycle (storage and voiding). Particularly crucial are cognition (eg, decision making, anticipation, awareness of environment/social context, and conscious perception of sensation), motor functions (eg, mobility, balance, and dexterity), sensory nerve activity, and autonomic functions (eg, regulation of the detrusor and sphincter). The neurological functions act together to make sure that both urine storage and voiding reflect timings and contexts appropriately, with full voluntary control (Figure 1).

Neurological diseases are diverse and differ in terms of the parts of the nervous system affected (eg, the cognitive-predominant effects of dementia) and their behavior (eg, progressive, such as multiple sclerosis, or non-progressive, such as spinal cord injury). Thus, neurological disease may have differing effects on cognitive, sensory, motor, and autonomic functions which manifest in the specific NLUTD experienced by the patient. Inevitably, the consequences of neurological disease extend beyond LUTD, and mean that affected patients have a range of issues that influence treatment potential and health risk. Problems with bowel function, sexual and reproductive function, cognition, mobility, and blood pressure control are particularly relevant.

In describing the features of an individual patient's dysfunction, clinicians should appreciate the distinction between symptoms, signs, and urodynamic observations as

set out in the ICS Standardisation of Terminology of Lower Urinary Tract Function² (for summary see³). A summary of the classification of neurological lesions,¹ including the potential clinical and urodynamic features, is given in Figure 2.

4 | NLUTD SYMPTOMS

People with NLUTD may describe storage, voiding, and post voiding symptoms consistent with the definitions used for the general population.^{2,3} Sometimes, a patient may not express that a symptom is present, so it is appropriate to discuss with the caregiver as well when establishing the presenting complaint. Storage symptoms may converge in **Neurogenic Overactive Bladder**, which is a symptom syndrome characterized by urgency, with or without urgency urinary incontinence, usually with increased daytime frequency and nocturia in the setting of a clinically relevant neurologic disorder with at least partially preserved sensation.

4.1 | Bladder and urethral sensation

Neurologically healthy people are intermittently aware of bladder sensations related to filling and voiding, and urethral sensation with voiding. Someone with NLUTD may describe alterations, for example:

Increased bladder sensation: the desire to void during bladder filling occurs earlier or is more persistent than that previously experienced. **Reduced:** the definite desire to void occurs later to that previously experienced despite an awareness that the bladder is filling. **Absent:** the individual reports no sensation of bladder filling or desire to void. Such patients may have a significant post voiding residual in the bladder, without any sensation of incomplete emptying.

Non-specific bladder awareness: the individual reports no specific bladder sensation, but may perceive, for example, abdominal fullness, vegetative symptoms, urethral sensations, or spasticity as bladder filling awareness or a sign of bladder fullness. This may indicate that the usual sensory nerve pathways are not communicating centrally. Instead anatomical routes which do not usually contribute to everyday sensations may be intact and functional.

In addition, some people report they are unable to feel flow of urine along the urethra. They may report that they can only discern whether bladder emptying is finished by looking, or listening for the splash of urine in the toilet to stop.

4.2 | Loss of urine

Mature CNS regulation ensures storage (detrusor relaxation with outlet contraction) and the transition to voiding (detrusor

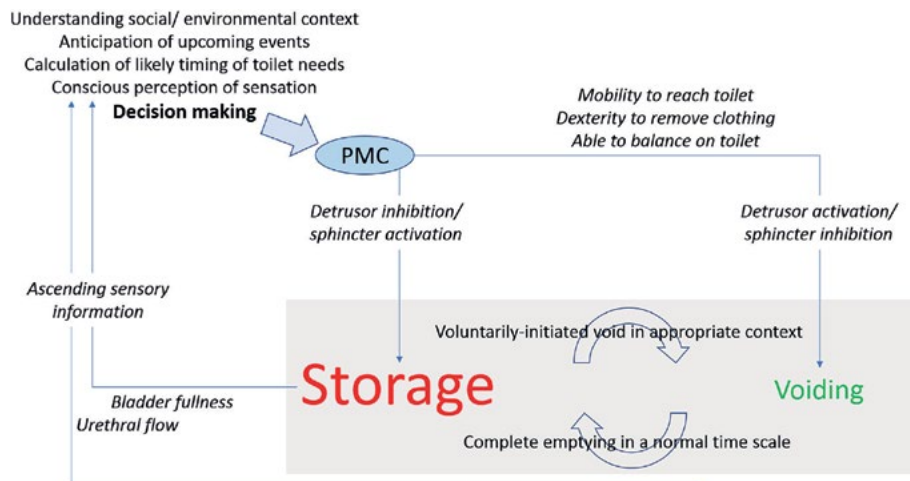


FIGURE 1 The micturition cycle viewed from the context of the person's social and environmental context. PMC, pontine micturition center

contraction with outlet relaxation) is under voluntary control. Various situations in NLUTD may lead to a loss of urine:

1. Incontinence; categorized into stress urinary incontinence, urgency incontinence and mixed urinary incontinence, and reflecting LUT dysfunction. Definitions used in NLUTD are the same as those used in the general population.
2. Involuntary passing of urine; no LUT abnormality is necessarily present, but instead the voiding reflex may activate at times not consciously initiated by the patient. This may be during occasions generally considered socially inappropriate. It may reflect a dysfunction in the cerebrum, for example, a stroke or dementia. Abnormal voiding reflexes, or disinhibition, may result in the person passing urine without voluntary control.
3. Factors that impair toilet use, such as immobility, cognitive disability, and decreased motivation.

Thus, some additional incontinence definitions are standardized in NLUTD:

- **Impaired cognition urinary incontinence** is periodic urinary incontinence that the individual with cognitive impairment reports to have occurred without being aware of it.
- **Impaired mobility urinary incontinence** is inability to reach the toilet on time for voiding because of physical or medical disability. This inability includes (any combination of) the individual's physical as well as social causes or reasons. Other signs or symptoms of LUTD should not be present, or should be reported by the professional (as primary or as accessory) (eg, "Urgency urinary incontinence" with "mobility impairment"; or

"Mobility impairment urinary incontinence" with "stress urinary incontinence.

- **Voiding dysregulation** is urination in situations which are generally regarded as socially inappropriate, such as while still fully dressed, or in a public setting away from toilet facilities.
- **Involuntary voiding** is both a symptom and a diagnosis of sporadic bladder emptying when awake, without intention to void. Usually the voiding reflex is preserved, and there is only lack of proper inhibition of the voiding reflex. If that happens when asleep it is called Acquired Enuresis.
- **Enuresis** is intermittent incontinence that occurs during periods of sleep. Enuresis is considered different from urgency urinary incontinence. Confirming the precise underlying mechanism(s) is often not possible in routine clinical practice.
- **Continuous (urinary) incontinence: complaint of continuous involuntary loss of urine.**

4.3 | Signs

NLUTD evaluation incorporates the examination used for the general population, since people with neurological disease are the same risk of aging-related and other changes as any other person. Accordingly, physical examination must include abdominal, pelvic and perineal examination, and should elicit the following where present:

- Incontinence
- Pelvic organ prolapse
- Pelvic floor muscle function

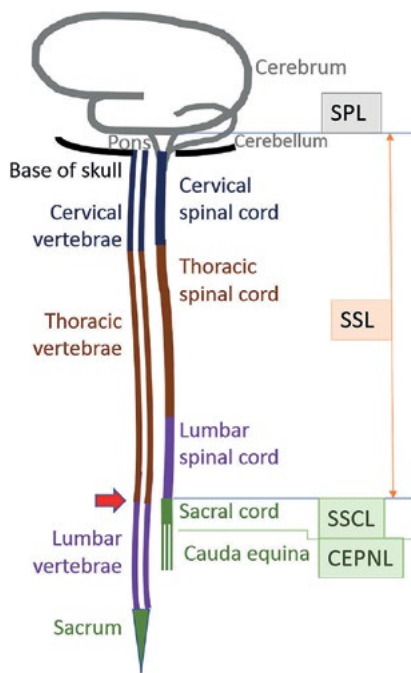


FIGURE 2 Classification of neurological lesions. Suprapontine Lesion (SPL) is a neurological lesion above the pons (forebrain or midbrain). NLUTD in SPL: there is a reflex contraction of the detrusor with impaired cerebral regulation and central inhibition and usually synergistic voiding/bladder emptying. Suprasacral spinal cord/pontine lesion (SSL) is a neurological lesion in suprasacral spine and/or pons. NLUTD in SSL: Detrusor overactivity (DO) and DO incontinence are common, with or without detrusor-urethral sphincter dyssynergia (DSD), often resulting in a significant post void residual (PVR) and “high pressure” bladder. Sacral Spinal Cord Lesion (SSCL) is a neurological lesion in the sacral spinal cord. NLUTD in SSCL; findings include acontractile detrusor with or without decreased bladder compliance and usually with impaired sphincter activity. Infrasaacral (cauda equina and peripheral nerves) Lesion (CEPNL) is a neurological lesion affecting the cauda equina and/or peripheral nerves. NLUTD in CEPNL: acontractile detrusor and/or SUI may be present. Mixed Neuronal Lesion results from lesions of the neural pathway at different levels of the central nervous system concurrently. Note that in the adult, vertebral levels and spinal cord levels do not lie adjacent. Thus a T12/L1 prolapsed intervertebral disc (classified by its vertebral level) will affect the sacral part of the spinal cord (red arrow)

- Palpable bladder after voiding
- Pad testing

A frequency micturition chart, frequency volume chart, or bladder diary² is needed within the constraints of patient capacity or carer availability. This may be particularly

important in NLUTD, where the underlying condition may give rise to an endocrine dysfunction, such as central diabetes insipidus.

Physical examination is also used to identify signs which could point toward the localization of the exact neurological deficits caused by the responsible condition, for example, perineal numbness.

5 | URODYNAMIC OBSERVATIONS

Bladder and bladder outlet function both need to be considered for a full understanding of a person's LUT. Since the pathophysiology is complex in NLUTD, and symptoms cannot be relied on for understanding mechanism, urodynamic testing provides a valuable insight into mechanisms and may identify observations that could indicate a risk to the patient's future health.

5.1 | Filling cystometry

- **Neurogenic detrusor overactivity** is characterized by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked in the setting of a clinically relevant neurologic disease. Provoked contraction may be elicited by cough, change of position, etc., or by urethral/sphincter to bladder reflex. **Neurogenic Detrusor Overactivity Incontinence is incontinence due to involuntary neurogenic detrusor overactivity.**
- **Detrusor Overactivity Leak Point Pressure (DOLPP)** is defined as the lowest detrusor pressure rise with detrusor overactivity at which urine leakage first occurs in the absence of voluntary detrusor contraction or increased abdominal pressure. This is in contrast to Detrusor Leak Point pressure where urine leakage occurs in the absence of either a detrusor contraction or increased abdominal pressure.²

Reduced **bladder compliance (the relationship between change in bladder volume and change in detrusor pressure²)** is an important observation (Figure 3) in interpreting the clinical risk for renal function.

In neurogenic LUTD, the cystometric capacity cannot be defined in the same terms as for filling cystometry for the general population. In the absence of sensation, the cystometric capacity is the volume at which the clinician decides to terminate filling. The reason(s) for terminating filling should be defined in the report, for example, high detrusor filling pressure, large infused volume or pain. If there is uncontrollable voiding/bladder emptying, it is the volume at which this begins. In the presence of sphincter incompetence the cystometric capacity may be significantly increased by occlusion of the urethra, for example, by a Foley catheter balloon.

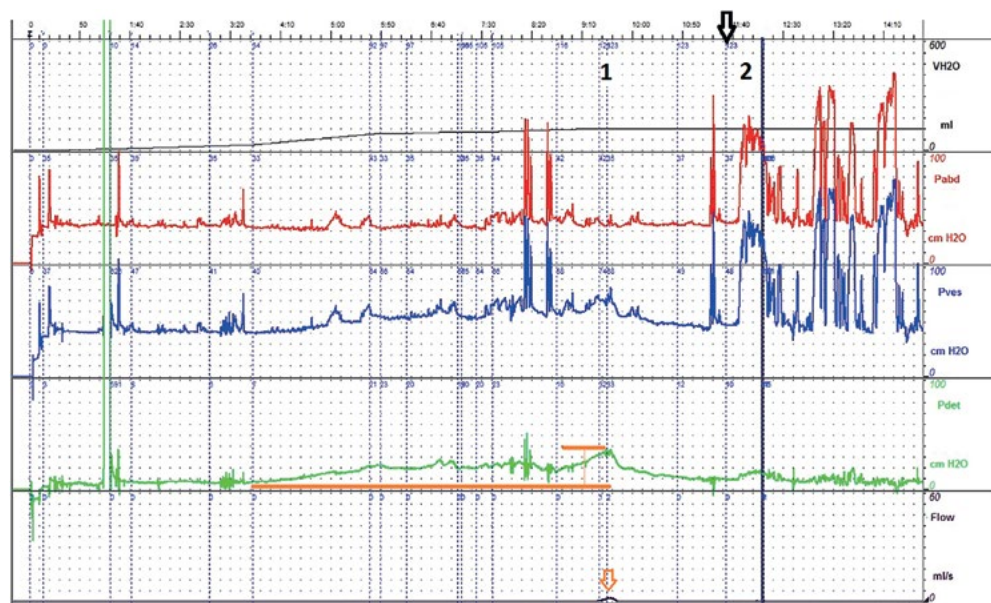


FIGURE 3 Filling cystometry in a sacral spinal cord lesion (SSCL) showing reduced compliance; the lower orange line indicates the phase during which the detrusor pressure (green trace, second from bottom) is climbing, even though the filling rate is slow (10 mL/min). The upper orange line indicates the detrusor leak point pressure. The change in volume over this time was $123-34 = 89$ mL, and the change in pressure was $33-7 = 26$ cm H₂O. Compliance (change in volume divided by change in pressure) was thus $89/26 = 3.4$ mL/cm H₂O. Detrusor Leak Point Volume (DLPV) is defined as a bladder volume at which first urine leakage occurs (1), either with detrusor overactivity or low compliance (orange arrow). The leakage is seen in the flow trace (black, bottom trace), and the leakage causes the elevated detrusor pressure to dissipate. The arrow indicates permission to void. However, there is no flow generated, and the patient does several Valsalva strains, shown by the substantial pressure rises in both abdominal pressure, and hence bladder pressure (2), signifying neurogenic acontractile detrusor. At time of urodynamics, neurological diagnosis had not previously been suspected, and subsequently he was identified to have multiple system atrophy

5.2 | Pressure flow studies

When passing urine, a slow stream may be explained by impaired detrusor contraction, bladder outlet obstruction (BOO), or a combination of both. Potential causes of neurogenic BOO include:

- **Non-relaxing urethral sphincter**, characterized by a non-relaxing, obstructing urethral sphincter resulting in reduced urine flow.
- **Delayed relaxation of the urethral sphincter**, characterized by impaired and hindered relaxation of the sphincter during voiding attempt resulting in delay of urine flow.
- **Detrusor-Sphincter Dyssynergia (DSD)**, which describes a detrusor contraction concurrent with an involuntary contraction of the urethral and/or peri-urethral striated muscle. Occasionally flow may be prevented altogether.

DSD is an indicator that the pontine micturition center is not communicating effectively with the sacral spinal cord, and occurs in people with a suprasacral spinal cord/pontine lesion. The term should not be used in other forms of NLUTD, and it is not a general term for neurogenic BOO.

Other causes of BOO present in the general population, such as benign prostatic obstruction, bladder neck obstruction, or urethral stricture in men, can also be present in people with neurological disease, and videourodynamics may be appropriate to discern the proximal site of BOO.

Impaired detrusor contraction can indicate:

- **Neurogenic detrusor underactivity**; a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span in the setting of a clinically relevant neurologic disorder.

- **Neurogenic acontractile detrusor**; the detrusor cannot be demonstrated to contract during urodynamic studies in the setting of a clinically relevant neurologic lesion (Figure 3).

Balanced bladder emptying is a bladder emptying with physiological detrusor pressure and low residual as perceived by the investigator, and should be defined in the report.

6 | NLUTD CLINICAL DIAGNOSES

- **Spinal Shock Phase** is usually temporary following acute neurologic insult or SCI that is characterized by loss of sensory, motor, and reflex activity below the level of injury. NLUTD in Spinal Shock is usually a temporary complete painless urinary retention.
- **Autonomic Dysreflexia** is a syndrome resulting from an upper thoracic or cervical spinal cord injury above T6, elicited by a stimulus in the field of distribution of the autonomous sympathetic nucleus, characterized by unregulated sympathetic function below the lesion and compensatory autonomic responses. It is potentially a medical emergency characterized by hypertension, bradycardia, severe headaches, and flushing above, with pallor below the cord lesion, and sometimes convulsions. An increase of blood pressure without any other symptoms is called Asymptomatic Autonomic Dysreflexia.

Urinary retention is an inability to properly empty the bladder. Retention may be complete or incomplete:

- **Acute retention of urine** is an acute event of painful, palpable or percussable bladder, when the patient is unable to pass any urine when the bladder is full. Although acute retention is usually thought of as painful, in certain circumstances pain may not be a presenting feature, for example, when due to prolapsed intervertebral disc, post-partum, or after regional anesthesia such as an epidural anesthetic. The retention volume should be significantly greater than the expected normal bladder capacity.
- **Chronic retention** is a non-painful bladder, which remains palpable or percussable after the patient has passed urine. Such patients may be incontinent. Chronic retention, excludes transient voiding difficulty, for example, after surgery for stress incontinence, and implies a significant residual urine.

7 | DIAGNOSING NEUROLOGICAL DYSFUNCTION

In order to understand the full picture of the neurological deficit, the history may be used to identify features which could localize the site of a problem or suggest the causative condition and its behavior. Such observations can be helpful to a patient's neurologist in localising areas of deficit. These features are important in defining a patient's condition, since it guides subsequent testing (such as the anatomical sites and scan protocols for MRI). For example, retrograde ejaculation reported by a man who has not had bladder neck or prostate surgery may indicate a neurological deficit in the thoracolumbar spine or related peripheral nerves; this may be accompanied by visualization of an open bladder neck during videourodynamic filling cystometry. Signs can also help; for example, loss of the anal reflex indicates a lesion affecting the sacral spinal cord or its sensory or motor nerves.

In rare but important cases, urinary dysfunction may present for urological evaluation in a patient with no known neurological background whose ultimate cause may subsequently prove to be a neurological disease. This can occur for example in MS, normal pressure hydrocephalus, multiple system atrophy, and early Parkinson's disease.⁴ Key symptoms include erectile dysfunction, retrograde ejaculation, enuresis, loss of filling sensation, or unexplained stress urinary incontinence.⁴ If there is any suspicion that an undiagnosed neurological disease could be present, questioning should enquire about visual symptoms, back pain, anosmia, bowel dysfunction and incontinence, or memory loss.⁴ Specialist evaluation is likely to be needed.

8 | CONCLUSIONS

NLUTD is categorized into: suprapontine; pontine/suprasacral spinal; sacral spinal; cauda equina/peripheral nerve; mixed lesions. Loss of urine can result from impaired cognition urinary incontinence, impaired mobility urinary incontinence, and voiding dysregulation. Urodynamic observations during filling cystometry may include altered sensations, neurogenic detrusor overactivity, and reduced bladder compliance. During pressure flow studies, there may be detrusor underactivity or bladder outlet obstruction (BOO). BOO may be caused by various forms poorly co-ordinated muscle activity in the bladder outlet. Symptoms, signs, and urodynamic observations may be useful in diagnosing the presence and specific location of neurological impairment.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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The fundamentals of chronic pelvic pain assessment, based on international continence society recommendations

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Aims: Chronic pelvic pain (CPP) is defined as a noncyclical pain that has duration of at least 6 months and can lead to decreased quality of life and physical performance. The pain can be attributed to problems in the pelvic organs and/or problems in related systems, and possible psycho-social attributes may contribute to the manifestation. Due to the complex nature, CPP syndromes are multifactorial and the terminology needs to reflect the setting.

Methods: The current review is a synthesis of key aspects of the recent International Continence Society Standardization for Terminology in CPP Syndromes.

Results: Nine domains can be used for a detailed description of CPP. They include four domains specific to the pelvic organs (lower urinary tract, female genital, male genital, gastrointestinal), two related to other sources of pain which may be perceived in the pelvis (musculoskeletal, neurological) and three which may influence the response to the pain or its impact on the individual (psychological, sexual, and comorbidities). For an individual patient with CPP, each domain should be reviewed in terms of symptoms and signs, noting that positive findings could reflect either a primary cause or a secondary consequence. The findings will guide further evaluations and subsequent treatment.

Conclusion: We present a synthesis of the standard for terminology in CPP syndromes in women and men, which serves as a systematic framework to consider possible sources of pain (pelvic organs or other sources) and the individual responses and impact.

KEYWORDS

chronic pelvic pain, lower urinary tract dysfunction, LUTS, pelvic floor muscle pain, standardization

1 | INTRODUCTION

CPP is defined as a noncyclical pain that has duration of at least 6 months, and it can lead to decreased quality of

life and physical performance.¹ The presentation can be a challenge to assess and treat. This is because the pain can potentially be attributed to several contributory factors, in the context of the varied nature of pain responses manifested by individuals. Healthcare professionals (HCPs) need to consider gynecological, urological, gastrointestinal, musculoskeletal, neurological, or

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

rheumatological factors, with possible psycho-social attributes. Due to its complex nature, CPP syndromes are multifactorial and the current terminology aims to standardize descriptions, regardless of which type of specialist is performing the evaluation.

2 | METHODS

A standard for terminology in CPP syndromes was developed in accordance with the International Continence Society (ICS) Standardization Steering Committee methodology.² The current review is a synthesis of the key aspects of the standard for practical use in everyday practice.

3 | OVERVIEW

For a patient presenting with pelvic pain, thorough history is crucial, including establishing that the pain has been present for at least 6 months, identification of any potential inciting event and/or triggers, character, radiation, and severity. An indication of the source of pain is vital, yet it can be obscured in individual cases by the range of possible primary sources and secondary consequences, and the varied responses. To ensure a systematic approach, the ICS sets out a series of “domains” which facilitate consideration of possible issues.

The domains of chronic pelvic pain (CPP) syndromes include four which consider the pelvic organs;

1. Lower urinary tract domain
2. Female genital domain
3. Male genital domain
4. Gastrointestinal domain

Two domains consider other sources of pain which may be perceived in the pelvis, even if the actual site of the problem may not be within the pelvis;

5. Musculoskeletal domain
6. Neurological domain

The final three domains relate to general factors that could influence the response to the pain or its impact on the individual;

7. Psychological domain
8. Sexual domain
9. Comorbidities

In any domain, features may be present as a result of a primary problem, or a secondary consequence. Each domain is evaluated with directed history-taking and a comprehensive physical examination done with a focus on the lower abdomen/pelvis to identify pain triggers and patterns of referred pain. The HCP can surmise the possible source of the

TABLE 1 Lower urinary tract domain

Symptoms	Signs	Evaluation	Syndrome/Disease
Bladder			
Increased daytime frequency	Suprapubic tenderness	Questionnaires	Hypersensitivity bladder
Increased night-time frequency	Tenderness of bladder	Voiding diary	Interstitial cystitis/bladder pain syndrome
Urgency	Tenderness of the pelvic floor muscles	Urine analysis	Interstitial cystitis/Hunner lesion
Hypersensitivity		Optional: urine culture/ cytology Intravesical anesthetic challenge	
Pain, pressure, discomfort with filling		Urodynamics Cystoscopy (biopsy)	
Hesitancy			
Intermittency			
Feeling of incomplete bladder emptying			
Urethra			
Frequency/urgency painful urination	Tenderness of the urethra	Urine analysis	Urethral pain

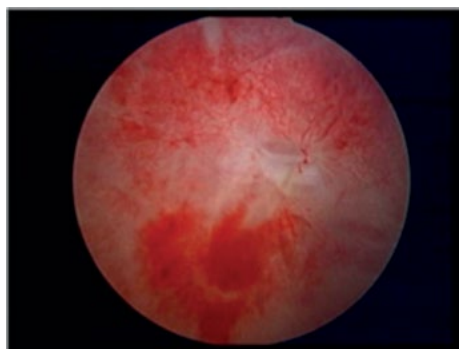


FIGURE 1 The endoscopic appearances of bleeding and ulceration during general anesthetic cystoscopy indicate that the lower urinary tract domain is a contributory factor in CPP, especially if there are pain reactions such as tachycardia, tachypnoea, and hypertension

pain, relevant additional factors, and potential secondary consequences. Specific assessment and treatment requires access to multidisciplinary support, and awareness of the initiatives and guidance developed by a range of organizations and expert groups.^{3–5} Imaging, endoscopy and special tests may be needed for evaluation of each domain considered influential for a patient. With the individual evaluation in mind, further investigation and initial therapy can be planned based on the multidisciplinary support and up-to-date awareness of clinical recommendations and guidelines.

As an example, chronic prostatitis will be associated with history and examination features in the male genital domain (the primary site of the problem), and the lower urinary tract and musculoskeletal domains (where secondary problems such as increased urinary frequency and muscle spasms may be experienced). The full scope of impact on the patient may be further driven by issues in the psychological and sexual domains.

3.1 | Domains related to the pelvic organs

The lower urinary tract domain (Table 1) incorporates the bladder and urethra. The global definitions for bladder pain syndrome (BPS) and interstitial cystitis (IC) are not fully standardized, as several professional organizations have an interest in the area. Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction proposed the definition of IC/BPS as “an unpleasant sensation (pain pressure, discomfort) perceived to be related to the urinary bladder, associated with lower urinary tract symptoms of more than 6 weeks duration in the absence of other identifiable causes.”⁶ For the bladder, patients may complain of increased urinary frequency (day and night), urgency, hypersensitivity, pain, pressure, discomfort, hesitancy, pain with filling, and sensation of incomplete emptying. The situation may be associated with relevant findings on general anesthetic cystoscopy (Figure 1). If the urethra is a significant contributor, pain is perceived usually when voiding and can be combined with a dull pressure that may radiate towards the groin or perineum.

The genital domains comprise the female genital domain (Table 2) and the Male Genital Domain (Table 3). Female patients may report pain with menstruation, abnormal bleeding, dyspareunia, vaginal discharge or itching, voiding/defecatory pain, and/or abdominal/pelvic pain. Pain mapping with a Q-tip is done to elicit localized areas of tenderness, which may be identified in the vagina or external genitalia. Generalized vulvar pain syndrome refers to pain/burning that cannot be localized by pain mapping. It is important to identify any ulcers, fissures, or cysts of the vulva. In addition, intra-abdominal signs related to the uterus and adnexa may indicate other pathology, such as fibroids, cysts, pelvic masses, endometriosis, or adhesive disease. These can present with uterine tenderness, cervical discharge or tenderness, or adnexal tenderness

Male patients may reports symptoms related to the lower urinary tract and sexual dysfunction. There may be complaints of dysuria, sensation of incomplete emptying,

TABLE 2 Female genital domain

Symptoms	Signs	Evaluation	Syndrome/Disease
Vagina			
Dyspareunia Sharp burning and/or stabbing Provocation of pain with touch	Tenderness Erythema	Pain mapping Q-tip touch sensitivity	Vaginal/vulvar/perineal pain
Intraabdominal female genital			
Dysmenorrhea Abnormal uterine bleeding Dyspareunia Itching, stabbing, burning pain Cyclic (episodic or persistent)	Tenderness: uterine/adnexal	Laboratory testing Pelvic ultrasound Laparoscopy/biopsy CT-scan	Ovarian Pelvic congestion Uterine Tubal

TABLE 3 Male genital domain

Symptoms	Signs	Evaluation	Syndrome/ Disease
Pain	Tenderness on rectal/genital examination	Questionnaires	Prostate pain
LUTS	Urethral discharge	Culture	
Dyspareunia		PSA/biopsy	
Erectile dysfunction (Persistent) or episodic		Cystoscopy/biopsy	
		Ultrasound	
	Tenderness on physical examination	Questionnaires	Scrotal pain
	Scars	Ultrasound	Epididymal pain
			Testicular pain
			Penile pain

TABLE 4 Gastrointestinal domain

Symptoms	Signs	Evaluation	Syndrome/Disease
Pain with defecation	Tenderness on rectal exam	Questionnaires	Anorectal pain
Evacuation dysfunction		Culture	
Pain/pressure with sitting		Colonoscopy/biopsy	
Abdominal pain	Abdominal tenderness	Ultrasound CT/barium enema/MRI	Colorectal pain
Nausea	Bloating		
Constipation/diarrhea			
Persistent or episodic			

TABLE 5 Musculoskeletal domain

Symptoms	Signs	Evaluation	Syndrome/Disease
Abdominopelvic pain	Altered muscle tone	Questionnaires	Pelvic muscle pain syndrome
	Tension: spasms	Pain mapping	Coccyx pain syndrome
Pain at rest, with movement/ sitting/sexual activity	Stiffness	Ultrasound	Pelvic joint, ligament, bony pain
Pain with voiding/defecation	Trigger point tenderness		
Unilateral/bilateral	Taut band		
Persistent or episodic	Twitch response, referred pain		

TABLE 6 Neurological aspects domain

Symptoms	Signs	Evaluation	Syndrome/Disease
Characteristic sensation of:	Tenderness (nerve distribution)	Questionnaires	Somatic neuropathic pain
Burning	Referred pain	Quantitative sensory testing	Complex regional pain syndrome
Throbbing	Possible skin change	Pain mapping	
Stabbing		Nerve block	
Shooting		imaging: Ultrasound MRI	
Electric shock-like Sensation			
paresthesia			
Atrophy			
Persistent or episodic			

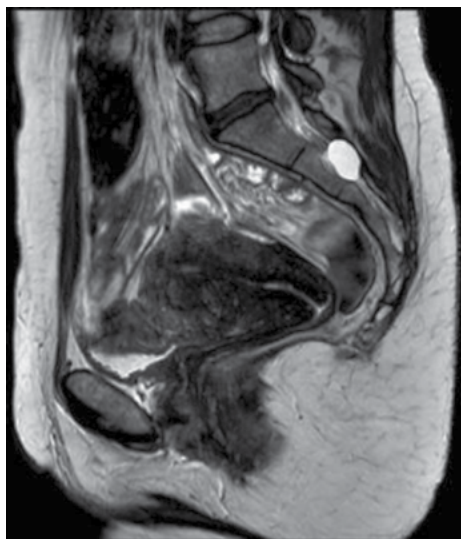


FIGURE 2 Observation of a sacral nerve root “Tarlov” cyst suggests the neurological domain may be a factor in a patient’s CPP

increased daytime frequency, change in urinary stream, urgency, and dyspareunia (assuming infection, surgical complications, or other pathology have been excluded). The assessment of CPP in males should prompt questioning to assess for onset, duration, inciting factors, laterality and any effect on urination and sexual function. A rectal examination is needed, and thorough evaluation of the genitalia, which may be performed in the supine and standing positions to identify any lesions, masses, and discharge.

Patients affected in the gastrointestinal domain (Table 4) commonly report constipation, diarrhea, defecatory pain, obstructive defecation, abdominal cramping, or rectal pain/pressure/burning. The main components are the anorectum or colorectum. Anorectal problems may result from hemorrhoids, abscesses, fissures, ulcers, levator ani syndrome, or chronic proctalgia. Colorectal problems may give rise to abdominal tenderness, watery/bloody diarrhea, or rectal bleeding and systemic features (weight loss and fever). Inflammatory bowel disease and malignancy must be excluded. Functional disorders should be ruled out, including irritable bowel syndrome.⁷

TABLE 7 Psychological aspects domain

Symptoms	Signs	Evaluation	Syndrome/Disease
Worry	Helplessness	Formal psychological assessment	Worry/anxiety/fear/depression
Anxiety	Hopelessness	Asking patient what is wrong and what worries him/her about pain	
Fear	Avoidance of certain activities	Questionnaires	
Catastrophizing			
Persistent or episodic			

TABLE 8 Sexual aspects domain

Symptoms	Signs	Evaluation	Syndrome/Disease
Lack of desire, arousal, orgasm	Depression	Questionnaires	Sexual dysfunction
Dyspareunia	Relationship issues	Laboratory	
Persistent or episodic		Doppler ultrasound	

TABLE 9 Comorbidities

Symptoms	Signs	Evaluation	Syndrome/Disease
Allergies	Fatigue	General medical evaluation	Allergies
Fatigue	Skin lesions	Laboratory Imaging	Chronic pain and fatigue syndrome
Widespread muscular and joint pain	Dry eye		Systemic autoimmune diseases
Irritation of the eyes	Muscular skeletal tenderness		
Dryness			
Sleep disorder			

3.2 | Domains related to other causes of pain

Musculoskeletal problems are common, and sometimes are hard to localize for the patient. In CPP, they may be the principle cause of pain, or they may be consequential as the patient makes physical adaptations to deal with their primary problem (Table 5). Features that indicate a primary or secondary musculoskeletal problem include; tenderness, abnormal movement and alterations in the muscle (tone, stiffness, tension, spasms, cramping, fasciculation, and trigger points). Pain may originate from muscles, fascia, ligaments, joints, or bones, so familiarity with the anatomy and approaches to clinical examination is needed. Particularly key regions include;

- Muscular: the pelvic floor⁸ (levator ani group/perineum), the lower abdominal wall, or posterior pelvic and gluteal regions.
- Joints, ligaments and bones: Coccyx pain syndrome, sacroiliac or pubic symphysis joints, sacrospinous or sacrotuberous ligaments, or the pubic ramus, ilium, and ischial spine

Where there is an issue in the neurological domain (Table 6), patients commonly use characteristic terms to describe pain (burning, stabbing, throbbing, tingling, stinging, electric shock-like) or they may report paresthesia. Somatic Neuropathic pain is secondary to a specific nerve injury, and is associated with symptoms related to the nerve distribution. In CPP, the relevant nerves could be sacral (Figure 2), pudendal, thoracolumbar, ilioinguinal, iliohypogastric, genitofemoral or obturator. A neuroma secondary to surgery or other trauma may give a localized tender point in the specific location, and if present should be identified and removed.

Complex regional pain syndrome (CRPS)⁹ is a situation whose precise etiology is uncertain, but it can be categorized by burning pain and changes in the skin (increased sensitivity, and changes in skin temperature, color, and/or texture). CRPS type 1 is triggered by tissue injury without an underlying nerve injury and CRPS type 2 is attributed to a history of a nerve injury.

Pain in someone with a history of surgery which involved placement of synthetic is a specific issue. It can present as pain during physical activity, dyspareunia, vaginal discharge, and/or exposure of the mesh in the vagina or surrounding tissues.

3.3 | Domains affecting response or impact

Psychological aspects are an important element in the individual situation (Table 7). Patients may report symptoms of anxiety, worry, low mood, sleep disturbances, helplessness, hopelessness, difficulty concentrating, and pain impairing enjoyment. Alternatively, people close to the affected person may observe these features.

Sexual function may be affected by CPP in both men and women, and relationships may be affected (Table 8). Patients may report decreased libido, inability to become aroused, dyspareunia, and difficulty achieving an orgasm, and there may also be partner concerns. Several disorders can be identified;

- Sexual desire disorders; Hypoactive sexual disorder or Sexual aversion disorder
- Sexual arousal disorder
- Orgasmic disorder
- Sexual pain disorder

A comorbidities domain is also included (Table 9), as patients with CPP syndromes have a higher prevalence of problems such as allergies, chronic fatigue syndromes, fibromyalgia, and autoimmune diseases that may affect multiple systems.

4 | CONCLUSIONS

The current document extracts some of the pertinent elements that should be identified in order to understand fully the range of factors potentially present in CPP. The domain structure serves as a checklist to aid consideration of the several issues, and thereby ensure key relevant factors are not overlooked. The approach aids a logical sequence in considering the pelvic organs, other potential sources of pain, and factors that affect individual pain response and its impact.

CONFLICTS OF INTEREST

Drs Neha Rana, Marcus J. Drake, Rebecca Rinko, and Melissa Dawson have nothing to disclose. Dr Kristene Whitmore reports grants from Allergan, grants from Astellas, and grants from Coloplast clinical research during the conduct of the study.

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How to use the Pelvic Organ Prolapse Quantification (POP-Q) system?

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Aims: To set out the basic description of pelvic organ prolapse (POP) using the International Continence Society/International Urogynecology Association Pelvic Organ Prolapse Quantification (POP-Q) system.

Methods: The basic approach to use of the POP-Q was identified and summarized.

Results: Six defined points in the vagina are identified; points Aa and Ba for the anterior vagina, Ap and Bp for the posterior vagina, and C and D for the cervix/vault. Point D is not used in women who previously had a hysterectomy. The patient is asked to strain, ideally when in the standing position, to elicit the POP to its maximum extent. The location of the defined points is then gauged relative to the hymenal ring and recorded on a grid. Three additional measurements are taken to achieve a full description; the genital hiatus length, perineal body length, and total vaginal length. Staging a POP relies on identifying the lowest extent of any part of the six defined points; if any point reaches close to the hymenal ring (at least stage 2), the prolapse is usually symptomatic.

Conclusions: The POP-Q system is readily cataloged and offers detailed description of considerable benefit in clinical practice and research.

KEYWORDS

Pelvic organ prolapse quantification. POP-Q, Prolapse assessment

1 | INTRODUCTION

The International Continence Society (ICS), the American Urogynecologic Society, and the Society of Gynecologic Surgeons published a consensus document in 1996 to describing an objective system to describe female pelvic organ prolapse, which was called the Pelvic Organ Prolapse Quantification system (POP-Q).¹ This is the classification system that should be used to describe pelvic organ prolapse, as recommended by the ICS/International Urogynecology Association (IUGA) joint report on terminology for female

pelvic floor dysfunction.^{2,3} The POP-Q has been used variably in both clinical practice and research.^{4,5} The ICS/IUGA have recently made some suggestions to better define the disease of pelvic organ prolapse.³ The aim of this article is to briefly summarize the key points in performing the POP-Q examination system to assist in its routine use.

2 | METHODOLOGY

The technique of performing the POP-Q has been described in detail in the ICS/IUGA documents.^{2,3} We have summarized the key points that should be considered while performing the POP-Q examination.

Jan-Paul Roovers led the peer-review process as the Associate Editor responsible for the paper.

TABLE 1 Showing the POPQ measurements (Adapted from Haylen et al²)

POPQ: Measurements
The locations of the six defined points when the prolapse is fully reduced.
Anterior vaginal wall:
1. Point Aa: A point located in the midline of the anterior vaginal wall three (3) cm proximal to the external urethral meatus. The potential range of position of Point Aa relative to the hymen is -3 , indicating no anterior vaginal POP, to $+3$ cm which is full prolapse
2. Point Ba: A point that represents the most distal (ie, most dependent) position of any part of the upper anterior vaginal wall (between the vaginal cuff or anterior vaginal fornix and Point Aa). Point Ba coincides with Point Aa (-3 cm) in a woman who has no anterior POP. In a woman with severe POP, Ba coincides with Point C.
Upper vagina:
3. Point C: A point on either the most distal (ie, most dependent) edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar).
4. Point D: The posterior fornix in a woman who still has a cervix. ^a
Posterior vaginal wall:
5. Point Ap: A point located in the midline of the posterior vaginal wall three (3) cm proximal to the hymen. The potential range of position of Point Ap relative to the hymen is -3 to $+3$ cm
6. Point Bp: A point that represents the most distal position of any part of the upper posterior vaginal wall (between the vaginal cuff or posterior vaginal fornix and Point Ap).
Three further descriptive landmarks and measurements.
1. The genital hiatus (GH) is measured from the middle of the external urethral meatus to the posterior margin of the hymen.
2. The total vaginal length (TVL) is the length of the vagina (cm) from posterior fornix to hymen when Point C or D is reduced to its full normal position.
3. The perineal body (PB) is measured from the posterior margin of the hymen to the mid-anal opening.

^aPoint D is included as a point of measurement to differentiate suspensory failure of the uterosacral-cardinal ligament “complex” from cervical elongation. When the location of Point C is significantly more positive than the location of Point D, this is indicative of cervical elongation which may be symmetrical or eccentric. Point D is omitted in the absence of the cervix.

3 | RESULTS

POP-Q can be performed using the following four steps:

Step 1: Pre-procedure considerations

Examination should be performed with an empty bladder and if possible an empty rectum. A full bladder is potentially associated with underestimation of the POP-Q severity.⁶ Any position that best demonstrates the maximum extent of the

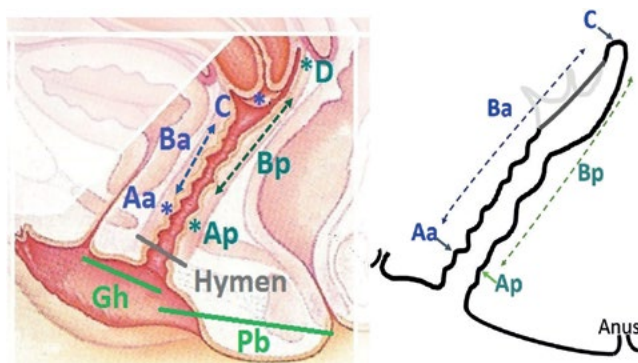


FIGURE 1 The six defined points used to quantify POP in women without (left) or with (right) a previous hysterectomy. Aa and Ap are 3 cm from the hymen when there is no POP, or any POP is fully reduced. POP-Q identifies where these points come to lie relative to the hymenal plane with the POP fully evident. Ba and Bp reflect the lowest point reached by a POP, relative to the hymenal plane. Any part of the vagina could potentially descend furthest, so Ba may lie anywhere from Aa-C. Bp may lie anywhere from Ap-D, or Ap-C in a woman post hysterectomy, from respectively reaching the locoincidence with Aa and Ap in a woman who does not have POP. Three measurements complete the description; the genital hiatus (Gh), the perineal body (Pb), and the total vaginal length (not shown)

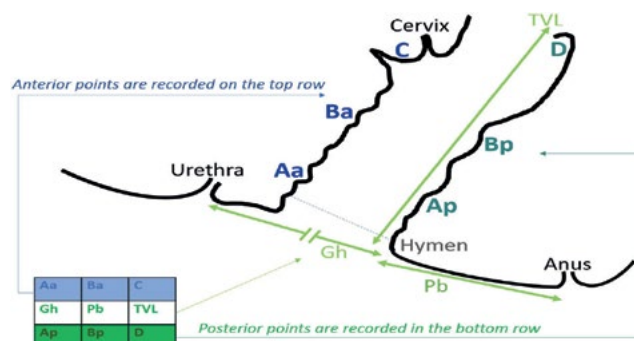


FIGURE 2 How the six defined point and three measurements relate to a 3×3 grid used for clinical documentation. Gh, genital hiatus; Pb, perineal body; TVL, total vaginal length

prolapse and which can be confirmed by the woman, by digital palpation or use of a mirror, should be used (left lateral, standing, lithotomy, or standing). Use a Sim's speculum if necessary to retract the anterior and posterior vaginal walls to assess for prolapse. The techniques and positions used should be recorded, as they may influence findings.⁷

Step 2: Measurements ("points to remember") (Table 1, Figure 1):

- There are six defined points (Aa, Ba, C, D, Ap, Bp) that are considered while recording the POP-Q, which are used to report the extent of descent or prolapse of the anterior vaginal wall, vaginal apex, and posterior wall.
- The positions of these six defined points are measured during maximal Valsalva or cough in relation to the hymen. If the point descends to the hymen it is measured as 0 cm, if it remains above the hymen it is measured in centimeters and described as negative integers and if it descends beyond the hymen it is

measured in centimeters and described as positive integers. For example, if point C remains 4 cm above the hymen during Valsalva/cough it is recorded as -4 cm. If point C descends 4 cm beyond the hymen during Valsalva/cough it is recorded as +4 cm.

- There are three further descriptive measurements, which are also recorded independent of the hymen (genital hiatus-point GH, perineal body-point PB, and total vaginal length at rest-point TVL). Of note, all of the POP-Q points are recorded during maximal Valsalva or cough except for point TVL which is recorded at rest with the prolapse reduced.

Step 3: Recording the measurements (Figure 2):

The above measurements are recorded on a 3×3 grid. The anterior vaginal wall and the cervix or vault are documented on the top row, the posterior vaginal wall, and the posterior fornix on the bottom row. The descriptive measurements of the genital hiatus, perineal

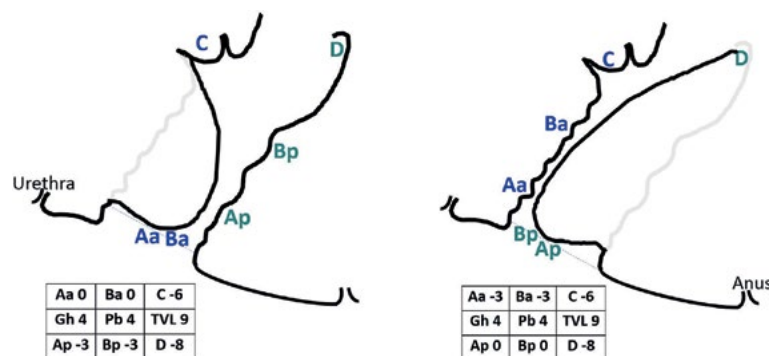


FIGURE 3 POPQ staging of a second stage anterior (left) and second stage posterior (right) vaginal wall prolapse

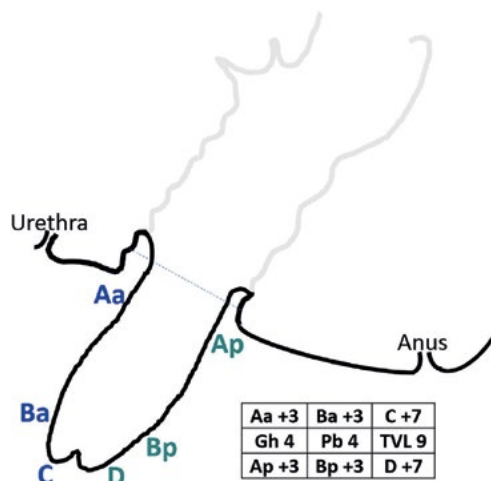


FIGURE 4 POPQ staging of a stage 4 pelvic organ prolapse (procidentia)

body, and total vaginal length at rest are recorded in the middle row.

Step 4: Staging of the prolapse

Depending on the measurements, prolapse of each of the compartments is staged based on its relationship to the hymen.

- Stage 0: No prolapse is demonstrated (points Aa, Ba, C, D, Ap, and Bp are all ≤ -3 cm).

- Stage I: The most distal portion of the prolapse is more than 1 cm above the level of the hymen (points Aa, Ba, C, D, Ap, and Bp are all < -1 cm).
- Stage II (Figure 3): The most distal portion of the prolapse is situated between 1 cm above the hymen and 1 cm below the hymen (any of the points Aa, Ba, C, D, Ap, and Bp has a value between -1 cm and $+1$ cm).
- Stage III: The most distal portion of the prolapse is more than 1 cm beyond the plane of the hymen, but not completely everted meaning no value is $\geq \text{TVL} - 2$ cm (any of the points Aa, Ba, C, D, Ap, Bp is $\geq +2$ and $\leq \text{TVL} - 3$ cm)
- Stage IV (Figure 4): Complete eversion or eversion to within 2 cm of the total vaginal length of the lower genital tract is demonstrated (any of the Points Ba, C, D, or Bp is $\geq \text{TVL} - 2$ cm).

The steps of performing a POP-Q are summarized in Figure 5 and some examples of POPQ recording and staging of various prolapse are demonstrated in Figures 3 and 4.

4 | DISCUSSION

Since its introduction in 1996, POP-Q has been used variably in peer-reviewed publications.⁸ It may be perceived as complex, but it has shown good inter-observer agreement and is the most common system used in peer-reviewed literature.⁹⁻¹¹ It has been criticized as being too complicated, difficult to use, teach, and communicate.¹² Various approaches and tools have been used to teach POP-Q and have all been shown to be effective.^{13,14}

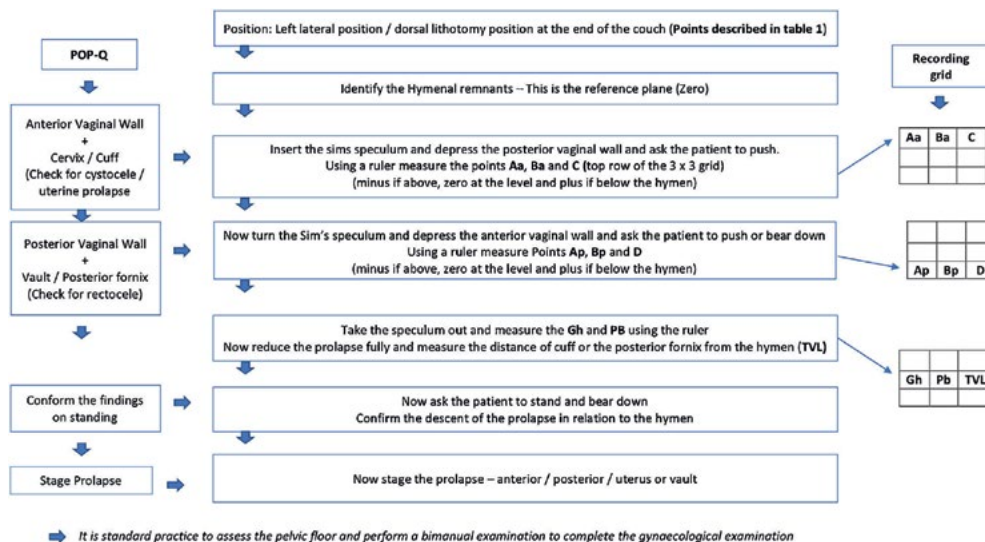


FIGURE 5 Practical aspects of performing POP-Q

4.1 | Clinical relevance of POP-Q

Women with POP generally present with several complaints of bladder, bowel, and pelvic dysfunction; however, the symptom of a vaginal bulge is considered specific to prolapse and correlates well with the severity for the prolapse.^{15,16} POP is generally considered to be symptomatic when the leading edge of the prolapse is at or beyond the level of the hymen (\geq stage 2 POP-Q).¹⁷ Another study suggested that the prolapse becomes symptomatic if it descends lower than a level 0.5 cm above the hymen (\geq Stage 2 POP-Q).¹⁸ Genital hiatus size is associated with and predictive of apical vaginal support loss.^{19,20} These factors need to be taken in to consideration when diagnosing and offering treatment options to women with prolapse.

5 | CONCLUSION

POP-Q is a useful way of objectively assessing and recording pelvic organ prolapse and helps in better communication of findings. Stage 2 or above POP-Q seems to correlate well with a symptomatic prolapse.

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The fundamentals of uroflowmetry practice, based on International Continence Society good urodynamic practices recommendations

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Aims: To review the recommendations on uroflowmetry in the International Continence Society (ICS) Standardization documents in order to identify a systematic approach to the delivery and interpretation of free flow rate testing in clinical practice.**Methods:** Expectations of service and good practice in uroflowmetry described in the ICS standards on Urodynamic Practice, Urodynamic Equipment, and Terminology for Lower Urinary Tract Function were identified and summarized.**Results:** Urodynamic centers should provide a suitable uroflowmetry testing environment. Equipment should be calibrated and maintained according to manufacturer requirements. Patients should be well-informed in advance of the test. They should be advised to avoid: knocking the machine; allowing the stream to move; squeezing the urethra; and body movements. It is generally appropriate to get more than one flow trace for each patient. Voided volume should be representative for the patient, for example by comparing with values recorded on a Bladder Diary. Post void residual (PVR) should be measured soon after testing. After the test, the urodynamicist should review the trace and ensure maximum flow rate and end of micturition are correctly identified in case the equipment has inappropriately taken the values from a trace artefact.**Conclusions:** The summary provides a systematic approach to ensure a representative, high quality, non-invasive flow test is carried out for individual patients.**KEYWORDS**

free flows, standards

1 | INTRODUCTION

Urodynamics is the general term to describe the measurements that assess the function and dysfunction of the lower urinary tract (LUT) by any appropriate method. In

the clinical assessment of LUT symptoms (LUTS), evaluating the nature of an individual's voiding is a fundamental component of the diagnostic pathway, especially for men. Uroflowmetry is a non-invasive urodynamic test in which specific measurements are made of the rate of flow of urine and the volume voided. It is normally followed by an ultrasonically scanned measurement of post void residual (PVR) urine volume, and an interpretation of the flow pattern recorded by the machine over the duration of the void.

The work was undertaken at Bristol Urological Institute, Southmead Hospital, Bristol, UK.

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

A recent think tank on uroflowmetry¹ recommended that specific, practical guidance be made available to increase the quality of uroflowmetry testing. Accordingly, the current article reviews the recommendations on uroflowmetry in the International Continence Society (ICS) Standardization documents in order to identify a systematic approach to the delivery and interpretation of free flow rate testing in clinical practice.

2 | METHODS

The ICS, through its Standardization Steering Committee (SSC), has an ongoing strategy to standardize LUT terminology and functional assessment, and link it to published evidence.² We reviewed key expectations of service and good practice in uroflowmetry described in the ICS standards on Urodynamic Practice,^{3,4} Urodynamic Equipment,⁵ and Terminology for LUT Function.^{6,7} The current document is a synthesis of the key aspects applicable to uroflowmetry.

3 | GENERAL COMMENTS

A good urodynamic practice comprises: a clear indication for, and appropriate selection of, relevant test measurements and procedures; precise measurement with data quality control and complete documentation; accurate analysis and critical reporting of results. These general principles apply to all forms of urodynamic testing, including uroflowmetry.

Departments should develop uroflowmetry protocols on the basis of the ICS Urodynamic standards,³⁻⁵ they should facilitate specific staff training and undertake regular evaluation of performance and adherence.³ ICS Terminology Standards should be used when alluding to LUT symptoms, signs, and urodynamic observations.^{6,7} Equipment should meet the requirements of the ICS guideline on equipment performance.⁵

Uroflowmetry is a test that measures the urinary stream as volume passed per unit time in milliliters per second (mL/s).⁴ Maximum flow rate (Q_{max}) and total volume voided must be reported.⁴ The PVR should also be reported. This is the remaining intravesical fluid volume determined immediately after completion of voiding. The technique (eg, ultrasound or catheter) used to measure the PVR should be specified.

4 | EQUIPMENT AND ENVIRONMENT

The basic set up for a flow test environment is illustrated in Figure 1. The requirement of a uroflowmeter is that it can continuously measure the flow rate of urine voided and the total volume voided. The method used to make this measurement is not clinically significant. Accuracy need only

be to ± 1 mL/s of true flow rate and to $\pm 5\%$ of true volume voided (or ± 2 mL if that is greater than 5%).⁵

Units should regularly check the performance of their system and calibrate according to manufacturer recommendation.⁵ Flowmeter calibration can be verified by pouring a precise volume into the flowmeter and checking the recorded volume. Calibration should be verified regularly, for example, at the start of every clinic or week of clinics, and documented. If frequent recalibration is necessary, the flow transducer might need to be replaced.

Uroflowmetry equipment should be placed in a private, quiet environment³ that can be easily cleaned, with the machine ready for immediate use, as many LUTS patients having flow rate testing will experience urgency. PVR measurement is ideally done in the same room and immediately following the void. A sluice room with connecting door to the flow test room is preferable to an unconnected room.

5 | PREPARATIONS IN ADVANCE OF A UROFLOWMETRY TEST

An explanatory leaflet about uroflowmetry with sufficient information, which uses clear, unambiguous wording, will be appreciated by most patients. To reduce possible waiting time, patients can be asked to attend the clinic with a comfortably full bladder.

When sent the explanatory leaflet, the patient can also be asked to complete a frequency volume chart (FVC) or Bladder Diary. A FVC records the time of each micturition and the voided volumes, while a Bladder Diary also captures symptoms and events such as fluid intake, urgency, pain, incontinence episodes, and pad usage.^{6,8} Average and maximum voided volumes, voiding frequency, and day/night urine production can be determined.



FIGURE 1 A suitable environment for uroflowmetry. The flowmeter can be accessed quickly from the waiting area if the patient experience urgency, achieves privacy (here by having a curtain in addition to a locked doorway), is easy to clean, and has direct access to a sluice room (not in above picture). Female uroflowmetry would have a commode seat in addition to the funnel

6 | FLOW RATE TESTING

Patients should be asked to pass urine when they feel a “normal” desire to void,⁴ and should undergo uroflowmetry in their preferred position. Intracorporeal modulations of the

flow rate should be minimized, for example, by asking the patient to relax and not to strain.⁴ Men should be asked not to move the urine stream around the funnel, and not to squeeze the penis, both of which will affect the flow rate measurement (Figure 2).⁷

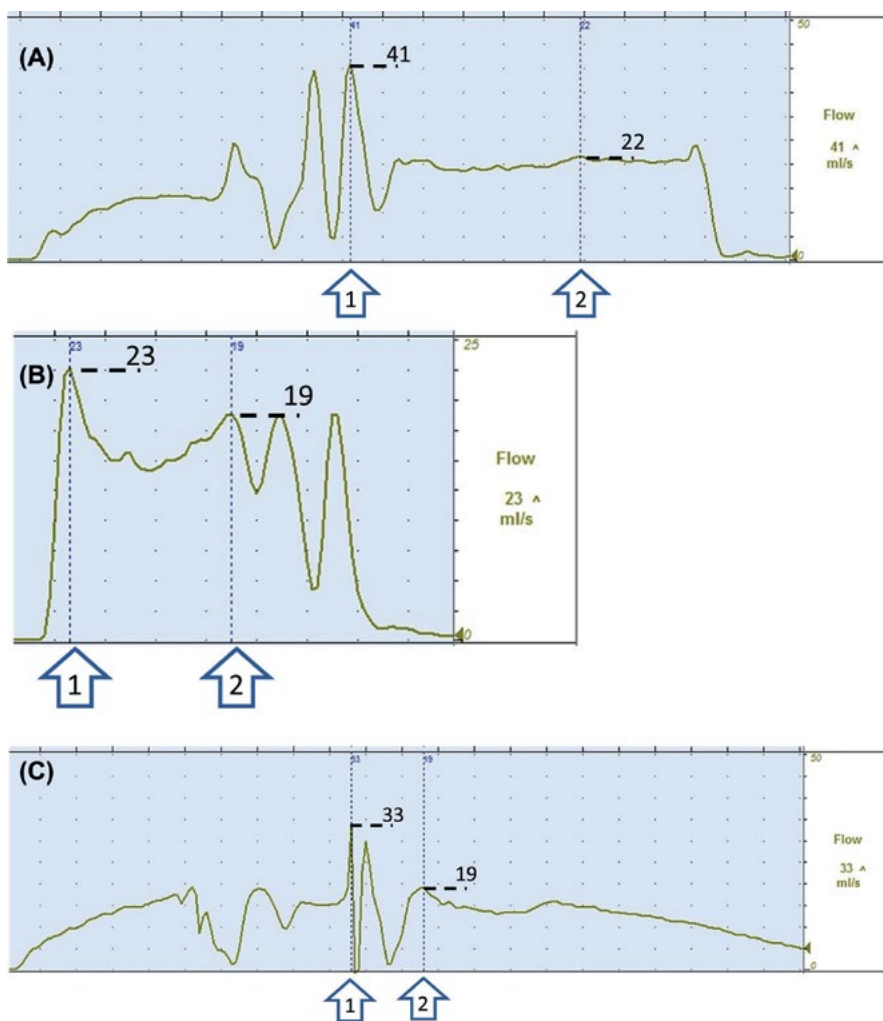


FIGURE 2 Some artefacts encountered in uroflowmetry, and the importance of correcting for the error in Q_{\max} to establish the representative parameter. A, A male patient moving the urine stream back-and-forth across the funnel. B, A male squeezing and releasing the urethra at the start of flow, with straining toward the end of flow. C, A “knock artefact” (arrowed), resulting from a patient inadvertently kicking the uroflowmetry machine. In each case, the uroflowmetry machine has given a Q_{\max} value which is a result of the artefact, displayed on the right hand side, and taken from the point marked with arrow “1.” This is not representative of the patient’s own function, so the urodynamicist has scrutinized the trace after the test and selected the highest point in the trace that does appear to result from the patient’s own unimpeded bladder and outlet behavior, at the point marked with arrow “2.” This means the representative values change, for instance in A from 41 to 22 mL/s, which may well result in a clinically significant difference in interpretation. Before a flow test, the patient should be instructed to keep his stream in the same part of the funnel, not to squeeze his penis, and try to avoid knocking the machine

TABLE 1 Task list to assist good practice in uroflowmetry

Task No.	Good practice question	If “No,” correction needed
1	Has equipment calibration been checked?	Check calibration
2	Is the patient aware of the reason for the test and what is required of them?	Explain to patient
3	Has the bladder diary been completed and examined?	Discuss with patient to gain estimates
4	Does the patient have a normal desire to void?	Wait until normal desire
5	Is the equipment set at the right height and position?	Adjust to suit patient
6	After the void, has urinalysis been carried out?	Perform urinalysis
7	Is the void known to be a representative normal void?	Repeat flow test after drinking
8	Is the trace clear of artefacts from movement of body, flowmeter or urine stream?	Adjust trace markers if possible, and instruct patient for improved next flow
9	Is Q_{\max} marked at a point away from artefacts?	Move Q_{\max} marker to smoothed maximum position
10	Are the markers for start and end of void away from artefacts or drops of urine?	Move markers away from artefacts
11	Does the scale of printing make the flow trace clearly visible?	Adjust scale of display/print
12	Has the residual urine volume been measured immediately after voiding?	Measure volume, including comment on any time delay
13	Does the report include: Q_{\max} , voided volume, residual volume, Void%, flow and voiding times, flow trace shape description, whether flow is representative? The report may also include if required: Clinical history summary, urinalysis, bladder diary summary and any lifestyle advice given.	Complete report

Practitioners should check if the voiding is representative, based on the patient's report, and comparing with other information, such as Bladder Diary volumes. Increasing bladder volume increases the potential bladder power,⁴ notably in the

range from empty up to 150-250 mL. At volumes higher than 400-500 mL, the detrusor may become overstretched and contractile strength may decrease. Thus, interpretation should evaluate the bladder volume at time of testing (voided volume plus PVR).

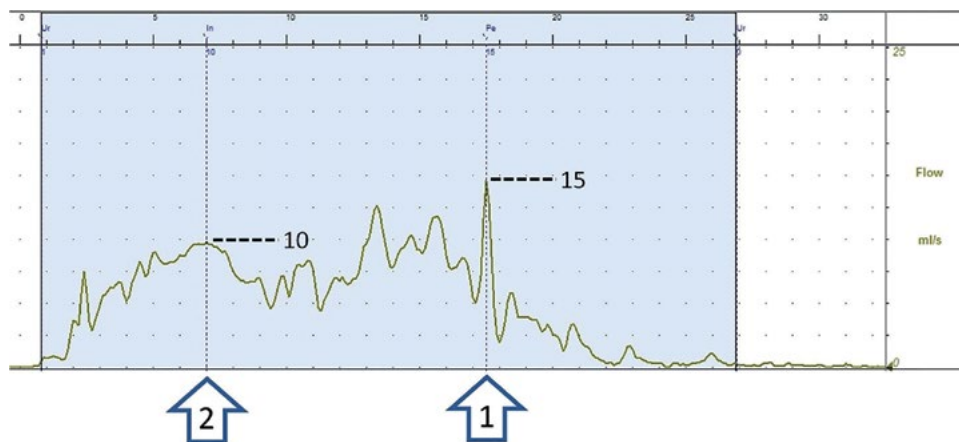


FIGURE 3 Example of a female patient who may have some pelvic floor contractions during voiding, leading to the uneven shape of the curve. This patient may also have moved about on the commode seat, giving rise to the particularly sharp spike. The computer-generated report reads $Q_{\max} = 15$ mL/s, taking the value at arrow “1.” After the test, the urodynamicist identified this is not representative, and moved the cursor to the position of arrow “2,” where a portion of the flow unaffected by pelvic floor contraction and patient movement suggests an interpretable and representative flow. Q_{\max} value was accordingly corrected to 10 mL/s, and should be recorded as such, with comment on whether the flow was representative

Consider repeating the uroflowmetry if the result has not been representative for the patient or it indicates abnormality, with reasonable fluid intake and diuresis time before the flow is repeated.⁹

A list of tasks to aid good practice is contained in Table 1.

7 | QUALITY CONTROL

Several artefacts can occur which are readily identified: knocking of the flowmeter (Figure 2C), passing of feces or disposal of tissues result in high, sudden values of flow rate and/or volume. If such fast changes are observed and confirmed with the patient, instruction of the patient will improve the next flow test.

Moving the urine stream back and forth across the funnel results in phasic variations around the true flow rate (Figure 2A). Some men have developed the habit of squeezing the penis to build up pressure, in order to give a faster flow after release. This “squeeze and release” habit gives gaps in the flow followed by high flow rate spurts, illustrated in Figure 2B. In both cases, the patient should be instructed not to do so, in order to better evaluate the LUT itself. For some patients, pelvic floor muscle action or body movement can result in smaller, artefactual variations in flow rate, see Figure 3. Uroflowmetry machines will automatically, and perhaps wrongly, measure the highest peak of flow, rather than smooth out the flow rate to remove these artefacts. Accordingly, in each of these situations, the operator will need to move the Q_{\max} marker to a nearby point, or smooth the flow signal by eye, in order to establish the clinically representative value (Figures 2 and 3). A moving average using a 2 s window is advised.³

If the flow and voiding times are being reported, the operator will need to check that the end of flow is correctly marked by the machine. If drops due to coughs or other movement are included in the voiding time, the final marker will need to be moved back to the true end of micturition (Figure 4) and only then should the time values be recorded.

8 | REPORTING

All results and observations should be carefully reported. It is good clinical practice to integrate the uroflowmetry results with the history, examinations and Bladder Diary summary. A urinalysis should also be evaluated and reported with the flow results, since current urinary tract inflammation could alter the patient's flow characteristics.

The report after uroflowmetry should include; voiding position, Q_{\max} (corrected for any artefacts), voided volume and PVR. Flow time and voiding time may be reported if required. The ICS suggests a standard reporting format of “VOID: Maximum Flow Rate/Volume Voided/Post Void Residual

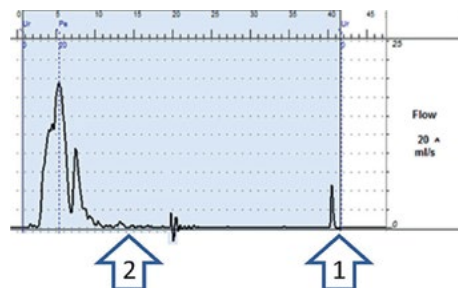


FIGURE 4 Similar to correcting the Q_{\max} value after a test, the indicator identifying the end of micturition may need to be moved, from the point marked by arrow “1” to the point marked by arrow “2” arrow, if the patient experiences a post micturition dribble, or if the machine gets knocked as the patient moves away

Volume,” where flow rate is rounded to the nearest integer and volume rounded to the nearest 10 mL.³ Scaling of the printout has been suggested as follows: 1 mm can equal 1 s on the x-axis and 1 mL/s and 10 mL voided volume on the y-axis,³ but the trace must be clearly readable whatever scale is used.

Nomograms have been produced (summarized in Gammie et al¹) that show the likelihood of the Q_{\max} and voided volume recorded resulting from a normal urinary tract. Clinicians must be aware that these nomograms are not diagnostic, but may be a useful screening tool for dysfunction.

Comment may also be made when reporting on the voided percentage (Void%) and the flow curve shape. Void% is the numerical description of the voiding efficiency, which is the proportion of bladder content emptied. Calculation: volume voided/(volume voided + PVR) *100%.

The shape or pattern of the flow curve may suggest specific types of abnormality, but reliable and specific information about the cause cannot be derived from a flow curve alone.^{1,3} The shape of the flow curve can be described as continuous or intermittent, and smooth or fluctuating.⁶

9 | CONCLUSIONS

This summary provides a systematic approach to ensure a representative, high quality, non-invasive flow test is carried out for individual patients. Adherence to the fundamentals of the ICS Standards, as synthesized in this review and summarized in Table 1, will enable urodynamic units to deliver high quality of uroflowmetry studies.

CONFLICTS OF INTEREST

Dr Andrew Gammie reports grants from Andromeda, Digitimer, and Laborie, other from Astellas and Ipsen, outside the submitted work. Dr Marcus J. Drake reports

grants, personal fees, and non-financial support from Allergan, Astellas, and Ferring, personal fees from Pfizer, outside the submitted work.

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Fundamentals of urodynamic practice, based on International Continence Society good urodynamic practices recommendations

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Aims: To review the recommendations on basic urodynamic testing in the International Continence Society (ICS) standardization documents, specifying key recommendations for delivery and interpretation in clinical practice.

Methods: Fundamental expectations described in the ICS standards on good urodynamic practices, urodynamic equipment, and terminology for lower urinary tract (LUT) function were identified and summarized.

Results: The ICS standard urodynamic protocol includes clinical history, including symptom and bother score(s), examination, 3-day voiding chart/diary, representative uroflowmetry with post-void residual, and cystometry with pressure-flow study (PFS). Liquid filled catheters are connected to pressure transducers at the same vertical pressure as the patient's pubic symphysis, taking atmospheric pressure as the zero value. Urodynamic testing is done to answer specific therapy-driven questions for treatment selection; provocations are applied to give the best chance of reproducing the problem during the test. Quality of recording is monitored throughout, and remedial steps taken for any technical issues occurring during testing. Labels are applied during the test to document events, such as patient-reported sensation, provocation tests, and permission to void. After the test, the pressure and flow traces are scrutinized to ensure artefacts do not confound the findings. An ICS standard urodynamic report details the key aspects, reporting clinical observations, technical, and quality issues. Urodynamic services must maintain and calibrate equipment according to manufacturer stipulations.

Conclusions: The review provides a succinct summary of practice expectations for a urodynamic unit offering cystometry and pressure flow studies (PFS) to an appropriate standard.

KEYWORDS

LUTS, overactive bladder, standardization, urodynamics

Alan Wein led the peer-review process as the Associate Editor responsible for the paper.

1 | INTRODUCTION

Urodynamics is the general term to describe the measurements that assess the function and dysfunction of the lower urinary tract (LUT) by any appropriate method. The aim of urodynamics is to make clinical observations while taking these measurements, in order to surmise the underlying causes for the symptoms, and to quantify the related pathophysiological processes. This should establish objectively the presence of a dysfunction and understand its clinical implications. This may either confirm a clinical diagnosis or give a new, specifically urodynamic, diagnosis.

The International Continence Society (ICS), through its Standardization Steering Committee (SSC), has an ongoing strategy to standardize LUT terminology and functional assessment, and link it to published evidence.¹ Several ICS publications underpin the professional standard in Urodynamic testing, and describe in detail the underlying thinking and the evidence base. The current document is a synthesis of the key aspects applicable for the more common Urodynamic tests used in clinical pathways.

2 | METHODS

We reviewed recommendations in the ICS standards on urodynamic practice,^{2,3} pressure flow studies (PFS),⁴ urodynamic equipment,⁵ terminology for LUT function,^{6,7} and a publication on artefacts.⁸ The review focusses on cystometry and PFS in adults without relevant neurological abnormalities and with intact “normal” anatomy of the LUT. Flow rate testing⁹ and video-urodynamics¹⁰ are described in separate documents.

2.1 | General comments

A good urodynamic practice comprises: a clear indication for and appropriate selection of relevant test measurements and procedures; precise measurement with data quality control and complete documentation; accurate analysis; reporting of results which evaluates urodynamic observations and places them into the patient's clinical context.

Departments should develop urodynamic practice protocols on the basis of the ICS urodynamic standards,^{2,3,5} they should facilitate specific staff training and undertake regular evaluation of performance and adherence.² ICS terminology standards should be used when alluding to LUT symptoms, signs, and urodynamic observations.^{6,7} Equipment, including the catheters and transducers, should meet the requirements of the ICS guideline on equipment performance.⁵

2.2 | Equipment

The basic requirement of a standard urodynamic system is that it can measure at least two pressures and calculate

detrusor pressure (p_{det}) in real time, defined as the simultaneous difference between intravesical (p_{ves}) and abdominal (p_{abd}) pressures. It can measure the flow rate of the voided volume and regulate the rate of fluid infusion. It has an on-line display of pressures and flow, with adequate scale and resolution; no information should be lost electronically when tracings go off-scale on display. It is possible to record standard information about sensation and additional comments (event recording).⁵

Systems using liquid-filled catheters and external transducers are recommended by the ICS.^{2,3} The transducer is levelled to the pubic symphysis, an anatomical landmark for the bladder, and the zero-point set to atmospheric pressure. Equipment should have the facility to move the transducers vertically in order to bring the transducers back to the level of the symphysis pubis, since patients may change position during a test. Micro-tip or air-filled catheters are not interchangeable with liquid-filled systems²; centers that utilize them should provide reference values for their data.

Using ICS standard pressures based on liquid-filled systems allows comparison of data between patients and centres. New technologies need to prove their usefulness and accuracy compared to existing ICS standard urodynamic tests before clinical application.¹¹ To date, there are no standardized pressure measurements for air-charged catheters.

2.2.1 | Calibration

Pressure transducer calibration is achieved by exposing the catheter tip to two different well-defined pressures (a pressure difference of ≥ 50 cmH₂O is recommended).⁵ The calibration should be verified regularly (eg, every 10 urodynamic measurements for non-disposable transducers) and documented.

Flowmeter calibration can be achieved by pouring a precise volume at a constant flow into the flowmeter and checking the recorded volume. Calibration should be verified regularly (eg, every 10 urodynamic measurements). If frequent recalibration is necessary, the flow transducer might need to be replaced.

Infusion pumps are tested by measuring the time to deliver a known volume. The filling catheter should be connected, as peristaltic type pumps (where a series of rollers compress a flexible tube) may show errors due to downstream resistance. Load cell measurement of infused volume is advised, as peristaltic pumps may turn even when the downstream tube is blocked.

2.3 | Preparations in advance of a urodynamic test

A leaflet clearly explaining urodynamic investigation in adequate detail will be appreciated by most patients. A table suggesting content to include in an information leaflet is

available.² Instructions must be given to the patient regarding continuation of usual LUT management (eg, medication).

A urinalysis to screen for infection or haematuria should be evaluated.

Patients should attend with a completed frequency volume chart (FVC) or bladder diary.^{6,12} They can be used to determine fluid intake, maximum and average voided volume, voiding frequency, and day/night urine production. This information supports the patient's symptom reporting, and aids plausibility control of subsequent urodynamic studies (eg, to prevent over-filling of the patient's bladder).

Urodynamic tests should be requested with the goal of answering a specific question.³ "Formulating the urodynamic question" is a process of reviewing the clinical assessment already available and what potential therapy options may subsequently be appropriate, so the test can identify appropriate treatment options and potential adverse effects.

2.4 | ICS standard urodynamics protocol

- Clinical history, including valid symptom and bother score (s) and medication list.

- Relevant clinical examination (abdominal/pelvic/genital examination, and checking for possible neurological disease or oedema).
- Three day FVC or bladder diary.¹³
- Representative uroflowmetry with post-void residual (PVR).⁹
- A complete ICS standard urodynamic test²: Uroflowmetry and PVR plus cystometry and pressure-flow study (PFS).

Cystometry²: Continuous liquid filling of the bladder via a transurethral (or other route eg, suprapubic) catheter, at least with intravesical and abdominal pressure measurement and display of detrusor pressure, including quality checks and provocations to aid eliciting symptoms. Cystometry ends with "permission to void" or with severe incontinence. The fluid type and temperature, filling method and rate, catheter sizes, pressure recording technique, and patient position should all be specified.

Pressure-Flow study²: The intravesical and abdominal pressures are measured, from "permission to void," while uroflowmetry is performed with a transurethral (or suprapubic) catheter in place. The position of the patient, the catheter sizes and the pressure and flow recording technique should be specified.

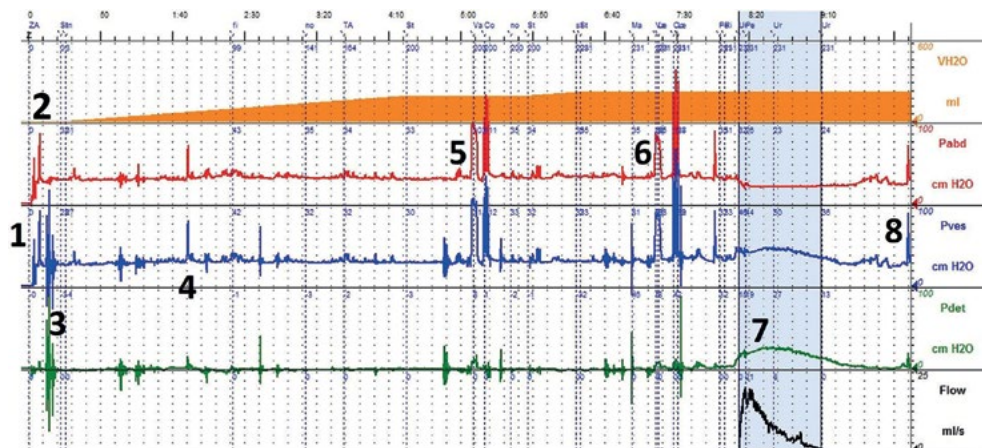


FIGURE 1 A specimen urodynamic test for a female patient. Transducers are zeroed to atmosphere at the start, as the p_{abd} and p_{ves} are at zero (1), before patient pressures are exposed to the transducers. When the transducers are connected to the patient (2), the clear rises in p_{abd} and p_{ves} are termed the "resting pressures"; the resting pressures of p_{abd} and p_{ves} are never zero (unless the urodynamic practitioner makes the technical mistake of zeroing the displayed pressures while recording from the patient, or the transducers are not placed in the required plane level with the pubic symphysis). In this case, p_{abd} and p_{ves} are both within normal limits, and similar magnitude, so p_{det} is zero. A cough test shows equal response on p_{abd} and p_{ves} (2). Some artefactual noise is recorded when the p_{ves} line is knocked (3). Cough tests are carried out and live signal is present throughout the test (4). At (5), filling is paused and a Valsalva manoeuvre and a stress cough test is carried out, but no leak occurs. Further filling is done, and these two tests repeated at (6) where leakage occurs on both (markers confirm this, and small changes in the flow trace have occurred but are not visible at this scale). After "permission to void" is given, the patient voids (7) and care is taken with the placement of the Q_{max} marker, and with the slight fall in p_{abd} at this point. Finally, a cough test (8) verifies that pressure transmission has remained good throughout the voiding phase

2.5 | Practice of cystometry and pressure flow studies

A good urodynamic investigation is performed interactively with the patient.³ It should be established how the patient's symptoms relate to what they experienced during the test. There should be continuous observation of the signals as they are collected, and assessment of the plausibility of all signals. Direct inspection of the raw pressure and flow data before, during, and at the end of micturition is essential, because it allows artefacts and untrustworthy data to be recognized and eliminated.⁴ The flow pattern in a PFS should be representative of free flow studies in the same patient. An overall study trace is illustrated in Figure 1.

Electronic marking of events is important for subsequent analysis; the position of event markers should be adjustable after the test has finished, and the meaning of any abbreviations used for labels should be clear.⁵

2.5.1 | Pressure recording

Zero pressure is the value recorded when a liquid-filled transducer is open to the environment (either disconnected

from any tubes, or when the open end of a connected liquid-filled tube is at the same vertical level as the transducer). "Set zero" or "balance" can then be undertaken, making atmospheric pressure the zero baseline for the test. Intravesical pressure (p_{ves}) or abdominal pressure (p_{abd}) is thus the excess pressure above atmosphere at the hydrostatic level of the symphysis pubis. "Set zero" is not done when catheters are already recording from the patient; this is a common mistake in many urodynamic units.

- ICS standard cystometry is performed using liquid filled catheters, with external transducers at the reference level of the top of the symphysis pubis.^{2,3,6} To achieve this, most urodynamic machines have a movable platform for the transducers, so they can easily be placed at the same height from the ground as the patient's symphysis.
- Use the thinnest possible transurethral double or triple lumen catheter or a suprapubic catheter. Two-catheter techniques (separate filling and pressure recording catheters) are an acceptable alternative.²
- Fix the catheters as close as possible to the anus and urethral meatus with tape, without blocking the urinary meatus.

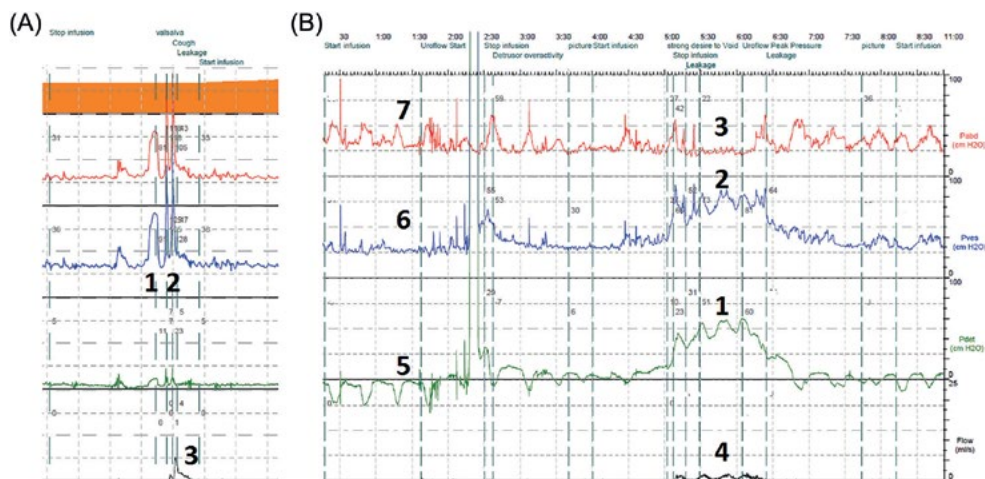


FIGURE 2 Urodynamic observations during filling cystometry. A, USI; the filling pump is stopped, and the patient is asked to do a Valsalva manoeuvre (1) and to do a sequence of 2 or 3 good coughs (2). This patient leaked with the coughs (3), and no DO was present, so the urodynamic observation of USI was documented. B, DO is the presence of a bladder contraction during filling (1), which may be spontaneous or provoked. It is essential to review all the lines in the trace before reporting DO, to confirm there is a bladder contraction (2) and minimal abdominal activity (3; though a small abdominal contraction might be seen if the patient tries to prevent leakage by contracting their pelvic floor). In this case, there is also incontinence (4), so the urodynamic observation here is DO incontinence (DOI). In the same trace, there are also fluctuations in the calculated detrusor pressure (5) which might be misinterpreted as DO. However, these are below the baseline, and there is no change in bladder pressure associated with them (6). Instead, there are phasic pressure changes visible in the abdominal pressure trace (7), indicating the presence of rectal contractions. Practitioners need to recognise that a true change in abdominal pressure shows up in both p_{ves} and p_{abd} ; a phasic change in one line which is absent in the other indicates a contraction of the organ containing the catheter tip (bladder or rectum, respectively)

- Rectal placement of a fully liquid filled open catheter, or punctured balloon catheter, to measure p_{abd} is ICS standard. Vaginal or stoma placement is used only if rectal placement is impossible.

Prevention of liquid leaks and air bubbles in the pressure tubing system is needed throughout testing, and should be corrected when identified.³ Coughs or other abdominal pressure rises are used to ensure that the abdominal and intravesical pressure signals respond equally (see Figure 3).

2.5.2 | Cystometry

Filling cystometry is done in the upright/vertical position (standing or normally seated) whenever physically possible. Detection of detrusor overactivity (DO) and urodynamic stress incontinence (USI) are influenced by the position of the patient; sitting or standing has a higher sensitivity.²

2.5.3 | Filling rate

Maximum physiological filling rate is estimated by body weight in kg divided by four,⁶ thus typically in the range of 20-30 mL/min. More rapid filling is referred to as non-physiological filling rate.³

For a balance between a filling rate that is slow enough to be representative and fast enough to complete the cystometry efficiently, consider a filling rate in mL/min of roughly 10% of the largest voided volume (reported on a FVC; and allowing for PVR).²

Diuresis adds bladder volume that is not recorded by the urodynamics system, but that is relevant for interpretation of the results. Cystometric capacity is most reliably determined by calculation of voided volume plus PVR immediately after PFS.³

2.5.4 | Sensations

Three sensation parameters are recorded⁶: first sensation of filling (FSF), first desire to void (FDV), and strong desire to void (SDV). The patient also may report sensation(s) suggesting “urgency,” which can be marked specifically. When indicating the volumes at which these sensations occurred, the report should make allowance for the fact that the volume instilled into the bladder by the machine is not necessarily the actual liquid volume in the bladder (eg, if the bladder was not empty at the start of the filling cystometry, or if the patient is experiencing diuresis).

1. FSF: “Tell me the moment when you perceive that your bladder is not empty anymore.”²

2. FDV: “Tell me when you have the sensation that normally tells you to go to the toilet, without any hurry, at the next convenient moment.”⁶
3. SDV: “The moment that you would definitely visit the nearest toilet to pass urine.” There should be no pain or any fear of losing urine.

The end of filling should relate to a “strong but not uncomfortable need to void,” indicated by SDV on the urodynamic graph. A specific marker to indicate permission to void must be used if there is a delay between halting the pump and permission to void. If another reason is chosen for concluding filling, this should be indicated.

Incontinence, fear of leakage, pain, or other signs or symptoms during the test should be specifically marked on the urodynamic graph.

2.5.5 | Provocation

Urodynamic stress test² (Figure 2) is used for any physical effort of the person tested, to elevate abdominal pressure during cystometry, with the aim of examining USI. The exact approach to stress testing during urodynamics has not been standardized. Thus, the provocation method, pressure measuring catheter (size) and method, the leak detection method, and the intravesical volume(s) may be reported.

Leak point pressure (LPP)² is the pressure (spontaneous or provoked) that has caused fluid to be expelled from the bladder at the moment that it is visible outside the urethra. No ICS (or commonly agreed) standard technique or protocol is available and a variety of terms and techniques are used.

DO (Figure 2) is characterised by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked.⁶ Cough-associated DO²: Reported when the onset of the DO (with or without leakage) occurs immediately following the cough pressure peak. Cough-associated DO incontinence is a form of DO and must not be confused with USI.

2.5.6 | Pressure-flow studies

The relevance of instruction, position, and privacy while undertaking PFS is equal to uroflowmetry. PFS is done comfortably seated (women, some men) or standing if that is the preferred position (men). Pressure-flow analysis is only validated for voluntarily initiated micturitions and not for incontinence.

- PFS begins immediately after permission to void and ends when the detrusor pressure has returned to the baseline

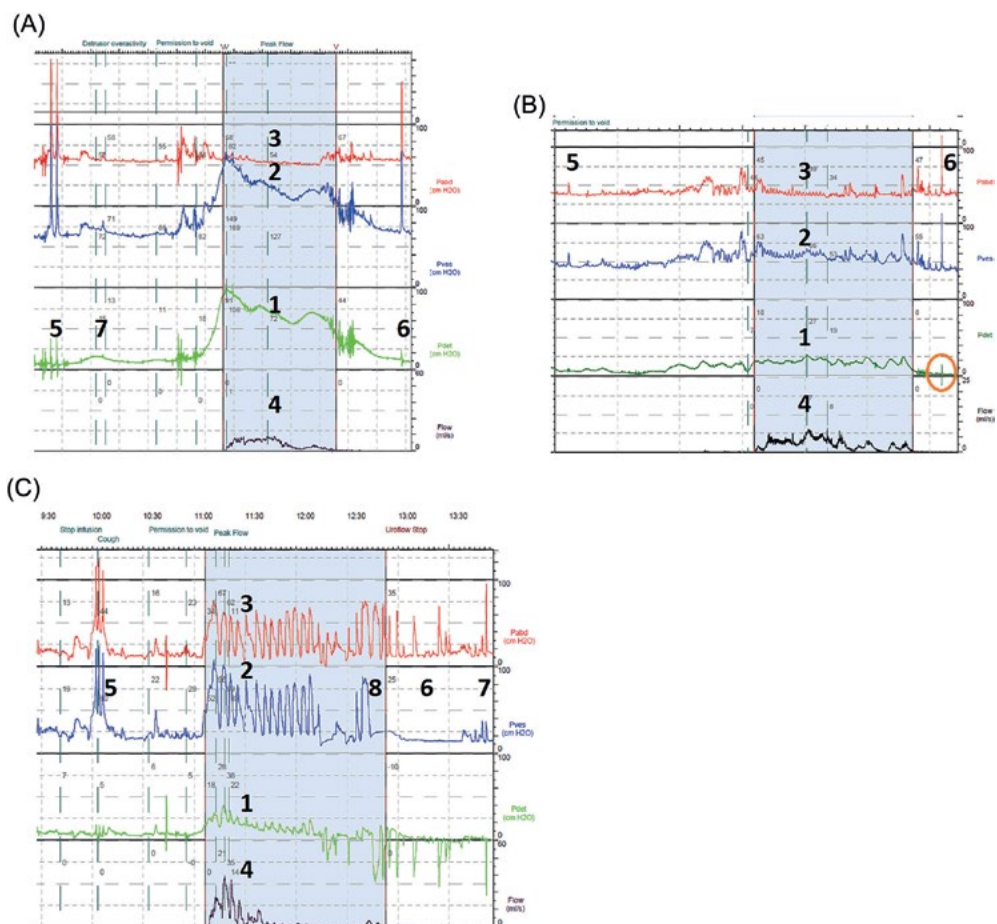


FIGURE 3 Urodynamic observations during PFS.⁴ A, Bladder outlet obstruction (BOO) is indicated by a high pressure generated yet only a slow stream. It is ascertained by evaluating the detrusor pressure ($P_{\text{det}Q_{\text{max}}}$; 1) at the time of maximum flow rate (Q_{max} ; 4). It is important to check that the detrusor pressure reflects the bladder pressure (2), rather than a drop in the abdominal pressure (3). In this male case, Q_{max} was 8, $P_{\text{det}Q_{\text{max}}}$ was 72, and there was no drop in abdominal pressure, so the bladder outlet obstruction index ($P_{\text{det}Q_{\text{max}}}-2Q_{\text{max}}$) was 56, that is, BOO was present. Fidelity of pressure recording must always be checked by asking patient to cough before (5) and after (6) voiding to be sure both P_{ves} and P_{abd} detect the pressure spike equally. This patient also had DO (7). B, Detrusor underactivity (DUA); Detrusor underactivity is defined as a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span.⁶ In this case, detrusor pressure is low (1) and Q_{max} (4) is slow, with a weak bladder contraction (2) and no change in p_{abd} (3). There is a marked delay between permission to void (5) and start of flow. Cough subtraction before (5) and after (6) the void are good. At 6, the cough subtraction (orange circle) shows a biphasic artefact, meaning a slight deflection upwards and an equal deflection downwards; this is acceptable, and is a consequence of the slight discrepancy in the exact moment the impulse reaches the respective transducer for the two measured pressures (p_{ves} and p_{abd}). C, Straining is sometimes done by a patient to try and help initiate or sustain voiding, or to speed it up. In this case, there is a small detrusor contraction during voiding (1), but at the same time there are marked strains indicated by the intermittent peaks in vesical (2) and abdominal (3) pressure. Caution is needed to decide the corrected value of Q_{max} (4), as it should not be taken during a strain. The cough subtraction before voiding is fine (5), but not so after voiding (6), where this is a spike elicited by coughing only in the p_{abd} trace. A reduced signal is seen in the p_{ves} at (7), explaining the poor post void cough subtraction. The last moment of proper vesical pressure recording is at (8), and since this is after the completion of flow, the PFS can be considered meaningful

- value and/or the flowrate to zero and/or the patient considers the micturition completed.
- Use the shortest possible meatus-to-flowmeter distance, raising the flowmeter to suit the individual patient.
- Correction for delay between pressure and flow recording may be needed.
- Cough checking of catheter response is always required after pressure-flow.

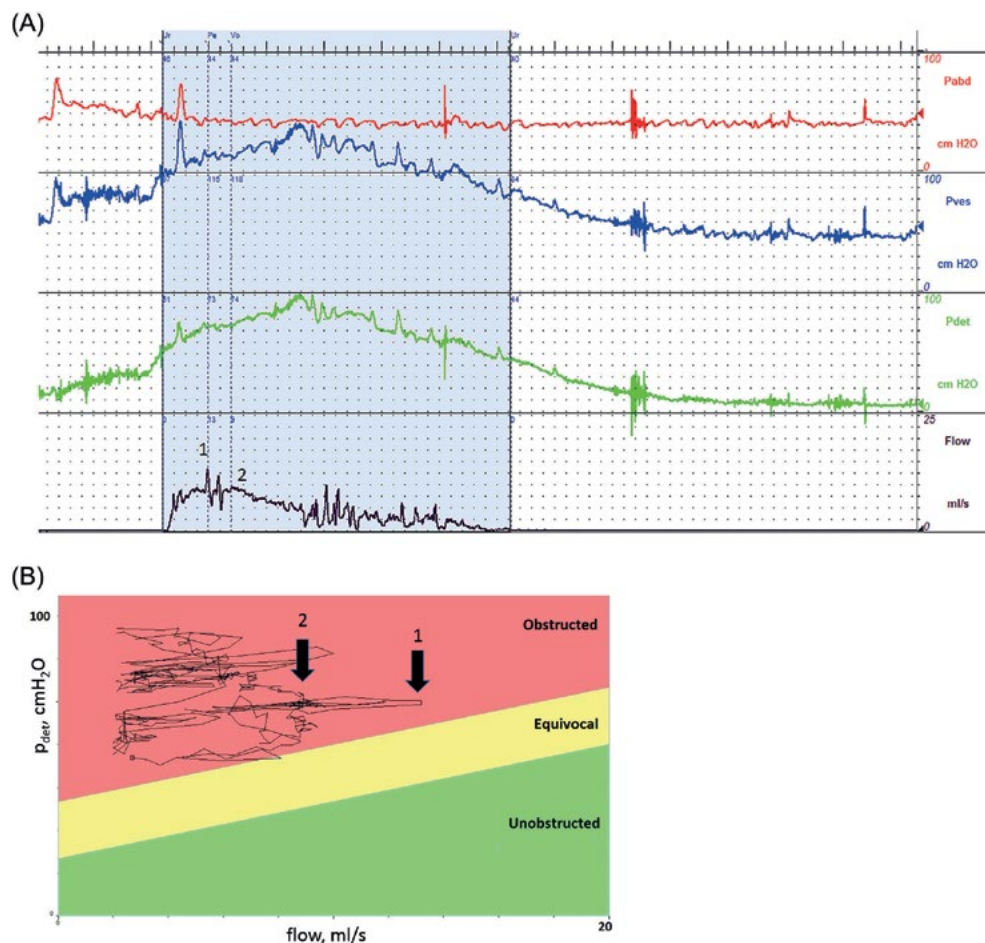


FIGURE 4 Calculating the bladder outlet obstruction index (BOOI) and bladder contractility index (BCI), for describing PFS in men (no equivalent parameters have been identified as yet for women). A, Pressure flow study for a man with voiding LUTS. The machine placed the maximum flow rate at point 1. However, this was on the tip of an unnatural spike, so the urodynamicist checked the shape of the flow trace, and considered that point 2 reflected the flow of the patient's urine most faithfully. Thus, this was considered the corrected maximum flow rate (Q_{max}), with a value of 9 mL/s. p_{det} at this point ($p_{detQ_{max}}$) was 74. From the equation $BOOI = p_{detQ_{max}} - 2 \cdot Q_{max}$, the value for this patient was $74 - 18 = 56$. Any value of BOOI above 40 in a man (with a prostate) indicates obstruction. From the equation $BCI = p_{detQ_{max}} + 5 \cdot Q_{max}$, the value of BCI for this patient was $74 + 45 = 119$. Any value of BCI above 100 in a man (also with a prostate) indicates normal contractility. B, The ICS recommends that the PFS is plotted graphically on a P/Q plot. On the P/Q plot, "1" shows the artefactual peak due to the flow spike. The P/Q plot allows the investigator to see how the artefact almost changes the diagnosis, by nearly crossing one of the lines on the nomogram. "2" shows the corrected position, away from the flow spike and clearly in the unobstructed region. Failure of machine software using current technology to identify artefacts, like that shown at 1, means that traces must be checked for plausibility, since otherwise obstruction and contractility may be wrongly derived from the pressure flow study, leading to inappropriate treatment decisions for the patient

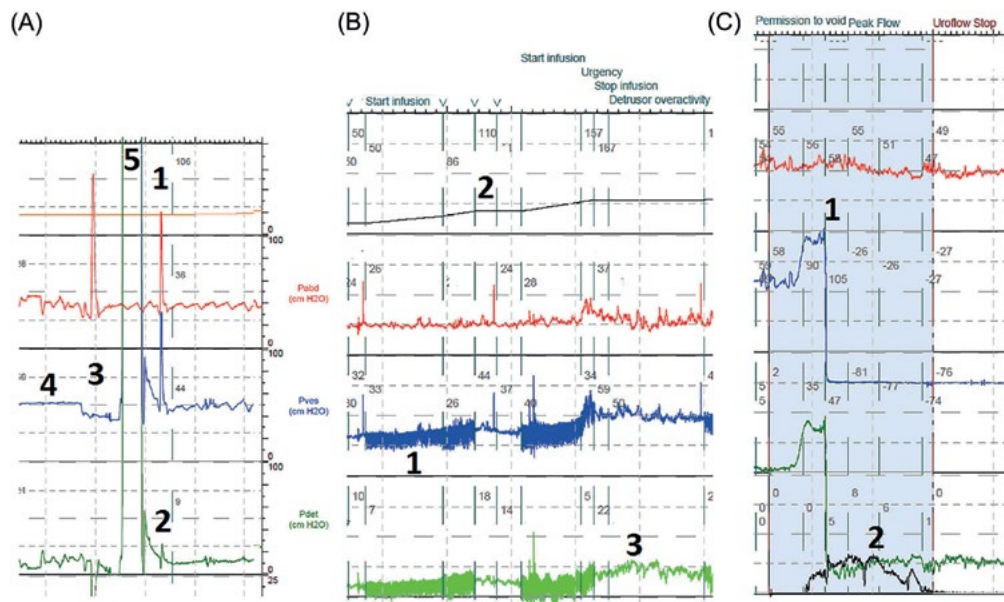


FIGURE 5 Artefacts that can cause difficulty with identifying representative information and misinterpretation of urodynamic findings. A, A cough pressure peak (1) is recognizable during post-test evaluation as a phasic positive pressure change observed in p_{ves} and in p_{abd} . With liquid-filled catheters, it is usual that the bladder line is of smaller diameter than the abdominal line, so complete cancellation of a cough in the detrusor trace is unlikely. Thus, a symmetric biphasic wave on the detrusor trace (2) is acceptable. Poor pressure transmission is suggested when the cough pressure peak signals on p_{ves} and p_{abd} are not nearly equal, or one of them is absent, as illustrated at 3. This follows a phase of “dead signal,” meaning that it is not showing small pressure fluctuations and is not adequately responding on straining, patient movements, or coughing (4). Flushing the vesical pressure line (5) is a common approach to solving a dead signal or poor pressure transmission, and should be verified with a subsequent cough test, as illustrated. B, Pump vibrations: visible as stable frequency oscillations of small but constant amplitude if a dual-lumen is used, or if the filling tube touches the pressure connecting tube and the pump is switched on (1), clearly identified as they stop when the pump is off (2). This patient was observed to have DO (3; pump turned off at this time). C, Expelled catheter: this is observed as a sudden drop in either p_{ves} or p_{abd} , usually below zero (1). In this case, the vesical catheter was expelled before Q_{max} (2) in a pressure flow study, which means it is not possible to interpret the pressure-flow relationship at this key point during voiding. If this hinders answering the urodynamic question, the test will have to be repeated

Normal voiding function: Flow rate (and pressure rise) are within normal limits; flow begins more or less directly after permission to void, and ends with an empty bladder.

“Situational inability to void” or “Situational inability to void as usual”²; when the person performing the test, communicating with the patient, feels the attempted voiding has not been representative.

Bladder outflow obstruction (BOO) (Figure 3) is defined as a (specified) cut-off of bladder outflow resistance based on the pressure/flow relation (ratio) that is considered clinically relevant.²

A slow stream may be caused by BOO or detrusor underactivity (Figure 3). Presentation of pressure-flow studies should be with a plot of the flow rate (delay corrected) rate on the X-axis and the synchronous detrusor pressure on the Y-axis, in addition to the time-based graphs.² The ICS pressure flow

nomogram can be used to present this data for male patients, for whom BOO can be quantified with the BOO Index, and underactivity with the bladder contractility index¹⁴ (Figure 4). While these indices are often stated by the urodynamic software, the urodynamicist is duty-bound to check the plausibility of the results, as the machine may wrongly identify an artefact as the Q_{max} , and give entirely wrong results with potentially disastrous consequences for the patient.

2.5.7 | Repeat testing

- When an error or artefact is observed, the person performing the test should act accordingly, and prevent continuation in case of an error.
- Do not routinely undertake immediate repetition of invasive urodynamics “for confirmation” if the test was

technically adequate and representative, and has answered the clinical question.

- Immediate repetition of the test is appropriate when doubt exists as to whether the test has answered the clinical question.
- Repetition of a urodynamic test subsequently is needed when technical errors and artefacts have been observed at post-test analysis.

Artefacts such as a signal which is non-responding (dead), has stepwise changes in pressure, or has negative pressures, often can be corrected only with speculation about the underlying causes. Studies with such artefacts should be repeated. A few common artefacts can be accepted, for example, rectal activity, biphasic spikes at cough tests (Figure 3B), or insufficient p_{abd} response during straining.

The urodynamic findings and the interpretation of the results should be documented immediately, that is, before the patient has left the urodynamic laboratory. Doing so allows for a second test if required.

2.6 | Technical and clinical quality control

The following three criteria form the minimum recommendations for ensuring quality control of pressure recordings:

1. Resting values for abdominal, intravesical, and detrusor pressure are in a typical range (see below);
2. The abdominal and intravesical pressure signals are “live,” with minor variations caused by breathing or talking being similar for both signals; these variations should not appear in p_{det} ;
3. Coughs or other abdominal pressure rises are used throughout, including before and after voiding, to ensure that the abdominal and intravesical pressure signals respond equally. This is because pressure recording quality can deteriorate quickly during a test, and wrong conclusions might be drawn if not identified quickly. Since the test is used to recommend treatment options, possibly including surgery, the consequence of a wrong conclusion can be detrimental for the patient.

Initial resting pressure² is the p_{ves} and the p_{abd} pressure at the beginning of the cystometry. Typical ranges for p_{ves} and p_{abd} are: supine 5-20 cmH₂O; sitting 15-40 cmH₂O; standing 30-50 cmH₂O.³ Usually both recorded pressures are almost identical (and they must not be zero: see Figure 1), so that the initial p_{det} is between -5 and +5 cmH₂O in the majority.¹⁵ Gentle flushing of both catheter channels and/or filling 20-30 mL into the bladder may be needed before the initial resting pressures are registered.

The use of rectal transducers assumes they measure resting abdominal pressure, but they can also measure rectal

contractions,⁵ seen as positive waves on p_{abd} and reflected as negative p_{det} waves. If either detrusor or rectal contractions occur, the recorded pressures in p_{ves} and in p_{abd} will differ. The relation between signal changes and patient sensation/activity are checked for plausibility and documented during the test.

2.6.1 | Features, artefacts, and errors

Patient movement, external manipulation of the catheter and other influences cause signal patterns that should be recognized during the test and at (re-) evaluation of graphs.

- Position change²: A change in patient position, either active or passive (eg, tilting), is visible on the cystometry trace by a lasting change of equal magnitude in both p_{ves} and p_{abd} .

A position change should be followed by adjustment of the external pressure sensors height to the new level of the pubic symphysis, so that the physiological p_{ves} and p_{abd} are observed again; p_{det} should be unaffected.

- Rectal contractions: temporary phasic increases visible in the p_{abd} trace, without synchronous change in p_{ves} , resulting in negative deflections of p_{det} (Figure 2B).
- Dropped p_{abd} at void: during the voiding time, p_{abd} decreases below the previous resting pressure (as a consequence of pelvic [and abdominal] muscle relaxation). This will artefactually increase p_{det} , and so affect the pressure-flow analysis result.
- Straining: observable as a temporary increase in both p_{ves} and p_{abd} pressure.
- After-contraction: a continued or new detrusor pressure rise immediately after flow ends. It is important to note if this occurs with the complete emptying of the bladder. This may be the reason why some patients feel they have an urgency sensation at the end of voiding.

Artefacts affect interpretation of urodynamic findings (Figure 5), and could lead to mis-diagnosis in severe examples. Step-wise or prolonged constant slope pressure changes imply a non-physiological cause (eg, movement, blockage or disconnection, or leakage of a catheter), which should be resolved.³ A detailed review of urodynamic artefacts has been published.⁸

2.6.2 | Post-test analysis

Once a test is completed, it should be scrutinized to confirm technical quality and exclude the possibility that artefacts have influenced key observations. Liquid leaks and air

TABLE 1 Checklist for fundamentals of urodynamic practices

Question	What is the urodynamic question? Will patient management change as a result? Does the bladder diary/symptom score affect these? Does the patient's report match the above?
Setup	
Calibrate	Check that the equipment is registering pressure and volume accurately
Prepare	Fill the domes and tubes with water, and mount them on the transducers Catheterise the patient, connect tubes and flush with water Level transducers with symphysis pubis bone
Quality	
Zero to atmosphere	Ensure taps are closed to patient, and open to air when zero is pressed.
Check resting pressures are normal	Supine: p_{abd} and p_{ves} 5-20 cmH ₂ O Seated: p_{abd} and p_{ves} 15-40 cmH ₂ O Standing: p_{abd} and p_{ves} 30-50 cmH ₂ O for all positions, p_{det} -5-+5 cmH ₂ O
Continuous monitoring	Check regularly that pressure transmission is equal on both lines, for example, coughs, blowing Check that live patient signal is present throughout Check that baseline pressures do not drift Troubleshoot above during the test, temporarily stopping recording/filling if necessary Stop or reduce fill rate if urgency is excessive, or compliance poor Change patent position as required (eg, discomfort, stress testing) Consider repeating test if urodynamic question not answered
Interpretation	Place markers on the trace frequently, for example, sensation, patient position, stress tests, permission to void Adjust positions of markers after completion of test if needed Take a when interpreting, for example, rectal contractions, knocking of flowmeter
Report	Bladder during filling Urethra during filling Bladder during voiding Urethra during voiding Reproduction of symptoms Management plan

bubbles in the pressure tubing system should be recognized and reported during post-test analysis, if not identified during the procedure, to prevent mis-diagnosis.⁸

Post-processing automated analysis is an optional extra in urodynamic equipment, and established nomograms and calculated parameters may also be provided. Such analysis could be affected by artefacts (eg, Q_{max} caused by knocking the flow meter, p_{max} from cough),⁵ and the urodynamicist must check the trace to be certain that misinterpretation does not result. The user should have the ability to check the values for feasibility and change the relevant ones if necessary. Software should not filter or remove artefacts, but should be able to ignore them for analysis.

2.7 | The urodynamics report

Bladder storage function should be described according to bladder sensation, detrusor activity, bladder compliance, and bladder capacity.⁶ The urethral closure mechanism during storage may be competent or incompetent. Voiding is described in terms of detrusor and urethral function and assessed by measuring urine flow rate and voiding pressures. An "ICS standard urodynamic (time based) graph" and an "ICS standard pressure-flow plot" are required elements in the ICS standard urodynamics report.

- Reporting includes the following elements (summarized from GUP2016²):
 - a Overall judgement of the technical quality, clinical reliability, representativeness, and methods of assessment.
 - b Uroflowmetry: voiding position, Q_{max} , voided volume, PVR.
 - c Introduction of catheters: sensation, muscular defence, obstruction(s).
 - d Patient position(s) during cystometry and PFS.
 - e Patient's ability to report filling sensations and/or urgency and/or urine loss.
 - f Method of urodynamic stress test and accessory tests (if applicable).
 - g Diagnoses: filling sensation (with volumes); cystometry; PFS (bladder outflow function, detrusor contraction).

All results and observations should be carefully reported. It is good clinical practice to integrate the urodynamic test results with the history, examinations, and other tests.

Table 1 gives a proposed checklist for Fundamentals of Urodynamic Practice.

3 | CONCLUSIONS

A good study is one that is easy to read and one from which any experienced urodynamicist will abstract the same

results and come to the same conclusions (GUP2002). Adherence to the fundamentals of the ICS standards, as synthesized in this review, will enable urodynamic units to ensure the quality of urodynamic studies and compare findings with other units.

CONFLICT OF INTEREST

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Basics of videourodynamics for adult patients with lower urinary tract dysfunction

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Aims: Videourodynamics is the addition of imaging to invasive urodynamics and one of the methods to ensure objective diagnosis in persons with signs or symptoms of lower urinary tract dysfunction. This manuscript has the aim to outline the basics of the practice of videourodynamics and to elementary explain interpretation of the results.

Methods: Literature sources and expert opinion were arranged to provide the reader with an introductory overview of current knowledge.

Results: Videourodynamics was—like most diagnostics in health care—introduced on the basis of plausibility and expert conviction but has stood the test of time. Videourodynamics has, especially in patients with congenital or acquired neurogenic dysfunction of the lower urinary tract, undisputedly although not precisely quantifiable, added to (lower urinary tract) health care quality.

Conclusion: The manuscript summarizes the basic elements of indication, practice, and interpretation of videourodynamics.

KEYWORDS

meningomyelocele, neurogenic lower urinary tract dysfunction, practice recommendations, spinal cord injury, videourodynamics

1 | DEFINITION

The ICS good urodynamic practice¹ states that standard invasive urodynamics may be combined with imaging. Invasive urodynamics performed with contrast fluid as the filling medium is termed videourodynamics: X-ray (image amplifier) pictures or cine-loops are made at relevant moments.¹ This report states that the contrast medium should be specified and the total patient radiation dose should be reported. Videourodynamics is not further discussed in the good urodynamic practices document and we provide the basic principles of this technique in this manuscript, with the goal to briefly introduce the practice

and technique as well as the clinical purpose and application of the test to the not-expert.

2 | REQUIREMENTS

In addition to the standard urodynamic (UDS) set-up,¹ videourodynamics (VUDS) requires that the bladder is filled with (iodine) contrast fluid. The technique of VUDS has been introduced in the early seventies of last century^{2,3} and the technique as was introduced in those early days has remained throughout the years.^{4,5} All publications that explain the principles are expert opinion driven and all clinical studies, describing the application of the technique are single center retrospective reviews. We have extracted practical elements from a few reviews and instructional manuscripts.^{6,7}

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

Diverse brands and types of contrast fluid are available. In general it is reasonable to use the contrast that is used on the radiology department to perform cysto-urethrography. As an example, the American College of Radiology provides a detailed description of the technique⁸ and links, to documents that list available contrast agents. Recent studies about the type of contrast media and the quality of imaging are rare but earlier fundamental research demonstrates that very dense medium may obscure details.⁹ Contrast agents have a different density compared to that of urine and or saline, which are usually applied for urodynamic measurements. The difference in weight requires specific calibration of the UDS equipment; the infusion pump and the flow meter, to ensure the machine does not overestimate volumes, because of the larger relative weight of the fluid.

A fixed X-ray unit that can move from 90° to 180° (allowing an antero-posterior, lateral as well as an oblique view), or a C-arm can provide for imaging in a fluoroscopy-proof room. Modern image intensifier, flat-panel and digital radiology equipped systems significantly reduce radiation dose when compared to the “old” x-ray film. Fluoroscopy rooms (also for VUDS) require shielded walls, shielded door(s) and usually have an x-ray glass control window. Shielding must be calculated by a physicist or radiation expert and is based on the specific imaging equipment utilized. The shielding typically will involve several different lead thicknesses depending upon primary beam and secondary scatter radiation fields, surrounding occupancy factors and other considerations. The patient and the medical team involved should be adequately protected and wear dosimeters.

VUDS should be performed in the patient's natural position, if possible. This will require a radiolucent toilet seat to allow fluoroscopy of voiding in a sitting position. A standing position should also be available to enable (stress) evaluation of urinary incontinence in men and women and or voiding in the standing position. Many patients, however, especially those with neurogenic dysfunction of the lower urinary tract (LUT) never void and or are unable to sit or stand. For those patients it should be considered, or preferred, to perform UDS in supine position. Both in seated as well as in supine position the relevant elements of the system should be upholstered adequately to prevent skin damage, especially again, for the patients with loss of sensation and LUT dysfunction.

VUDS software combining the X-ray images with the UDS trace, and presenting the data either on a split screen or by superposition, is widely commercially available although the precise association of the images with synchronous pressures is rarely reported.

Radiation exposure should be As Low As Reasonably Achievable (ALARA) without sacrificing diagnostic

accuracy, and the radiation time and dose should always be reported, making patient dose monitoring essential.¹ Urodynamicists that wish to perform VUDS, as well as physicians should be well-trained to ensure that video-monitoring is performed adequately. Snapshots at clinically relevant moments (eg, during provocative measures or bladder pressure rises) are usually sufficient and long cine-loops are rarely relevant. The radiation field should be limited to the anatomical region of interest (sparing the gonads if possible). Pulsed digitally enhanced or low-dose setting continuous fluoroscopy with spectral beam filtration, optimal selection of the tube current and high voltage by an automatic brightness control system should be used to reduce radiation exposure. Certainly regular servicing as per local maintenance plan is important. A relatively low effective dose is achievable, as was demonstrated in a cohort with historical controls. A mean fluoroscopic time of around 60 s for VUDS including filling, stress testing, and voiding observations has been possible.¹⁰ Plausibly, observations done do not often need reconfirmation (with repeated images), and a few snapshots at critical moments are conceivably sensitive to observe anatomical abnormalities in combination with the (dys) function of the LUT. Regrettably not much scientific evidence is published, regarding this.

3 | VIDEO-URODYNAMIC FINDINGS

The possible findings during VUDS are listed in Table 1. The key to VUDS is to adequately relate the anatomical findings (see Figures 1-4) to the urodynamic observations.

For example, a critical part in the follow-up and management of patients with neurogenic dysfunction (NLUTD) is to ensure low-pressure urine storage, thereby protecting the upper urinary tract (UUT). An unsafe bladder, prone to cause UUT damage, was defined in adult patients with spinal dysraphism as a bladder with a high end filling pressure (>40 cmH₂O), poor compliance (<10 mL/cmH₂O) and high detrusor leak point pressure (>40 cmH₂O)¹¹ criteria that can be deducted from conventional UDS.¹² High bladder pressures during the storage phase can, however, cause vesico-ureteral reflux (VUR) (eg, Figure 4). Secondary, this VUR can create a pop-off of bladder pressure as (one of) the UUT(s) now absorbs the pressure. This may lead to overestimation of bladder compliance. Therefore, VUDS have a clear advantage over conventional UDS when hydronephrosis was documented in the patient or when VUR is suspected or known by other means. VUR can be related to bladder function; passive VUR at low intravesical pressures, for example, due to an insufficient ureteric orifice as is frequently existing in congenital ureteral anomalies, for example, doubling versus active VUR occurring during

TABLE 1 Video-urodynamic observations in relation during anatomical site and urodynamic phase

Anatomical site	Video-urodynamic finding
Ureters and renal pelvis	Vesico-ureteral reflux + grade
Bladder	Trabeculation Diverticula Christmas tree appearance Postvoid residual (+ quantification) Vesico-vaginal fistula Filling “defect” (eg, prostate median lobe, bladder tumor, bladder stone)
Bladder base	Cystocele + grade (at rest, during stress testing, and during voiding)
Bladder neck	Filling: Bladder neck incompetence (during stress testing) Filling: Bladder neck opening during detrusor overactivity contractions Voiding: Bladder neck dysfunction or dyssynergia Voiding: Bladder neck fibrosis
Urethra	Urinary incontinence Urethral stricture Urethral diverticula Urethrovaginal fistula (Neurogenic) detrusor—(external urethral) sphincter dyssynergia

elevated pressure as a consequence of reduced compliance or synchronous with a detrusor contraction during filling or during—high pressure—dyssynergic voiding. It is important to note that in patients with spinal dysraphism, anatomical

abnormalities of the LUT are more prevalent than in patients with acquired NLUTD due to the abnormal muscle functional as well as anatomical development of the LUT and pelvic floor even before birth, as a consequence of the lack of (early) normal innervation.

Abnormalities in the shape or outline of the bladder should be related to the functional and the cystometric capacity. Bladder diverticula, for example, can serve as a pressure sink or can be responsible for postvoid residual (eg, Figure 3).

VUDS can also aid in the diagnosis of urinary incontinence. Male (post-prostatectomy) PRP-UI has been suggested as an indication for VUDS on the basis of expert conviction.^{13,14} Whether VUDS is of advantage in uncomplicated PRP-UI; men without any other urological history or (neuro-) urological co-morbidity, than UDS has not been assessed yet. In women with recurrent signs and symptoms of UI on the other hand, VUDS can aid in the evaluation and may guide the management, but this also has not been evaluated prospectively with regard to improvement in management selection and or outcome. Therefore, the added value of fluoroscopy to UDS in women with recurrent UI after initial (surgical) intervention has yet to be determined. In NLUTD, VUDS can also be used to determine detrusor leak point pressure; it is possible to observe contrast fluid entering the urethra via the X-ray; however, all leak points are designed or calibrated with externally visible leakage.

In young men with non-neurogenic LUTS, a single center report suggests that VUDS can offer guidance in diagnosing

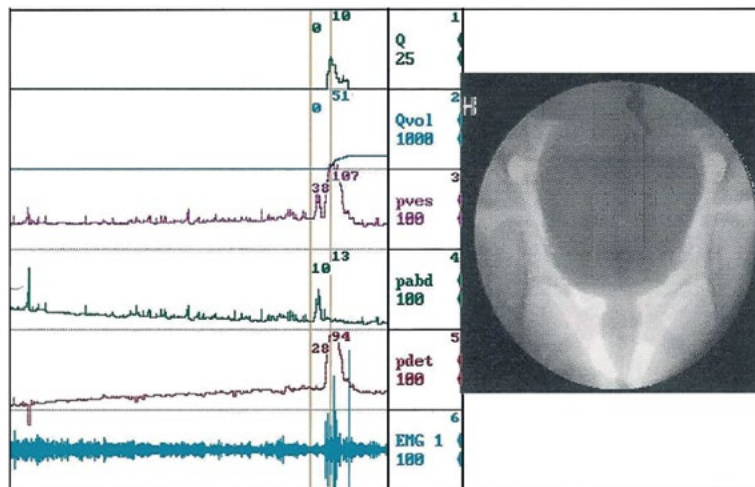


FIGURE 1 Voiding phase of VUDS bladder contour has normal appearance and bladder neck and prostatic urethra are clearly visible. Pressure flow analysis demonstrate that this patient has a normal contraction (BCI 144) and a bladder outflow obstruction grade 4 (or ICS-BOOI: 74)

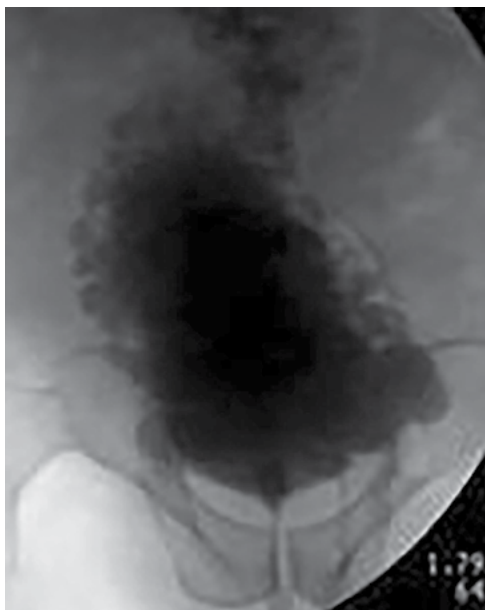


FIGURE 2 Cystogram showing trabeculation over the entire bladder

the location or cause of bladder outflow obstruction (BOO): bladder neck dysfunction versus bladder neck fibrosis¹⁵ versus urethral stricture. Some reports also suggest that VUDS can be useful for women with voiding difficulties to distinguish the effect of pelvic organ prolapse or dyssynergia in women with consistent intermittent or fluctuating flow,^{16,17} however, the precise predictive value of observations with the video-part of the study are poorly described and difficult to reproduce.

Other indications for VUDS are listed in Table 2. In general, fluoroscopy can be added to the urodynamic evaluation if there is suspicion of an anatomical anomaly contributing to the patient's LUTD or when a relevant neurological disease is causing the dysfunction and an anatomical cause or consequences are expected.

4 | GUIDELINES

The evidence supporting VUDS in non-neurogenic LUTS is low grade; sparse, incomplete, and almost exclusively based on expert opinion and single center uncontrolled studies.¹⁸ Data on the effect of VUDS with or without comparison with UDS on management selection and outcomes are also lacking. Nevertheless, the aim of VUDS is to achieve a more accurate diagnosis in these patients and hence improve the therapeutic decision-making, however, usually at the cost

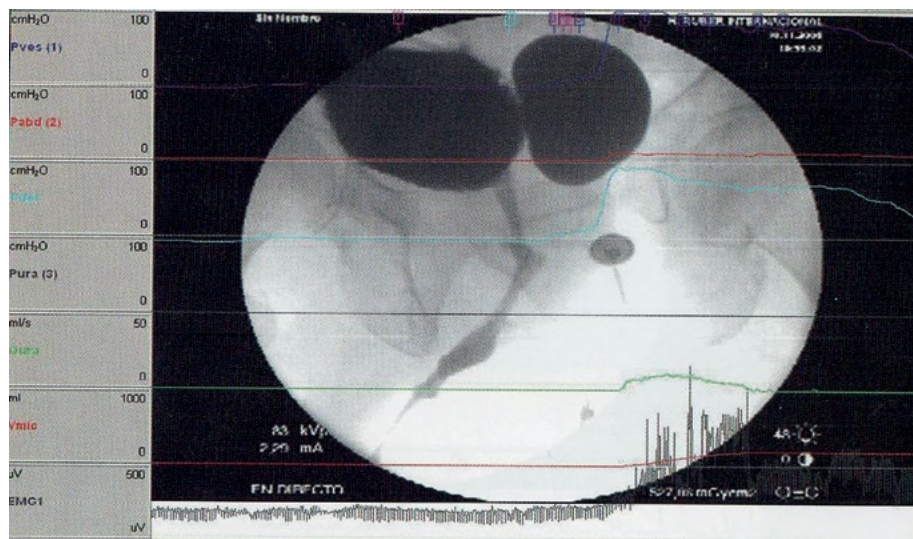


FIGURE 3 A relatively large diverticulum, filled during voiding; normal appearance of urethra, but pressure flow parameters (over-projected: not zeroed to atmosphere as per ICS standard; low flow and relatively high detrusor pressure) indicate bladder outflow obstruction (should be graded on [ICS] pressure flow plot)

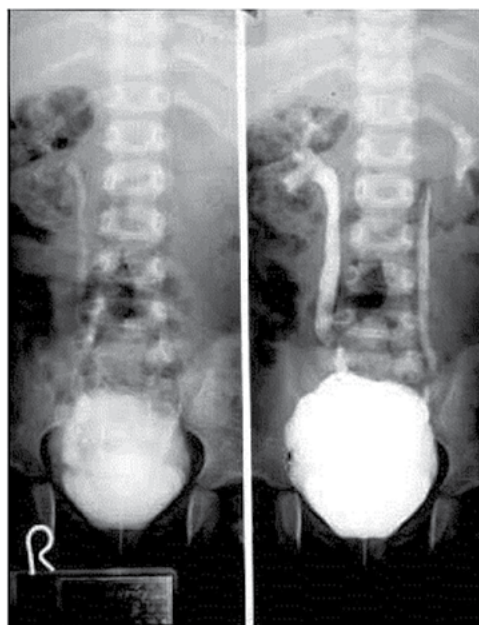


FIGURE 4 Vesico-ureteral reflux initially at the right hand side and subsequently on both sides

TABLE 2 Indications for considering fluoroscopy during the urodynamic evaluation

Neurological findings or history of relevant neurologic disease
(History of) congenital genitourinary anomaly (eg, ectopic ureter, posterior urethral valves, prune-belly syndrome, vesico-ureteral reflux)
Bladder outflow obstruction or urinary retention associated with complex history
History of pelvic radiotherapy or intrapelvic surgery
History of pelvic reconstructive surgery, SUI surgery, urethral stricture repair, POP reconstruction, urethral diverticulectomy
Suspicion of vesico-vaginal or urethro-vaginal fistula
Suspicion of urethral diverticulum
Pre- and post-renal transplant

of patient comfort, making the chance of not representative outcome of studies more likely, especially in patients without neurological disease.

The European Association of Urology (EAU) recommends, based on level 4 evidence, VUDS as the optimum procedure for invasive UDS in neuro-urological patients.^{19,20} In male LUTS VUDS are considered applicable if this is needed for the clinician to understand the pathophysiological mechanism of a patient's LUTS although this is also based on experts impressions.²¹ The British National Institute for "Health" and Care Excellence (NICE) recommends to offer VUDS to people who are known to have a high risk of renal complications from their LUT function (eg, people with spina bifida, spinal cord injury, or anorectal abnormalities).²²

The American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) states that, when available, clinicians may perform VUDS in patients with relevant neurologic disease at risk for neurogenic bladder dysfunction, in patients with other neurologic disease and elevated PVR.²³ Clinicians may also perform VUDS in properly selected patients to urodynamically grade and to anatomically localize bladder outflow obstruction, based on this association statement.²³

5 | CONCLUSION

Medical imaging has developed in a century.²⁴ Imaging finds its application in healthcare via the evolution of technical

possibilities in combination with plausibility, and expert opinion. Randomized prospective studies that demonstrate the effect of diagnosis with and without imaging, on outcome of management have not been published. The development of videourodynamic evaluation is no exception. It is difficult to precisely delineate the indications for the study, as well as to assess its precise surplus for predictive value of the diagnostic strategy, however, it is undoubtedly plausible and useful to combine reliable objective functional physiological measurements (UDS) with anatomical information of synchronous imaging in a proportion of patients with lower urinary tract dysfunction.

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Why ICS standardization of lower urinary tract symptoms matters

Why does a red traffic light mean “STOP” everywhere? Or why are you able to browse the Internet from anywhere over the world? These are just a few examples from our daily life that illustrate the need for standardization and the use of a common and correct terminology.

Standards make the world a safer place. Our health is dependent on standards, going from the definition of safe drinking water, over the quality of medical equipment to the creation of terminology, standards, and guidelines in healthcare.

Standards and terminology define what is being talked about. This is especially necessary in critical communication, but also to ensure the safe diagnosis and treatment of patients. It is important that the term for a symptom, condition or disease has the same meaning for every healthcare professional on this planet. If you hear of a new development at a congress or in publication, you need to understand it fully in order to adopt it properly into your practice. When talking with patients, both of you need to understand what the other is saying. Achieving this is the aspiration of the International Continence Society (ICS) standardizations.¹ They are a series of evidence based pragmatic documents, some of them developed in partnership with other professional bodies, covering the field of lower urinary tract function and dysfunction, and urodynamic assessment.²⁻⁴


Similar words can have different meanings in different languages, or translation. Notably an English term in another language can change the linguistic meaning or can have different connotations than in the original language. For example many languages do not make a distinction between urinary urge and urinary urgency. The ICS has clearly defined this difference to make it clear that urgency is pathological, as in overactive bladder, and urge is the normal sensation associated with a strong desire to pass urine. So as to be consistent for inclusion of patients in clinical trials on Overactive Bladder Syndrome potentially being run in several countries, correct interpretation of the inclusion and exclusion criteria is essential. For these trials it is of paramount importance to recruit only patients with urgency, and not those describing the normal sensation of urge. Standards help in managing cultural and linguistic diversity and differences. Such terminology efforts are crucial for the advancement of research and clinical practice.

Standards allow sharing of technology and innovation and information. If we would not use a standardized terminology and a set of standards in urodynamics, results from one center would not be interchangeable with those from another center. This would lead to an unnecessary duplication of examinations, when a patient would be referred to another center. Technology is highly dependent on terminology and standardization.⁵ Standards also make information retrievable and speed up research. Every book or published article can be found with internet search engines or through library systems, thanks to unique identifiers that have been attributed according to international standards. Just imagine to have gone back in time and to be dependent on an old-fashioned librarian and his reference system on little cards, before you could read an interesting article or book. Standards help tremendously in speeding-up research and interaction between researchers.

We strongly encourage all healthcare professionals to engage with the ICS standardizations, so as to push forward the progress in this field. Once it is in universal use, the ICS terminology offers a backbone for communications between professionals and also with patients.

CONFLICTS OF INTEREST

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4. Toozs-Hobson P, Freeman R, Barber M, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for reporting outcomes of surgical procedures for pelvic organ prolapse. *Int Urogynecol J*. 2012;23:527–535.
5. Seth JH, Sahai A, Khan MS, et al. Nerve growth factor (NGF): a potential urinary biomarker for overactive bladder syndrome (OAB)? *BJU Int*. 2013;111:372–380.

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Critical steps in developing professional standards for the International Continence Society

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Aims: Standardization on the basis of systematic assessment of evidence has become an indispensable element of modern healthcare. International Continence Society (ICS) has initiated and produced extremely well cited standardization documents. The process of standardization is recently depicted in a published manuscript, to keep up with modern society healthcare demands.

Methods: A narrative review of the ICS history and current state of standardizations for the terms, assessment and the management of patients with lower urinary tract dysfunction.

Results: This article highlights the philosophy and the historical context of standardization and explains the core elements of modern day standardization. The article also demonstrates the scientific relevance of the ICS standards, on the basis of reference-counts.

Conclusion: The history and the relevance of ICS standards are summarized.

KEYWORDS

health care quality, lower urinary tract dysfunction, systematic assessment and diagnosis

1 | INTRODUCTION

The Mars Climate Orbiter was a space probe launched by NASA on December 11, 1998 to study the Martian climate. However, on September 23, 1999, communication with the spacecraft was lost as the spacecraft went into orbital insertion, due to ground-based computer software which produced output in non-SI units of pound (force)-seconds (lbf/s) instead of the SI units of newton-seconds (N/s) specified in the contract between NASA and Lockheed. The spacecraft encountered Mars on a trajectory that brought it too close to the planet, causing it to pass through the upper atmosphere and disintegrate.¹ SI units are standard units of technical measurement, allowing communication about

technical issues. Standardization is relevant, in technical science as well as in medical science. Standard terms, classifications and disease and management patterns were sought, in fact since the early days of healthcare, for example, by Hippocrates. Maybe in the more modern society further standardization began in the 16th century, where parish clerks were asked to classify mortality and standard terms were developed with this aim. This can be seen as the later basis for health epidemiological observations. In the beginning of 20th century a standard nomenclature for diseases was developed that progressed into the nowadays International Classification of Diseases (ICD) and Systematized Nomenclature of Medicine (SNOMED, now SNOMED-CT).²

Medical societies are established around (clinical-medical) specialisms to improve knowledge and accountability. The Continence Club was established in Exeter (UK) in 1971, renamed to International Continence Society that same year and had the purpose to “. . . provide a link for the interchange of ideas and results for clinicians and physicists interested in

Clinical trial: No.

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

TABLE 1 “General” (not specific) ICS standardization documents with publication year and between brackets, a double or triple publication are showed

Scopus EXPORT DATE: 15 May 2018 searched quote: “standard* lower urinary tract function”		
Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, Van Kerrebroeck P, Victor A, Wein A. The standardization of terminology of lower urinary tract function: Report from the standardization sub-committee of the international continence society (2002) <i>Neurourology and Urodynamics</i> , 21 (2), pp. 167–178.	2002 (1)	Cited 4360 times.
Bump, RC, Mattiasson, A, Bo, K, Brubaker, LP, DeLancey, JOL, Klarskov, P, Shull, BL, Smith, ARB. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction (1996) <i>American Journal of Obstetrics and Gynecology</i> , 175 (1), pp. 10–17.	“ICS approved”	Cited 2616 times.
Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, Van Kerrebroeck P, Victor A, Wein A. The standardization of terminology in lower urinary tract function: Report from the standardization sub-committee of the International Continence Society (2003) <i>Urology</i> , 61 (1), pp. 37–49.	2002 (2)	Cited 1583 times.
Good Urodynamic Practices: Uroflowmetry, filling cystometry, and pressure-flow studies (2002) <i>Neurourology and Urodynamics</i> , 21 (3), pp. 261–274.		Cited 1006 times.
Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardization of terminology of lower urinary tract function. The International Continence Society Committee on Standardization of Terminology. (1988) <i>Scandinavian Journal of Urology and Nephrology, Supplement</i> , 114, pp. 5–19.	1988 (1)	Cited 951 times.
Haylen, BT, De Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, Monga A, Petri E, Rizk DE, Sand PK, Schaer GN. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction (2010) <i>International Urogynecology Journal</i> , 21 (1), pp. 5–26.		Cited 771 times.
Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, Van Kerrebroeck P, Victor A, Wein A. The standardization of terminology of lower urinary tract function: Report from the Standardization Sub-committee of the International Continence Society (2002) <i>American journal of obstetrics and gynecology</i> , 187 (1), pp. 116–126.	2002 (3)	Cited 607 times.
Griffiths D, Hofner K, Van Mastrigt R, Rollema HJ, Spangberg A, Gleason D. Standardization of terminology of lower urinary tract function: Pressure-flow studies of voiding, urethral resistance, and urethral obstruction (1997) <i>Neurourology and Urodynamics</i> , 16 (1), pp. 1–18.		Cited 324 times.
Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardization of terminology of lower urinary tract function recommended by the international continence society (1990) <i>International Urogynecology Journal</i> , 1 (1), pp. 45–58.	1988 (1)	Cited 305 times.
Bates P, Bradley WE, Glen E, Griffiths D, Melchior H, Rowan D, Sterling A, Zinner N, Hald T. The standardization of terminology of lower urinary tract function (1979) <i>Journal of Urology</i> , 121 (5), pp. 551–554.		Cited 233 times.
First Report on the Standardization of Terminology of Lower Urinary Tract Function: PRODUCED BY THE INTERNATIONAL CONTINENCE SOCIETY, FEBRUARY, 1975 (1976) <i>British Journal of Urology</i> , 48 (1), pp. 39–42.		Cited 215 times.
Austin PF, Bauer SB, Bower W, Chase J, Franco I, Hoebeke P, Rittig S, Vande Walle J, Von Gontard A, Wright A, Yang SS, Nevés T. The standardization of terminology of lower urinary tract function in children and adolescents: Update report from the standardization committee of the international children's continence society (2014) <i>Journal of Urology</i> , 191 (6), pp. 1863–1865.		Cited 193 times.
The standardization of terminology of lower urinary tract function (1990) <i>BJOG: An International Journal of Obstetrics & Gynecology</i> , 97, pp. 1–16.		Cited 118 times.
Glen ES, Bradley WE, Melchior H, Rowan D, Sterling AM, Sundin T, Thomas D, Torrens M, Warwick RT, Zinner NR, Chairman TH. Fourth Report on the Standardization of Terminology of Lower Urinary Tract Function: Terminology related to neuromuscular dysfunction of the lower urinary tract: PRODUCED BY THE INTERNATIONAL CONTINENCE SOCIETY (1981) <i>British Journal of Urology</i> , 53 (4), pp. 333–335.		Cited 90 times.
Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardization of terminology of lower urinary tract function – Produced by the international continence society committee on standardization of terminology (1989) <i>World Journal of Urology</i> , 6 (4), pp. 233–245.	1998-9 (3)	Cited 52 times.
Austin PF, Bauer SB, Bower W, Chase J, Franco I, Hoebeke P, Rittig S, Walle J.V, Von Gontard A, Wright A, Yang SS, Nevés T. The standardization of terminology of lower urinary tract function in children and adolescents: Update report from the standardization committee of the International Children's Continence Society (2016) <i>Neurourology and Urodynamics</i> , 35 (4), pp. 471–481.		Cited 47 times.

(Continues)

TABLE 1 (Continued)

Scopus EXPORT DATE: 15 May 2018 searched quote: "standard* lower urinary tract function"		
Bates CP, Bradley WE, Glen ES, Griffiths D, Melchior H, Rowan D, Sterling A, Hald T. Third Report on the Standardization of Terminology of Lower Urinary Tract Function: Procedures related to the evaluation of micturition: Pressure-flow relationships. Residual urine: PRODUCED BY THE INTERNATIONAL CONTINENCE SOCIETY, FEBRUARY 1977* (1980) <i>British Journal of Urology</i> , 52 (5), pp. 348–350.	1977 (3)	Cited 43 times.
Bates P, Bradley WE, Glen E, Griffiths D, Melchior H, Rowan D, Sterling AM, Zinner N, Hald T. Standardization of terminology of lower urinary tract function First and second reports: International Continence Society (1977) <i>Urology</i> , 9 (2), pp. 237–241.	1977 (4)	Cited 34 times.
Abrams P, Blaivas JG, Stanton SL, Andersen JT, Fowler CJ, Gerstenberg T, Murray K. Sixth report on the standardization of terminology of lower urinary tract function. Procedures related to neurophysiological investigations: electromyography, nerve conduction studies, reflex latencies, evoked potentials and sensory testing. The International Continence Society Committee on Standardization of Terminology, New York, May 1985. (1986) <i>Scandinavian Journal of Urology and Nephrology</i> , 20 (3), pp. 161–164.	1985 (1)	Cited 26 times.
Nevéus T, Von Gontard A, Hoebeke P, Hjalmas K, Bauer S, Bower W, Jørgensen TM, Rittig S, Van De Walle J, Yeung, C-K, Djurhuus JC. The standardization of terminology of lower urinary tract function in children and adolescents: Report from the Standardization Committee of the International Children's Continence Society (ICCS) (2007) <i>Neurourology and Urodynamics</i> , 26 (1), pp. 90–102.		Cited 20 times.
Bates P, Bradley WE, Glen E, Melchior H, Rowan D, Sterling A, Hald T. The standardization of terminology of lower urinary tract function (1976) <i>European Urology</i> , 2 (6), pp. 274–276.		Cited 15 times.
Andersen JT, Blaivas JG, Cardozo L, Thuroff J. Seventh report on the standardization of terminology of lower urinary tract function: Lower urinary tract rehabilitation techniques (1992) <i>Scandinavian Journal of Urology and Nephrology</i> , 26 (2), pp. 99–106.		Cited 14 times.
Abrams P, Blaivas JG, Stanton SL, Andersen JT, Fowler CJ, Gerstenberg T, Murray K. Sixth report on the standardization of terminology of lower urinary tract function – Procedures related to neurophysiological investigations: Electromyography, nerve conduction studies, reflex latencies, evoked potentials and sensory testing (1986) <i>World Journal of Urology</i> , 4 (1), pp. 2–5.	1985-6 (2)	Cited 9 times.
Bates P, Rowan D, Glen E. Second report on the standardization of terminology of lower urinary tract function. Produced by the International Continence Society committee on standardization of terminology Copenhagen, August 1976 (1977) <i>European Urology</i> , 3 (3), pp. 168–170.	1977 (2)	Cited 8 times.
Bates P, Bradley WE, Glen E, Melchior H, Rowan D, Sterling A Hald T. First report on the standardization of terminology of lower urinary tract function: Incontinence, cystometry, urethral closure pressure profile and units of measurement (1977) <i>Urologia Internationalis</i> , 32 (2–3), pp. 81–87.	1977 (1)	Cited 7 times.

The third column shows the number of citations to the specific document as obtained from Scopus.com (May 2018).

urodynamic studies . . . treating related disorders.”³ To this aim, as a logical consequence, “. . . to set it [the new society (ICS)] on the way to becoming a professional body”³ a “standardization of terminology of lower urinary tract function” was developed and published simultaneously in diverse journals.⁴ Terms for urodynamic observations were developed since then and refined, together with improvements in the techniques used to objectively measure lower urinary tract functions, independent from the patients expression of symptoms. New ICS standardization documents have been published in the years that followed.

2 | MATERIAL AND METHODS

A narrative review of the evolution of the process of standardization in healthcare, in general and specific for ICS is presented. Scopus—website counts are used to demonstrate

the scientific relevance of the published manuscripts of ICS standards.

3 | RESULTS

2.1 | Standard for standards

Early standards in health care have been eloquence based. A group of renowned experts sat together and developed the text of the standard, on the basis of their knowledge. That actual knowledge failed against big data was demonstrated in the late 1960s. A clinical epidemiological book discussed the complexity of medical decision making, and was the starting point for nowadays clinical epidemiology. Clinical epidemiology became a tool to be the more reliable basis for (more) systematic diagnosis and management.⁵ This clinical epidemiology, and systematic reviewing of research data were deployed into evidence based medicine later.⁶

Also early ICS standards have been developed in the “good old boys sat around the table” (GOBSAT)—manner. In 2012, however, the ICS standardization committee has published a standard to deviate from GOBSAT and to introduce—evidence based-(healthcare and) ICS standards.⁷ This manuscript highlights also that the ICS standardization committee had modernized itself and became a standardizing steering committee, with the aim to oversee and guide (ad hoc) working groups to deliver new ICS standards. The renewed process and structure of standards production were defined, to ensure careful inclusion of evidence in the standard and to explicitly grade evidence and also indicate expert opinion where evidence is lacking. In summary of the earlier published document, the process consists of a proposal stage, a preparatory stage, a committee stage and an approval stage

and has also defined an implementation stage.⁷ An idea for a new standard should be proposed to the ICS standardization steering committee who will establish an opinion- and background-balanced working group with a chairperson. The “balance,” referred to in the standard⁷ includes that the background should as diverse as possible, around the topic of the standardization, not only in opinion and profession but also including partnership of other organizations (outside ICS) when that is deemed potentially rewarding. The working group, when established, searches for relevant evidence and makes summaries of answers for clinical questions associated with the topic of the standard. Terms may also be searched for existence in scientific databases or in the, here above mentioned, international nomenclature—sets, or medical dictionaries, before introduction in the (new) standard.

TABLE 2 The top ranking documents with (clinical OR practice) standard* in the title with the number of citations to the specific document (may 2018) are showed

Scopus EXPORT DATE: 15 May 2018 Search quote: “Standard*”- in Title.	
Standardization of spirometry (2005) European Respiratory Journal, 26 (2), pp. 319–338.	Cited 6495 times.
Standardization of spirometry: 1994 Update (1995) American Journal of Respiratory and Critical Care Medicine, 152 (3), pp. 1107–1136.	Cited 5248 times.
Bone histomorphometry: Standardization of nomenclature, symbols, and units: Report of the asbmr histomorphometry nomenclature committee (1987) Journal of Bone and Mineral Research, 2 (6), pp. 595–610.	Cited 4397 times.
The standardization of terminology of lower urinary tract function: Report from the standardization sub-committee of the international continence society (2002) Neurourology and Urodynamics, 21 (2), pp. 167–178.	Cited 4360 times.
The consortium to establish a registry for Alzheimer’s disease (CERAD). Part II. Standardization of the neuropathologic assessment of Alzheimer’s disease(1991) Neurology, 41 (4), pp. 479–486.	Cited 3495 times.
The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction (1996) American Journal of Obstetrics and Gynecology, 175 (1), pp. 10-17	Cited 2616 times.
Lung volumes and forced ventilatory flows. Report Working Party Standardization of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. (1993) The European respiratory journal. Supplement, 16, pp. 5-40	Cited 2523 times.
Standard of spirometry- 1987 update. Statement of the American Thoracic Society. (1987) The American review of respiratory disease, 136 (5), pp. 1285–1298.	Cited 2070 times.
Design and standardization of PCR primers and protocols for detection of clonal immunoglobulin and T cell receptor gene recombinations in suspect lymphoproliferations: Report of the BIOMED 2 concerted action BMH4- CT98-3936 (2003) Leukemia, 17 (12), pp. 2257–2317.	Cited 1834 times.
The standardization of terminology in lower urinary tract function: Report from the standardization sub- committee of the International Continence Society (2003) Urology, 61 (1), pp. 37–49.	Cited 1583 times.
A Specific Laboratory Test for the Diagnosis of Melancholia: Standardization, Validation, and Clinical Utility (1981) Archives of General Psychiatry, 38 (1), pp. 15-22	Cited 1579 times.
Revised Recommendations of the International Working Group for diagnosis, standardization of response criteria, treatment outcomes, and reporting standards for therapeutic trials in acute myeloid leukemia (2003) Journal of Clinical Oncology, 21 (24), pp. 4642–4649.	Cited 1471 times.
Standardization of uveitis nomenclature for reporting clinical data. Results of the first international workshop (2005) American Journal of Ophthalmology, 140 (3), pp. 509-516	Cited 1435 times.
A working formulation for the standardization of nomenclature in the diagnosis of heart and lung rejection: Heart rejection study group (1990) Journal of Heart Transplantation, 9 (6), pp. 587-592	Cited 1301 times.

When the number of citations to the three versions of the 2002 document are added (4360 + 1583 + 607), 3th not shown, see Table 1), the total of 6650 would rank this document number 1 clinical standard in healthcare. Note also that the number 6 document is an “ICS-collaboration-endorsed” standard.

Objective evidence for management in new standard should be systematically gathered with structured searches of literature and Oxford grading. Theoretically a Delphi process would be applicable for sub-topics where evidence is lacking, however, this procedure is not without pitfalls, for example, has the danger of devaluating to the “old GOBSAT” manner,^{8,9} by overestimation of the experts knowledge⁸ and underestimation of the existence of evidence. Potential other pitfalls are, for example, imposing preconceptions of a problem and not allowing for the contribution of other related perspectives; poor techniques of summarizing and presenting the group responses; not exploring disagreements and; underestimating the demanding nature of a Delphi.⁸ A recent systematic review of reports based on the Delphi method found substantial variation in quality as consequence of lack of rigorousness of the application of the process.⁹ Ultimately the (new) standard terms are selected on the basis of arguments made transparent. Sensitive and systematic searching for existing evidence prevents reinvention of knowledge and has to provide the evidence base for the practice recommendations or for the terms. Finally the members and board of the ICS will see the draft standard and control, for process and structure, but also for missed evidence that may change the recommendations. Details of this process are given in the original publication but essentially the draft document is made available for all ICS members via the ICS website, and is also submitted to internal invited peer review and or discussed during an annual society meeting. The finally approved standard is published and, for example, relevant committees can take out relevant elements and make these into educational modules to be published as presentation on the ICS website to enhance implementation of standard good practice and terms by education.

3.2 | Scientific relevance

The International Continence Society has produced one of the most cited standards in healthcare.¹⁰ Table 1 shows the number of citations for the most “general” ICS standards on the basis of the counts given in Scopus.com website on May 15, 2018. Table 2 shows that the number of citations to the 2002 standardization document exceeds all documents with “practice guideline” or “practice standard” in the title when the three versions of the 2002 document (see Table 1) are grouped. (source: scopus.com). The references total of 6650 contains that the document is referred to every single day since its publication.

4 | DISCUSSION

The modern era standards should aim at that level and be the basis for good practice. ICS is still leading in the development of careful objective assessment of lower urinary tract

dysfunction as has been aimed in 1971. Objective assessment of dysfunction meets patients expectations also (or especially?) to date.¹¹ Modern era healthcare, however, also demands, more than in the early days of ICS, that patients quality of life and well-being are taken into account and that minimal or not invasive management is recommended to them, where possible. Not only terms and techniques for objective assessment and diagnosis should be renewed, in an evidence based fashion, also the assessment of the patients well-being deserves evidence based standardization. Furthermore standards for management may lead the way to improvements. The ICS standard for standardization may become the basis for systematic evidence based documents to enforce the International Consultation on Incontinence management recommendations¹² and may also expand to management of lower urinary tract dysfunctions without urinary incontinence.

5 | CONCLUSION

Standardization prevents miscommunication and therefore mismanagement, also in healthcare. ICS started with standardization, based on scientific progress and development and has continued this, in the lead, for almost 50 years. ICS Standardization is now standardized within the framework of Evidence Based Medicine and apart from further standardization of urodynamic assessment and evidence based objective pelvic floor muscle function evaluation standardization of quality of life assessment as well as standards for management may be future goals.

CONFLICT OF INTEREST

No.

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3. THE INTERNATIONAL CONSULTATION ON INCONTINENCE ALGORITHMS

Since its inception in 1998, the International Consultation on Incontinence, now in its 6th iteration, has brought together many of the world's leading experts to produce a unique scholarly knowledge synthesis of scientific work in the field of continence. Viewed by many senior and junior academics and clinicians as the "bible" of continence, the 6th edition is part of a productive partnership with the International Continence Society, seen by many as the "natural" home of the consultation. Its 23 or so chapters cover the range of scientific endeavour, from fundamental cellular mechanisms underlying incontinence and pelvic floor dysfunction to applied research in policy and health services research. In addition to providing an expert view of the state of the science, each committee rigorously examines the latest scientific evidence using the Oxford Grading system to produce recommendations for research and clinical practice in its areas of focus.

Each committee's findings were presented to a wide audience of ICS members at the 2016 ICS Annual Scientific Meeting in Tokyo where feedback was offered and considered prior to publication of the book "Incontinence". As part of its work, committees with a clinical focus produce an evidence informed algorithm for assessment and care for both initial and specialist assessment and management. The algorithms and their accompanying notes are published in *Neurourology and Urodynamics* as part of the Scientific Report from the Consultation¹ and are reproduced here as part of the programme of knowledge dissemination for the Consultation. Clearly production of such work is irrelevant without use, we therefore hope that you use these algorithms in practice and in presentation form in order to enhance to promote the highest quality of clinical care to patients.



Adrian Wagg
ICI Editor

on behalf of the Editors of the ICS and the ICS-ICI Steering Committee

1. Abrams P, Andersson KE, Apostolidis A, Birder L, Bliss D, Brubaker L, et al. 6th International Consultation on Incontinence. Recommendations of the International Scientific Committee: EVALUATION AND TREATMENT OF URINARY INCONTINENCE, PELVIC ORGAN PROLAPSE AND FAECAL INCONTINENCE. *Neurourol Urodyn*. 2018 Sep;37(7):2271-2.

2017

6th International Consultation on Incontinence

Co-sponsored by

International Consultation on Urological Diseases (ICUD)

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In collaboration with

major international associations of urology, gynaecology and urodynamics

and other medical associations

Recommendations of the International scientific Committee:

EVALUATION AND TREATMENT OF URINARY INCONTINENCE, PELVIC ORGAN PROLAPSE AND FAECAL INCONTINENCE

P. Abrams, K-E. Andersson, A. Apostolidis, L. Birder, D. Bliss, L. Brubaker, L. Cardozo, D. Castro, P.R. O'Connell, A. Cottenden, N. Cotterill, D. de Ridder, R. Dmochowski, C. Dumoulin, M. Fader, C. Fry, H. Goldman, P. Hanno, Y. Homma, V. Khullar, C. Maher, I. Milsom, D. Newman, J.M. Nijman, K. Rademakers, D. Robinson, P. Rosier, E. Rovner, S. Salvatore, M. Takeda, A. Wagg, T. Wagner, A. Wein

and the members of the committees

INTRODUCTION

The 6th International Consultation on Incontinence met between September 13-15th 2016 in Tokyo and was organised by the International Consultation on Urological Diseases and the International Continence Society (ICS), in order to develop consensus statements and recommendations for the diagnosis, evaluation and treatment of urinary incontinence, faecal incontinence, pelvic organ prolapse and bladder pain syndrome.

The consensus statements are evidence based following a thorough review of the available literature and the global subjective opinion of recognised experts serving on focused committees. The individual committee reports were developed and peer reviewed by open presentation and comment. The Scientific Committee, consisting of the Chairs of all the committees then refined the final consensus statements. These consensus statements published in 2017 will be periodically reevaluated in the light of clinical experience, technological progress and research.

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1. DEFINITIONS

The consultation agreed to use the current International Continence Society definitions (ICS) for lower urinary tract dysfunction (LUTD) including incontinence, except where stated. These definitions were published in the journal *Neurourology and Urodynamics* (2002; 21:167-178 and 2006; 25: and can be viewed on the ICS website: www.ics.org

The following ICS definitions are relevant:

1. LOWER URINARY TRACT SYMPTOMS (LUTS)

LUTS are divided into storage and voiding symptoms.

Urinary incontinence is a storage symptom and defined as the complaint of any involuntary loss of urine. This definition is suitable for epidemiological studies, but when the prevalence of bothersome incontinence is sought, the previous ICS definition of an “Involuntary loss of urine that is a social or hygienic problem”, can be useful.

Urinary incontinence may be further defined according to the patient’s symptoms

- **Urgency Urinary Incontinence** is the complaint of involuntary leakage accompanied by or immediately preceded by urgency.
- **Stress Urinary Incontinence** is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.
- **Mixed Urinary Incontinence** is the complaint of involuntary leakage associated with urgency, and also with effort, exertion, sneezing and coughing.
- **Nocturnal Enuresis** is any involuntary loss of urine occurring during sleep.
- **Post-micturition dribble** and **continuous urinary leakage** denotes other symptomatic forms of incontinence.

Overactive bladder is characterised by the storage symptoms of urgency with or without urgency incontinence, usually with frequency and nocturia.

2. URODYNAMIC DIAGNOSIS

- **Detrusor Overactivity** is a urodynamic observation characterised by involuntary detrusor contractions during the filling phase, which may be spontaneous or provoked.

Detrusor overactivity is divided into:

- **Idiopathic Detrusor Overactivity**, defined as overactivity when there is no clear cause
- **Neurogenic Detrusor Overactivity** is defined as overactivity due to a relevant neurological condition.
- **Urodynamic stress incontinence** is noted during filling cystometry, and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction.

3. BLADDER PAIN SYNDROME

Bladder pain syndrome is defined by ESSIC as chronic pelvic pain, pressure or discomfort of greater than 6 months duration perceived to be related to the urinary bladder accompanied by at least one other urinary symptom like persistent desire to void or urinary frequency. Confusable diseases as the cause of the symptoms must be excluded.

4. PELVIC ORGAN PROLAPSE

- **Urogenital prolapse** is defined as the symptomatic descent of one or more of: the anterior vaginal wall, the posterior vaginal wall, and the apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy. Urogenital prolapse is measured using the POP-Q system.
- **Rectal prolapse** is defined as circumferential full thickness rectal protrusion beyond the anal margin.

5. ANAL INCONTINENCE

Anal incontinence defined as “any involuntary loss of faecal material and/or flatus and/or mucus” and may be divided into:

- **Faecal incontinence**, any involuntary loss of faecal material
- **Flatus incontinence**, any involuntary loss of gas (flatus)
- **Mucus incontinence**, any involuntary loss of mucus only (not faeces)

* At the time of this consultation, these definitions are not included in the current ICS terminology.

2. EVALUATION

The following phrases are used to classify diagnostic tests and studies:

- **A highly recommended test** is a test that should be done on every patient.
- **A recommended test** is a test of proven value in the evaluation of most patients and its use is strongly encouraged during evaluation.
- **An optional test** is a test of proven value in the evaluation of selected patients; its use is left to the clinical judgement of the physician
- **A not recommended test** is a test of no proven value.

This section primarily discusses the Evaluation of Urinary Incontinence with or without Pelvic Organ Prolapse (POP) and Faecal Incontinence.

The recommendations are intended to apply to children and adults, including healthy persons over the age of 65.

These conditions are highly prevalent but often not reported by patients. Therefore, the Consultation strongly recommends case finding, particularly in high risk groups.

A. HIGHLY RECOMMENDED TESTS DURING INITIAL EVALUATION

The **main recommendations** for this consultation have been abstracted from the extensive work of the 23 committees of the 6th International Consultation on Incontinence (ICI, 2016).

Each committee has written a report that reviews and evaluates the published scientific work in each field of interest in order to give Evidence Based recommendations. Each report ends with detailed recommendations and suggestions for a programme of research.

The main recommendations should be read in conjunction with the management algorithms for children, men, women, the frail older person, neurogenic patients, bladder pain, pelvic organ prolapse, and anal incontinence

The initial evaluation should be undertaken, by a clinician, in patients presenting with symptoms/ signs suggestive of these conditions.

1. HISTORY AND GENERAL ASSESSMENT

Management of a disease such as incontinence requires caregivers to assess the sufferer in a holistic manner. Many factors may influence a particular individual's symptoms, some may cause incontinence, and may influence the choice and the success of treatment. The following components of the medical history are particularly emphasised:

1.1. Review of Systems:

- Presence, severity, duration and bother of any urinary, bowel or prolapse symptoms. Identifying symptoms in the related organ systems is critical to effective treatment planning. The use of validated questionnaires to assess symptoms are recommended.
- Effect of any symptoms on sexual function: validated questionnaires including impact on quality of life are a useful part of a full assessment.
- Presence and severity of symptoms suggesting neurological disease

1.2. Past Medical History:

- Previous conservative, medical and surgical treatment, in particular, as they affect the genitourinary tract and lower bowel. The effectiveness and side effects of treatments should be noted.
- Coexisting diseases may have a profound effect on incontinence and prolapse sufferers, for example asthma patients with stress incontinence will suffer greatly during attacks. Diseases may also precipitate incontinence, particularly in frail older persons.
- Patient medication: it is always important to review every patient's medication and to make an assessment as to whether current treatment may be contributing to the patient's condition.
- Obstetric and menstrual history.
- Physical impairment: individuals who have compromised mobility, dexterity, or visual acuity may need to be managed differently

1.3. Social History:

- Environmental issues: these may include the social, cultural and physical environment.

- Lifestyle: including exercise, smoking and the amount and type of fluid and food intake.

1.4. Other Treatment Planning Issues:

- **Desire for treatment** and the extent of treatment that is acceptable
- **Patient goals** and expectations of treatment
- **Patient support** systems (including caregivers).
- **Cognitive function:** all individuals need to be assessed for their ability to fully describe their symptoms, symptom bother and quality of life impact, and their preferences and goals for care. They must be able to understand proposed management plans and to discuss, where appropriate, alternative treatment options. In some groups of patients, formal testing is essential e.g. cognitive function testing for individuals for whom the clinician has concerns regarding memory deficits and/or inattention or confusion, and depression screening for individuals for whom the clinician has concerns about abnormal affect. Proxy respondents, such as family and caregivers, may be used to discuss the patient's history, goals of care, and treatment for individuals with dementia, but only if the individual is incapable of accurate reporting or weighing treatment decisions.

2. PHYSICAL EXAMINATION

The more complicated the history and the more extensive and/or invasive the proposed therapy, the more complete the examination needs to be. Depending on the patient's symptoms and their severity, there are a number of components in the examination of patients with incontinence and/or pelvic organ prolapse.

Physical examination should be performed regardless of whether the patient is a child, a woman, a man, someone with neurological disease or a frail elderly person.

2.1. General status:

- Mental status
- Obesity (BMI)
- Physical dexterity and mobility

2.2. Abdominal/flank examination: for masses, bladder distention, relevant surgical scars

2.3. Pelvic examination:

- Examination of the perineum and external genitalia including tissue quality and sensation.
- Vaginal (half-speculum/Sims) examination for pelvic organ prolapse (POP), which should be done in the vertical position

- Bimanual pelvic and anorectal examination for pelvic mass,
- Digital rectal examination to assess pelvic floor muscle function and the function of internal and external anal sphincter as well as puborectalis muscle.
- Stress test for urinary incontinence.

2.4. Neurological testing (see chapter on assessment)

3. URINALYSIS

In patients with LUTS, the possibility of a urinary tract infection should be evaluated, with appropriate testing (ranging from dipstick to urine microscopy and culture when indicated as UTI is a readily detected, and easily treatable cause of LUTS,

Conclusion

For simple treatments, particularly non-invasive and inexpensive therapies, management may start without the need for the further investigations listed below.

B. RECOMMENDED FURTHER ASSESSMENT PRIOR TO, OR DURING, SPECIALIST ASSESSMENT

The tests below are recommended when the **appropriate indication(s) is present**. Some recommended tests become highly recommended in specific situations.

This section should also be read in conjunction with the relevant committee reports.

1. FURTHER SYMPTOM AND HEALTH-RELATED QOL ASSESSMENT

1.1. Bladder Diary

In patients with **urinary symptoms** the use of a **bladder diary** (examples in Annex 1) is highly recommended to document the frequency of micturition, the volumes of urine voided, incontinence episodes and the use of incontinence pads.

1.2. Questionnaires

The use of the **highest quality questionnaires** (GoR A, where available) is recommended for the assessment of the patient's perspective of symptoms of incontinence and their impact on quality of life.

The ICIQ is highly recommended (GoR A) for the basic evaluation of the patient's perspective of urinary incontinence, with other GoR A questionnaires recommended for more detailed assessment. **Further development is required in the areas** of pelvic organ prolapse, bladder pain syndrome, and for specific patient groups, as only GoR B questionnaires are currently available (see Assessment Chapter).

2. RENAL FUNCTION ASSESSMENT

Standard biochemical tests for renal function are recommended in patients with urinary incontinence when there is the possibility of renal impairment.

3. UROFLOWMETRY

Uroflowmetry with the measurement of post void residual urine is recommended as a screening test for symptoms suggestive of urinary voiding dysfunction or physical signs of POP or bladder distension. Uroflowmetry should be part of the initial assessment if the result is likely to influence management eg in older men with possible prostatic obstruction.

4. ESTIMATION OF POST VOID RESIDUAL URINE (PVR)

In patients with suspected voiding dysfunction, PVR should be part of the initial assessment if the result is likely to influence management, for example, in neurological patients.

5. IMAGING

Although routine imaging is not recommended, imaging of the lower urinary tract and pelvis is highly recommended in those with urinary symptoms whose initial evaluation indicates a possible co-existing lower tract or pelvic pathology. Initial imaging may be by ultrasound, or plain X-ray.

Imaging of the upper urinary tract is highly recommended in specific situations. These include:

- Haematuria,
- Neurogenic urinary incontinence e.g. myelodysplasia, spinal cord trauma,
- Incontinence associated with significant post-void residual,
- Co-existing renal disease such as pyelonephritis or reflux, or loin/kidney pain,
- Severe pelvic organ prolapse, not being treated
- Suspected extra-urethral urinary incontinence,
- Children with incontinence and UTIs, where indicated

- Urodynamic studies which show evidence of poor bladder compliance or high pressure detrusor overactivity.

6. INVESTIGATIONS IN FAECAL INCONTINENCE AND RECTAL PROLAPSE

- Endoanal US or MRI prior to anal sphincter surgery is highly recommended, even when obvious anatomic defects are not evident.
- Defaecating proctography or dynamic MRI is recommended in suspected rectal prolapse which cannot be adequately confirmed by physical examination.
- Anorectal manometry is useful to assess resting and squeeze anal pressures. The resting and squeeze pressures represent the function of the internal and external anal sphincter, respectively.

7. ENDOSCOPY

Although routine cysto-urethroscopy is not recommended, LUT endoscopy is **highly recommended**:

- When initial testing is abnormal, e.g. haematuria and suggests other pathologies,
- When pain or discomfort feature in the patient's LUTS, these may suggest an intravesical lesion
- When appropriate in the evaluation of vesicovaginal fistula and extra-urethral urinary incontinence (in childbirth fistulae, endoscopy is often unnecessary).

In anorectal conditions, proctoscopy or flexible sigmoidoscopy should routinely be performed in the evaluation of patients with faecal incontinence. Colonoscopy, air contrast barium enema or CT colography is highly recommended in the presence of unexplained change in bowel habit, rectal bleeding or other alarm symptoms or signs (see Basic Assessment chapter).

8. URODYNAMIC TESTING

8.1. Urodynamic (multi channel pressure subtracted cystometry) evaluation is recommended

- When the results may change management, such as prior to most invasive treatments for UI and POP,
- After treatment failure, if more information is needed in order to plan further therapy,

- As part of both initial and long-term surveillance programmes in some types of neurogenic lower urinary tract dysfunction,
- In “complicated incontinence” (for details please see relevant subcommittee reports).

8.2. The aims of urodynamic evaluation are often diagnostic, but may also relate to prognostic factors, direct management or assess response to prior therapy, and also:

- To reproduce the patient’s symptoms and correlate these with urodynamic findings
- To assess bladder sensation
- To detect detrusor overactivity
- To assess urethral competence during filling
- To determine detrusor function during voiding
- To assess outlet function during voiding
- To assess residual urine

9. SMALL BOWEL FOLLOW-THROUGH, CT ENTOGRAPHY OR CAPSULE ENDOSCOPY

These tests are recommended in those with faecal incontinence and the presence of unexplained diarrhoea or when Crohn’s disease is suspected.

C. FURTHER DIAGNOSTIC TESTS TO BE USED AS APPROPRIATE

1. ADDITIONAL URODYNAMIC TESTING

Video-urodynamics may be useful in the management of UI in children, in patients who fail surgery and in some neurogenic patients, to obtain additional anatomical information. Either X-ray or US imaging can be used depending on the needs of the individual patient.

If a more **detailed estimate of urethral function** is required, then the following optional tests may give useful information:

- Urethral pressure profilometry
- Abdominal leak point pressures
- Video-urodynamics
- Electromyography of pelvic floor or urethral sphincter

If initial urodynamics have failed to demonstrate the cause for the patient’s incontinence then the following tests are optional:

- Repeated routine urodynamics or video-urodynamics
- Ambulatory urodynamics

2. PAD TESTING

Pad testing is an optional test for the routine evaluation of urinary incontinence and, if carried out, a 24 hr test is suggested.

3. NEUROPHYSIOLOGICAL TESTING AND IMAGING

The information gained by clinical examination and urodynamic testing may be **enhanced by neurophysiological testing** of striated muscle and nervous pathways.

Appropriately trained personnel should perform these tests. The following neuro-physiological tests can be considered in patients with peripheral lesions prior to treatment for lower urinary tract or anorectal dysfunction.

- Concentric needle EMG
- Sacral reflex responses to electrical stimulation of penile or clitoral nerves.

Imaging of the nervous system (and neighbouring structures, including spine, the abdominal cavity and pelvis) by MRI or CT, may confirm suspected involvement of the nervous system, and the nature of the cause.

4. FURTHER IMAGING

Cysto-urethrography, US, CT and MRI may have an indication:

- Suspected pelvic floor dysfunction
- Failed surgery, such as recurrent posterior vaginal wall prolapse or failed sling surgery
- Suspected fixed urethra

5. CYSTO-URETHROSCOPY

This is an optional test in patients with complicated, persistent or recurrent UI (e.g. after failed SUI surgery)

6. ANORECTAL PHYSIOLOGY TESTING

Endocoil MRI has high accuracy for detecting anal sphincter injury but is second line after endoanal ultrasound. Patients with faecal incontinence may benefit from assessment with MRI, particularly those with

anorectal malformations and/or previous anal sphincter surgery.

Defaecography may be useful and is recommended in patients with faecal incontinence, who have failed conservative therapies, and are possible candidates for laparoscopic ventral rectopexy.

3. MANAGEMENT CONSENSUS STATEMENTS

The consensus statements are derived from the **detailed work in the committee reports** on the management of incontinence in children, men, women, the frail elderly and neurological patients, as well as those with obstetric fistula, pelvic organ prolapse, bladder pain syndrome, and faecal incontinence. The management of incontinence is presented in **algorithm form with accompanying notes**.

The chapters analyze the evidence and give it a level of evidence (LoE) and this generates a GoR of recommendation (GoR)

The Consultation recognises that no algorithm can be applied to every patient and each patient's management must be individualised.

There are algorithms for

- I. Urinary Incontinence in Children
- II. Urinary Incontinence in Men
- III. Urinary Incontinence in Women
- IV. Fistulae
- V. Pelvic Organ Prolapse
- VI. Urinary Incontinence in Neurological Patients
- VII. Bladder Pain Syndrome
- VIII. Faecal Incontinence in Adults
- IX. Urinary and faecal Incontinence in frail Older Men and Women

These algorithms are divided into two for groups I to III, VII and X. The two parts, **initial management** and **specialised management** require a little further explanation.

Although the management algorithms are designed for patients whose predominant problem is incontinence, there are many other patients in whom the algorithms may be useful such as those patients with urgency and frequency, so-called "**OAB dry**

Management definitions

Management may be divided into

- Conservative, all methods that are non-medical and non-surgical, some of which do not target the disease process
- Medical (pharmacological) therapy

- Surgical therapy
- Conservative therapy includes
 - Lifestyle interventions e.g. weight loss
 - Bladder training
 - Pelvic floor muscle training (PFMT)
 - Containment products e.g. pads
 - Dependent continence strategies eg regular toileting

Consensus does not exist as to the use of the term "behavioural therapy" as some state that this term only includes bladder training and PFMT, whilst others consider that all conservative management contains a behavioural element, for example wearing and changing pads constitutes a change in behaviour. Hence the consultations recommendations list the elements of conservative management as relevant are intended for use by all clinicians including health care assistants/aides, nurses, physiotherapists, generalist doctors and family doctors as well as by specialists such as urologists, geriatricians and gynaecologists. The consultation has attempted to phrase the recommendations in the basic algorithms in such a way that they may be readily used by clinicians in all countries of the world, both in the developing and the developed world.

The algorithms for initial management

are intended for use by all **clinicians** including health care assistants/aides, nurses, physiotherapists, generalist doctors and family doctors as well as by specialists such as urologists, geriatricians and gynaecologists. The consultation has attempted to phrase the recommendations in the basic algorithms in such a way that they may be readily used by clinicians in all countries of the world, both in the developing and the developed world.

The specialised algorithms

The specialised algorithms are intended for use by **specialists**. The specialised algorithms, as well as the initial management algorithms are **based on evidence where possible**, and on the **expert opinion** of the 400 healthcare professionals who took part in the Consultation. In this consultation, committees ascribed levels of evidence to the published work on the

subject and devised GoRs of recommendation to inform patient management.

It should be noted that these algorithms, dated **April 2017**, represent the Consultation **consensus at that time**. Our knowledge, developing from both a research base and because of evolving expert opinion, will inevitably **change with time and relate to the unique context of individual patients seeking care**. The Consultation does not wish those using the algorithms to believe they are "carved in tablets of stone": there will be changes both in the relatively short term and in the long term.

1. ESSENTIAL COMPONENTS OF BASIC ASSESSMENT

Each algorithm contains a core of recommendations in addition to a number of essential components of basic assessment listed in sections I to III.

- General assessment
- Symptom assessment
- Assessment of quality of life impact
- Assessment of the desire for treatment
- Physical examination
- Urinalysis

2. JOINT DECISION MAKING

The patient's desires and goals for treatment: Treatment is a matter for discussion and joint decision making between the patient and his or her health care advisors. This process of consultation includes the specific need to assess whether or not the patient wishes to receive treatment and, if so, what treatments he or she would favour. Implicit in this statement is the assumption that the health care provider will give an **appropriate explanation of the patient's problem** and the **alternative lines of management**, and the potential **benefits** and **risks of treatment**. The assumption that patients almost always wish to have treatment is flawed, and the need to incorporate patient values and preferences is paramount.

In each algorithm, treatments are listed in **order of simplicity**, the least invasive being listed first. This order does not imply a scale of efficacy or cost, two factors which need to be considered in choosing the sequence of therapy. The order is likewise not meant to imply a suggested sequence of therapy, which should be determined jointly by the treating health care provider and the patient, considering all the relevant factors listed above.

In the **initial management algorithms**, treatment is **empirically based**, whilst the **specialised management algorithms** usually rely on precise diagnosis from urodynamics and other testing.

The assumption is made that patients will be reassessed at an appropriate time to evaluate their progress.

3. USE OF CONTINENCE PRODUCTS

The possible role of **continence products** to prevent, contain and/or manage bladder and/or bowel leakage should be considered at each stage of patient assessment and treatment, to maintain dignity and social functioning, and/or to support self-management or care by others.

Consider **temporary** use of continence products:

- While treatment is awaited.
- **In addition** to treatment; for example using pads and/or urinals when taking anti-muscarinics or carrying out pelvic floor exercises, until sufficient improvement is achieved.

Consider **permanent** use of continence products:

- When treatment is not chosen or not suitable for the individual
- When treatment does not achieve (complete) cure
- For **intermittent use**; for example when the patient has a cough, or needs to travel without reliable toilet access
- For **continuous use** if incontinence is unpredictable and/or frequent or if complications related to incontinence (e.g. skin breakdown) are imminent or present

Consider offering a **mixture** of continence products (disposable/washable; absorbent/non-absorbent) to optimise effectiveness and to reduce costs; e.g. different products for day and night; or for staying at home and for going out/travel/specific activities.

Further guidance on management with continence products is given in Chapter 20 and at the ICI/ICS supported website:

www.continenceproductadvisor.org

At the foot of each of the treatment algorithms below, the phrase "Consider CONTINENCE PRODUCTS for temporary support during treatment", emphasizes the importance of continence products for many sufferers of incontinence

I. URINARY INCONTINENCE IN CHILDREN

A. INITIAL MANAGEMENT

Children present specific management problems for a variety of reasons: assessment requires help from their parents and caregivers; consent to treatment may be problematic; and cooperation in both assessment and treatment may be difficult.

1. INITIAL ASSESSMENT SHOULD INVOLVE A DETAILED INVESTIGATION OF VOIDING AND BOWEL HABITS USING BLADDER/BOWEL DIARIES AND STRUCTURED AND VALIDATED QUESTIONNAIRES.

The child's social environment and general and behavioural development should also be formally assessed and recorded. Physical examination should be done to detect a palpable bladder, faecal loading and exclude anatomic and neurological causes. Urine analysis and culture is sufficient to exclude the presence of infection. If possible, the child should be observed voiding.

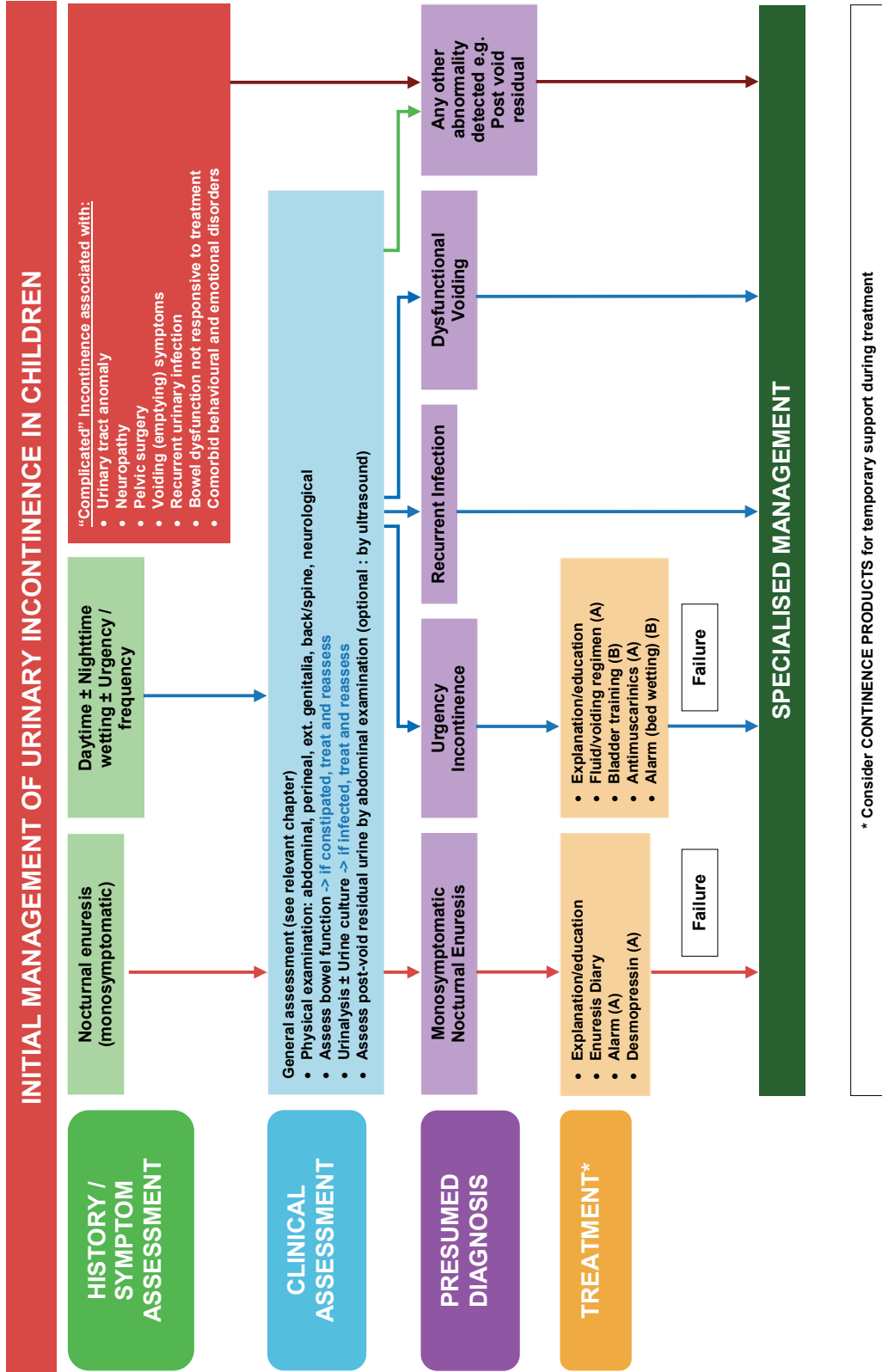
➤ **Referrals for specialist treatment are recommended for children who have complicated incontinence associated with:**

- Recurrent and febrile urinary infection
- Voiding symptoms or evidence of poor bladder emptying
- Urinary tract anomalies
- Previous pelvic surgery
- Neuropathy or neuropathic origin
- Bowel dysfunction not responsive to treatment

- Comorbid behavioural (e.g. ADHD and ODD) and emotional disorders.
- **Initial treatment is recommended for the remaining patients who have:**
- Nocturnal enuresis without other symptoms (monosymptomatic enuresis).
- Daytime symptoms of frequency, urgency, voiding postponement, straining, interrupted voiding, urgency incontinence with or without nighttime wetting.

2. TREATMENT

- Initial treatment for **mono-symptomatic nocturnal enuresis** should include:
 - Parental and child counselling and motivation
 - Review of bladder diary with attention to night-time polyuria
 - Age appropriate education and demystification or explanation
- A choice between either bed wetting alarm (GoR A) or anti-diuretic hormone analogues of desmopressin (GoR A). It may be a parental and child choice if advantages and disadvantages are well explained.
- Daytime incontinence should be managed holistically including:
 - Counselling, timed voiding, behaviour modification and bowel management when necessary (GoR B);
 - Antimuscarinics may be used if the child has OAB symptoms (GoR A)



I. URINARY INCONTINENCE IN CHILDREN

B. SPECIALISED MANAGEMENT

- **Two groups of children with “complicated” incontinence** should have specialist management from the outset (Fig. 2).
 - Children whose incontinence is due to, or associated with, **urinary tract anomalies and neuropathy**.
 - Children without urinary tract anomalies, but with **recurrent febrile infection** and, proven or suspected, **lower urinary tract dysfunction**.
 - Children who **fail the basic treatment**, but who have neither neurogenic nor anatomical problems, should also receive specialist management.
- Children with comorbid behavioural and emotional disorders require referral to mental health services, as compliance and treatment outcomes are lower.
- Assessment and treatment should follow evidence-based practice guidelines

1. ASSESSMENT

- As part of further assessment, the measurement of **urine flow** (in children old enough), together with the **ultrasound estimate of residual urine** and appearance of the bladder wall and rectum are highly recommended. An evaluation of the **upper urinary tracts with ultrasound is also highly recommended**.
- Those who do not improve **with treatment** and have neither neurogenic nor anatomical problems **should be reassessed** using bladder diaries, symptom questionnaires, urinalysis, uroflowmetry and residual urine determination.
- If there are recurrent and febrile infections**, upper tract imaging and possibly a VCUG should be considered. However, endoscopy is rarely indicated.
- **Urodynamics should be considered:**
 - If the type and severity of lower tract dysfunction **cannot be explained by clinical findings** or in the presence of possible relevant neuropathy or urinary tract anomalies. (GoR B)

- If **invasive treatment** is under consideration, for example, stress incontinence surgery if there is sphincteric incompetence, or bladder augmentation if there is detrusor overactivity. (GoR B)
- If **upper tract dilation exists** and is thought to be due to bladder dysfunction. (GoR A)
- **Invasive urodynamic studies are generally not recommended** if the child has normal upper tract imaging and is to be treated by noninvasive means. (GoR B)
- **Spinal Imaging** (US/X-ray/MRI) may be needed if a bony abnormality or neuro-logical condition is suspected. (GoR A)

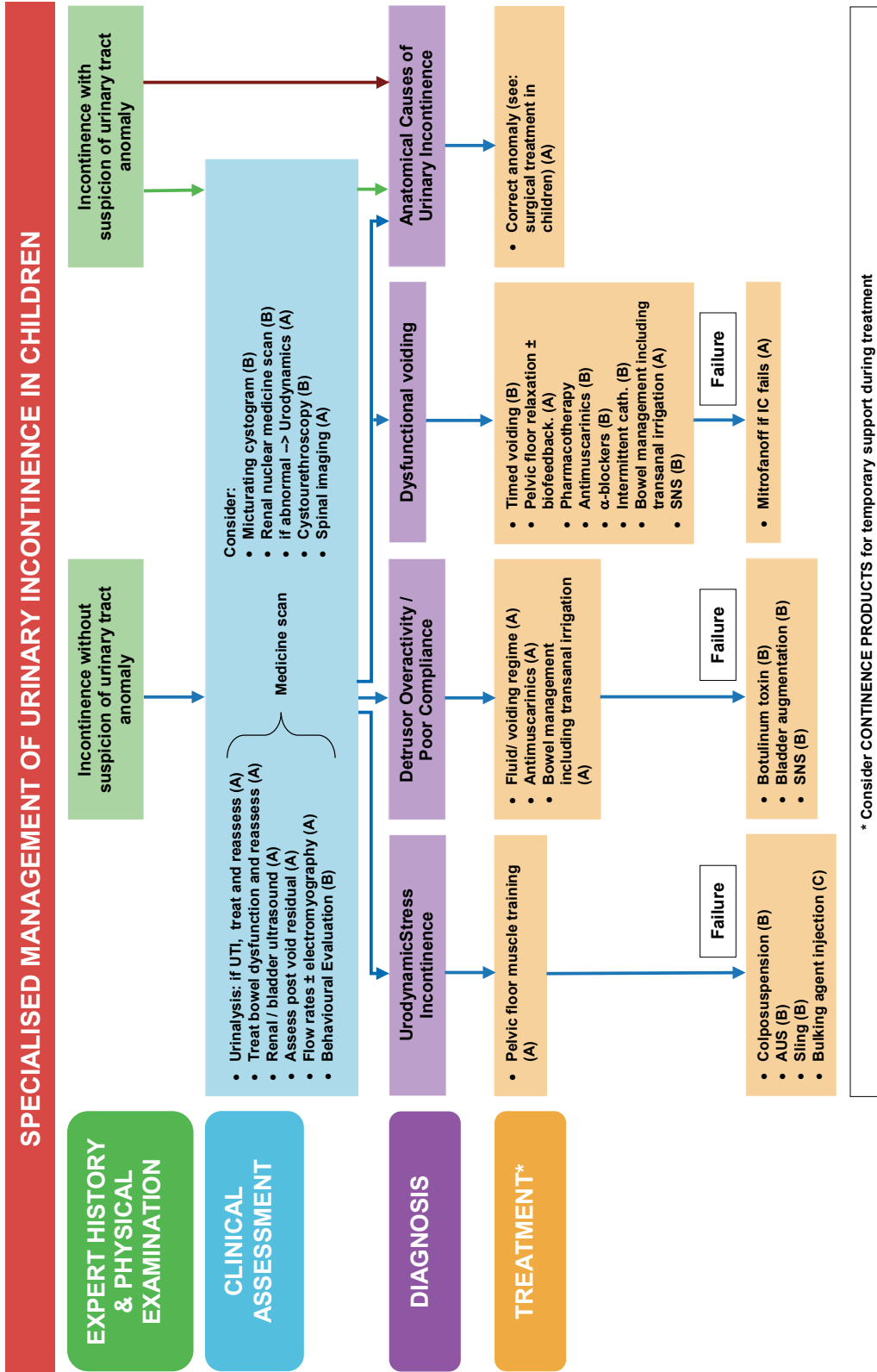
2. TREATMENT

The treatment of incontinence associated with **urinary tract anomalies** is complex and cannot easily be dealt with in an algorithm. In many children **more than one pathology** demands treatment. If there are **complex congenital abnormalities present**, the treatment is mostly surgical and it should be individualised according to the type and severity of the problem (please see Children’s Committee Report).

Care should be given by specialist children’s nurses and therapists.

- **Initial treatment should be non-surgical.**
 - **For stress urinary incontinence (SU):** pelvic floor muscle training (GoR C).
 - **For OAB symptoms:** fluid/voiding regimens and antimuscarinics (GoR A).
 - **For voiding dysfunction:** timed voiding, voiding re-education, pelvic floor muscle relaxation (+/- biofeedback), alpha-blocker therapy, and intermittent catheterisation (when PVR >30% of bladder capacity) (GoR A/B).
 - **For bowel dysfunction:** high fibre diet and laxatives as appropriate, and, transanal irrigation in severe cases (GoR A).

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- The child's progress should be assessed and, if quality of life is still significantly impaired, or if the upper urinary tracts are at risk, **surgical treatment** is likely to be necessary.
- **If surgical treatment is required**, then urodynamic studies are recommended to confirm the diagnosis.
 - **For USI**, colposuspension, sling surgery, bulking agent injection and AUS may be considered (GoR B).
 - **For DO/poor compliance**, botulinum toxin (for DO, and off-label) and bladder augmentation may be performed (GoR B).
 - **If the child cannot do IC** then a Mitrofanoff channel may be needed (GoR A).



TREATMENT*

* Consider CONTINENCE PRODUCTS for temporary support during treatment

II. URINARY INCONTINENCE IN MEN

2564

A. INITIAL MANAGEMENT

1. INITIAL ASSESSEMENT SHOULD IDENTIFY:

➤ “Complicated” incontinence group

Those with pain or with haematuria, recurrent infection, suspected or proven poor bladder emptying (for example due to bladder outlet obstruction), or incontinence following pelvic irradiation or radical surgery, are recommended for **specialised management**.

Poor bladder emptying may be suspected from symptoms, physical examination or if imaging has been performed by X-ray or ultrasound after voiding.

➤ **Four other main groups** of men should be identified by initial assessment as being suitable for **initial management**.

- Those with post-micturition dribble alone,
- Those with overactive bladder (OAB) symptoms: urgency with or without urgency incontinence, together with frequency and nocturia
- Those with stress urinary incontinence (most often post-prostatectomy),
- Those with mixed urinary urgency and stress incontinence (most often post-prostatectomy)

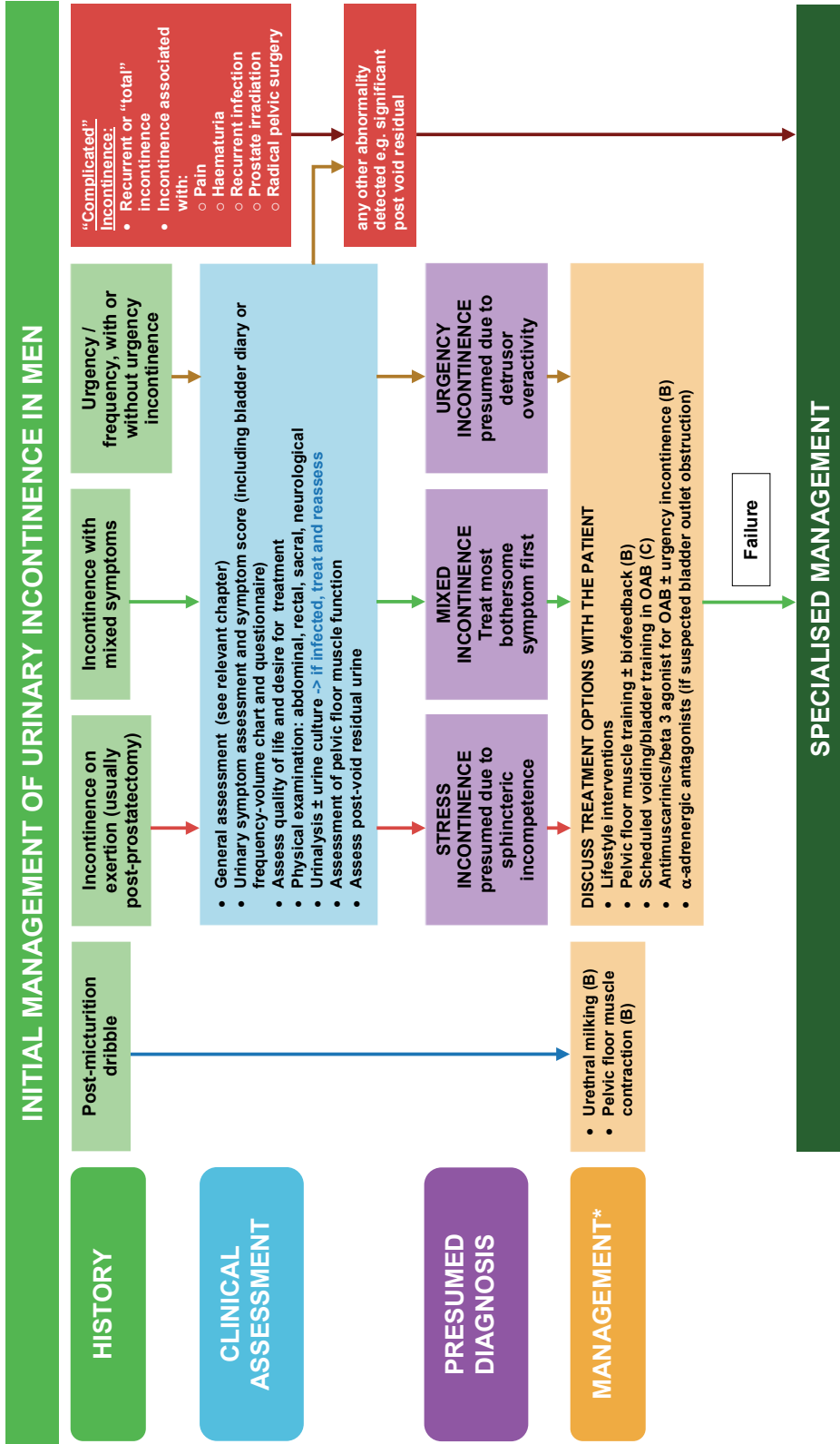
2. MANAGEMENT

- For men with **post-micturition dribble**, this requires no assessment and can usually be treated by teaching the man how to do a strong pelvic floor muscle contraction after voiding, or manual compression of the bulbous urethra directly after micturition. (GoR B)

- For men with **stress, urgency or mixed urgency** / stress incontinence, initial treatment should include appropriate lifestyle advice, pelvic floor muscle training, scheduled voiding regimens, behavioural therapies and medication. In particular:

- Lifestyle interventions (eg weight loss GoR B)
- Supervised pelvic floor muscle training for men with post radical prostatectomy SU1 accelerates recovery time(GoR B)
- Scheduled voiding regimen for OAB (GoR C)
- Antimuscarinic/beta 3 agonist drugs for OAB symptoms with or without urgency incontinence (GoR B) if the patient has no evidence of significant post-void residual urine
- α -adrenergic antagonists (a-blockers) can be added if it is thought that there may also be bladder outlet obstruction. (GoR C)
- **Should initial treatment be unsuccessful** after a reasonable time (for example, 8-12 weeks), **specialist advice** is highly recommended.

Clinicians are likely to wish to treat the **most bothersome symptom** first in men with symptoms of **mixed** incontinence.



* Consider CONTINENCE PRODUCTS for temporary support during treatment

II. URINARY INCONTINENCE IN MEN

2566

B. SPECIALISED MANAGEMENT

The specialist may first **reinstitution initial management** if it is felt that previous therapy had been inadequate.

1. ASSESSMENT

- Patients with “**complicated**” incontinence referred directly to specialised management, are likely to require **additional testing**, such as cytology, cystourethroscopy and urinary tract imaging.

If **additional testing is normal** then those individuals can be treated for incontinence by the initial or specialised management options as appropriate.

If **symptoms** suggestive of detrusor overactivity, or of sphincter incompetence **persist**, then **urodynamic** studies are advisable in order to arrive at a precise diagnosis, prior to invasive treatment.

2. TREATMENT

When basic management has been unsuccessful and if the patient's incontinence markedly disrupts his quality of life then **invasive therapies** should be considered.

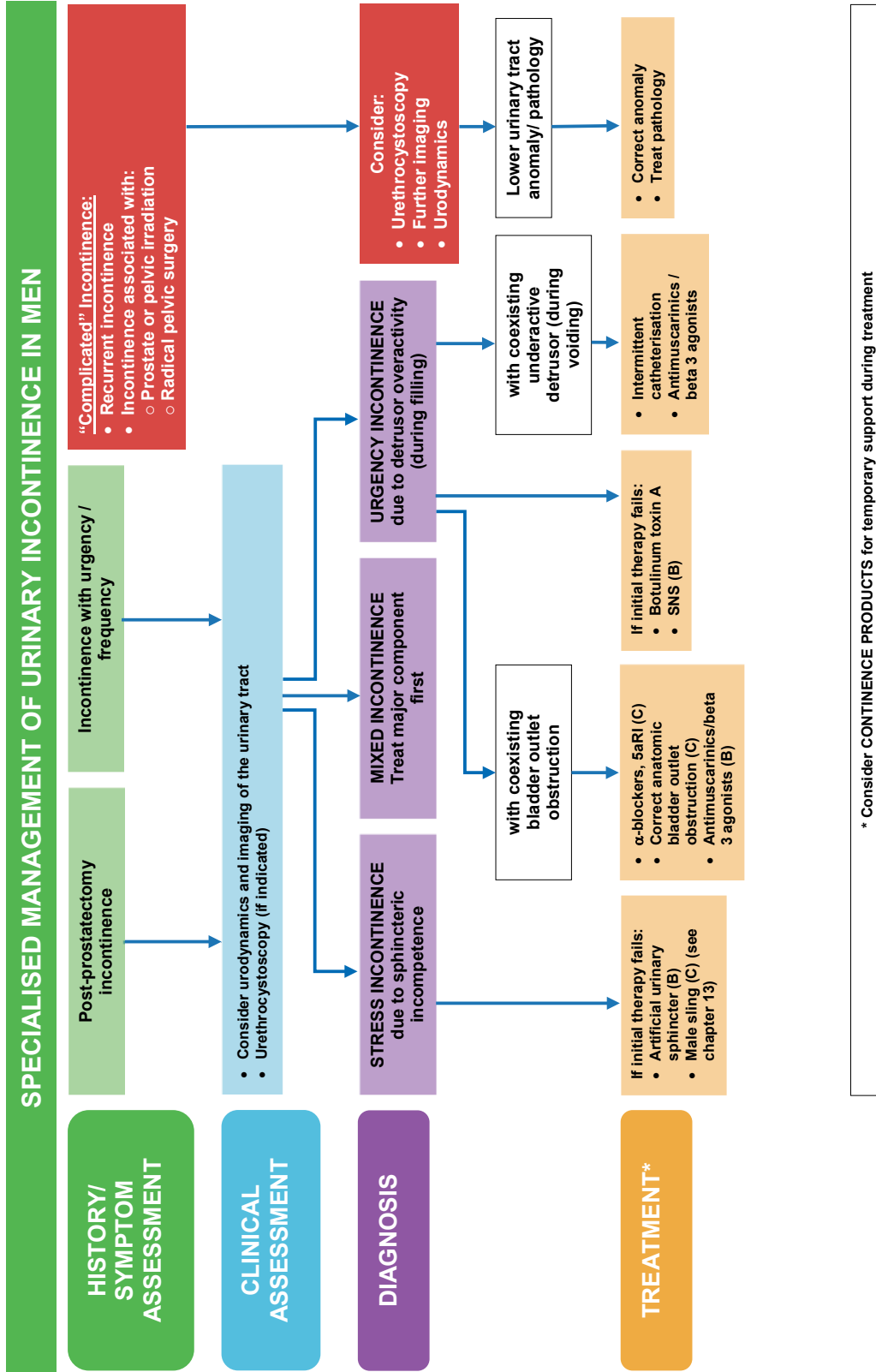
- For **sphincter incompetence** the recommended option is the artificial urinary sphincter (GoR B). Other options, such as a male sling, may be considered (GoR C).

- For **refractory idiopathic detrusor overactivity**, (with intractable overactive bladder symptoms) the recommended therapies are: Botulinum toxin A (GoR B), and SNS (GoR C).

When incontinence has been shown to be associated with **poor bladder emptying** due to **detrusor underactivity**, it is recommended that effective means are used to ensure bladder emptying, for example, intermittent catheterisation (GoR B/C).

- If incontinence is associated with bladder outlet obstruction, then consideration should be given to surgical treatment to relieve obstruction (GoR B). α -blockers and/or 5 α - reductase inhibitors would be an optional treatment (GoR C).

- There is increased evidence for the safety of antimuscarinics for overactive bladder symptoms in men, chiefly in combination with an α -blocker (GoR B).



III. URINARY INCONTINENCE IN WOMEN

2568

A. INITIAL MANAGEMENT

1. INITIAL ASSESSMENT SHOULD IDENTIFY:

- **“Complicated” incontinence group.**
Those with pain or haematuria, recurrent infections, suspected or proven voiding problems, significant pelvic organ prolapse or who have persistent incontinence or recurrent incontinence after pelvic irradiation, radical pelvic surgery, previous incontinence surgery, or who have a suspected fistula, should be referred to a specialist.
 - **Three other main groups** of patients should be identified by initial assessment.
 - Women with **stress incontinence** on physical activity
 - Women with **urgency, frequency** with or without urgency incontinence: overactive bladder (OAB)
 - Those women with **mixed** urgency and stress incontinence
- Abdominal, pelvic and perineal examinations should be a routine part of physical examination. Women should be asked to perform a “stress test” (cough and strain to detect leakage likely to be due to sphincter incompetence). Any pelvic organ prolapse or urogenital atrophy should be assessed. Vaginal or rectal examination allows the assessment of voluntary pelvic floor muscle function, an important step prior to the teaching of pelvic floor muscle training.

2. TREATMENT

- For women with **stress, urgency or mixed** urinary incontinence, initial treatment should include appropriate lifestyle advice, pelvic floor muscle training,

PFMT), scheduled voiding regimes, behavioural therapies and medication. In particular:

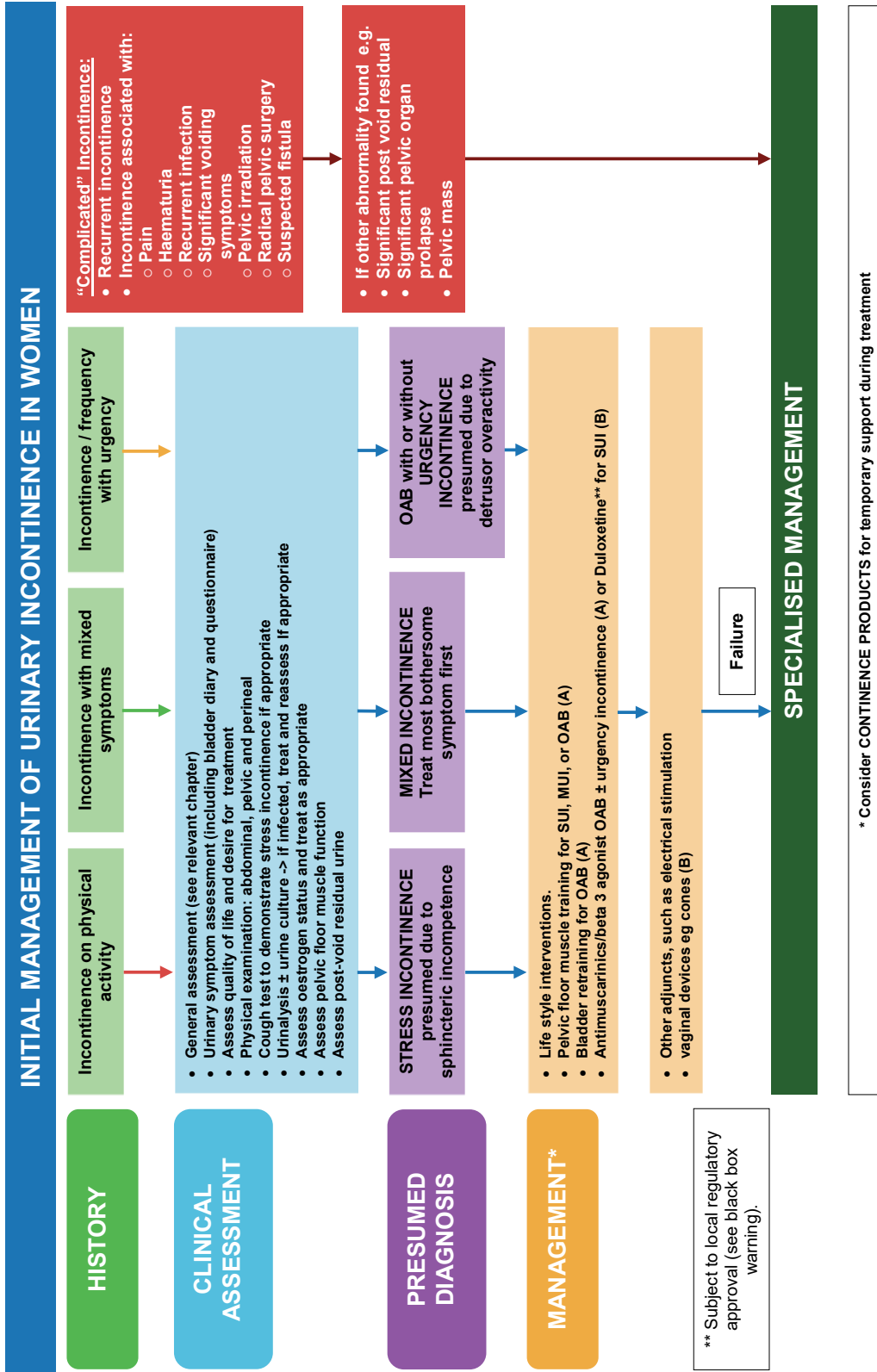
- **Advice** on caffeine reduction for OAB (GoR B) and weight reduction (GoR A).
- Supervised pelvic floor muscle training (GoR A), supervised vaginal cones training for women with stress incontinence (GoR B).
- Supervised bladder training (GoR A) for OAB.
- **If oestrogen deficiency** and/or **UTI** is found, the patient should be treated at initial assessment and then reassessed after using vaginal oestrogens for a suitable period (GoR B).
- **Antimuscarinics/beta 3 agonist** for OAB symptoms with or without urgency incontinence (GoR A); duloxetine* may be considered for stress urinary incontinence (GoR B)

PFMT should be based on sound muscle training principles such as specificity, overload progression, correct contraction confirmed prior to training and use of “the Knack” for 12 weeks before reassessment and possible specialist referral.

Clinicians are likely to wish to treat the **most bothersome symptom first** in women with symptoms of mixed incontinence. (GoR C).

- Some women with significant pelvic organ prolapse can be treated by vaginal devices that treat both incontinence and prolapse (incontinence rings and dishes).

*Duloxetine is not approved for use in United States. In Europe it is approved for use in severe stress incontinence (see committee report on pharmacological management for information regarding efficacy, adverse events, and ‘black box’ warning by the Food and Drug Administration of the United States).



** Subject to local regulatory approval (see black box warning).

* Consider CONTINENCE PRODUCTS for temporary support during treatment

“Complicated” Incontinence:

- Recurrent incontinence
- Incontinence associated with:
 - Pain
 - Haematuria
 - Recurrent infection
 - Significant voiding symptoms
 - Pelvic irradiation
 - Radical pelvic surgery
 - Suspected fistula

If other abnormality found e.g.

- Significant post void residual
- Significant pelvic organ prolapse
- Pelvic mass

III. URINARY INCONTINENCE IN WOMEN

2570

A. SPECIALISED MANAGEMENT

1. ASSESSMENT

Women who have “**complicated**” **incontinence** (see initial algorithm) may need to have additional tests such as cytology, urodynamics, cystourethroscopy or urinary tract imaging. If these tests are normal then they should be treated for incontinence by the initial or specialised management options as appropriate.

- Those women with persistent symptoms despite **initial management** and whose quality of life is impaired are likely to request further treatment. If initial management has been given an adequate trial then **interventional therapy may be desired**. When the results of urodynamic testing may change management, we highly recommend testing prior to intervention in order to diagnose the incontinence type and, therefore, inform the management plan. Urethral function testing by urethral pressure profile or leak point pressure is optional.

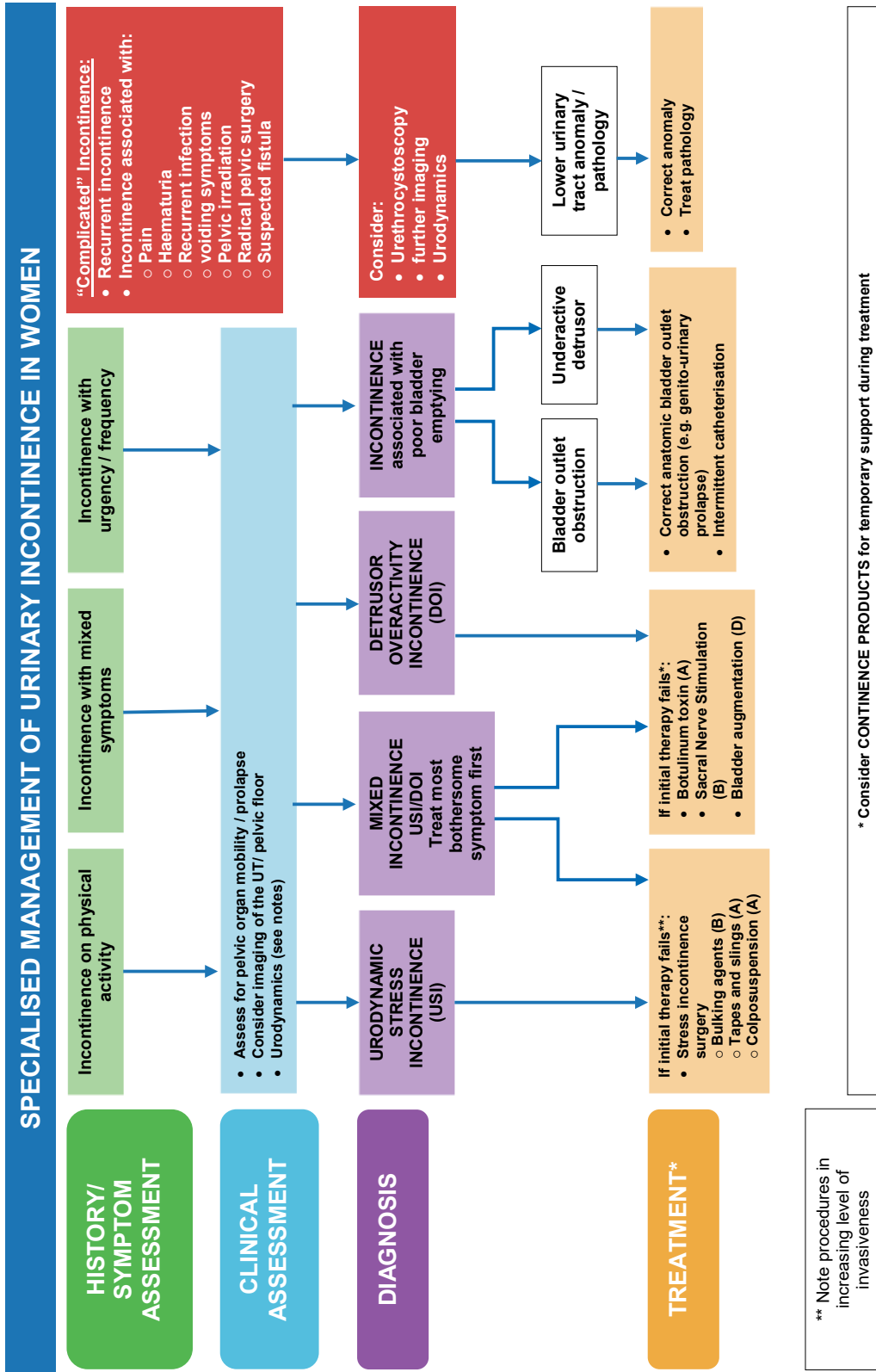
- Systematic assessment for **pelvic organ prolapse** is highly recommended and the POP-Q method should be used in research studies. Women with co-existing pelvic organ prolapse should have their prolapse treated as appropriate.

2. TREATMENT

- If **stress incontinence is confirmed** then the treatment options that are recommended for patients include the full range of non-surgical treatments, as well as colposuspension procedures, (GoR A) and bladder neck/sub-urethral sling operations (GoR A). All of these procedures have potential risks and associated complications which should be discussed with the individual. **The correction of symptomatic** pelvic organ prolapse may be desirable at the same time. For selected patients injectable bulking agents (GoR B) and the artificial urinary sphincter (GoR C) can be considered.

- **Refractory urgency incontinence** (overactive bladder) secondary to idiopathic detrusor overactivity may be treated by botulinum toxin A (GoR A), sacral nerve stimulation (GoR B) or bladder augmentation/intestinal cystoplasty (GoR D).

- Those patients with **voiding dysfunction** leading to significant post-void residual urine (for example, >30% of total bladder capacity) may have bladder outlet obstruction or detrusor underactivity. Prolapse is a common reversible cause, of voiding dysfunction.



IV. FISTULAE

2572

In the developing world fistulae occur as a consequence of poor perinatal care. Despite vast surgical experience in some centres, published research is of low quality.

In the developed world, iatrogenic urogenital fistulae are known complications of pelvic surgery and oncological treatments such as radiotherapy, chemotherapy or a combination of both. In the oncological context, fistulae may also occur as a result of primary or recurrent malignancy. The development of fistula following radiotherapy for primary treatment should trigger a search for evidence of tumour recurrence (GoR D). The use of neoadjuvant or adjuvant therapies is likely to be associated with a greater risk of fistula development than the primary treatment alone.

The most common non-obstetric causes of fistulae involving the gastro-intestinal tract are diverticular disease, Crohn's disease, malignancy and radiotherapy.

1. INITIAL ASSESSMENT

Early detection of fistulae could be improved by examining all women after their delivery, or prevented by Caesarian section for women who suffer prolonged labour and who are at risk of developing an obstetric fistula. Associated pathologies should be actively searched for and should be taken into account in the treatment plan: all components of the 'obstructed labour injury complex' should be examined. Prevention by better health education, and by avoiding harmful practices must be encouraged.

Classification of fistulae is recommended. Although many classification systems exist, the committee recommends the use of the Goh, WHO or Tafesse classification systems (GoR B)

The formal classification of the fistula should be done under anaesthesia when the patient is on the operation table, just before surgery.

- Leakage of stool, urine, or possibly both is the hallmark sign of a fistula. The leakage is usually painless, may be intermittent if it is position dependent, or may be constant.
- CT and cystoscopy appear more consistent in the confirmation and location of possible intestino-vesical fistulae, than other investigations (GoR C)

- Level 3 evidence indicates that the routine use of cystoscopy with dye testing at gynaecological surgery has high sensitivity, specificity and negative predictive value in the detection of ureteric injury, although false positive tests do occur. (GoR C)

- Ureteric injury or fistula may be suspected in patients following pelvic surgery if a fluid leak or pelvi-calyceal dilatation occurs postoperatively. (GoR D)

- Uretero-arterial fistula may be suspected in patients presenting with haematuria with a history of relevant pelvic surgery and indwelling ureteric stent. (GoR D)

- Elevated levels of creatinine in drainage fluid following pelvic surgery are suggestive of urine leaking due to a urinary tract injury. (GoR D)

2. MANAGEMENT OF NEW AND ESTABLISHED VVF

Management of VVF depends on whether the fistula is diagnosed within a few weeks of its occurrence or whether the woman presents late with an established fistula.

Early fistulae are those which are not re-epithelialised, and ischaemic and necrotic tissue can be present at the time of examination. There is evidence that early catheter care will result in the cure of a significant minority of VVFs. (GoR C)

Established fistulae are re-epithelialised and show no oedema, ischaemic changes or inflammation. These fistulae and those that fail catheter treatment should be treated surgically by an experienced surgeon. (GoR C)

3. TREATMENT

If catheter drainage fails, then fistula repair will be necessary. There are certain principles behind fistula repair:

- Necrotic tissue must be removed prior to fistula repair.
- Fistula repair must only be undertaken by a properly trained surgeon.
- Adequate post-operative care is essential.

- Proper follow-up should be arranged.

In principle, most fistulae can be dealt with by the vaginal approach, but an abdominal approach may be needed in some cases (e.g. concomitant reconstructive procedures e.g. ureteral reimplantation or bladder augmentation). (GoR C)

A tension-free single layer closure of the bladder wall and closure of the vaginal wall in a separate layer is advocated. A Martius flap in primary fistula repair is not recommended.

When reporting on outcome after fistula repair, authors should make a clear distinction between fistula closure rates and post-operative incontinence rates and the time at which the follow-up was organised.

Prevention of post-operative stress incontinence must be added to the surgical procedure if the urethral closing mechanism is involved. This can be done by a good repair of the pubocervical fascia and refixation or by adding a sling procedure.

Attention should be given as appropriate to skin care, nutrition, rehabilitation, counselling and support prior to and following fistula repair. (GoR D)

There is no proven benefit to delayed repair of vesicovaginal fistulae; the timing of repair should be tailored to the individual patient and surgeon requirements, but can be undertaken as soon as any oedema, inflammation, tissue necrosis, and infection have resolved. (GoR B)

There are no high quality data to indicate greater cure rates for any one technique as compared to others; level 3 evidence indicates similar success rates for vaginal and abdominal, and for transvesical and transperitoneal approaches. (GoR C)

A variety of interpositional grafts can be used in either abdominal or vaginal procedures, although there is little evidence to support their use in any specific setting. (GoR C)

Conventional and robotically-assisted laparoscopic approaches have both been shown to be feasible in selected cases; the indications for, or optimal patient for these techniques is not yet clear. (GoR C)

A period of continuous bladder drainage is crucial to successful fistula repair; there are no high level data to support any particular type, route, or duration of catheterisation. Current practice suggests, 10-14 days for simple and/or post-surgical fistulae; 14-21 days for complex and/or post-radiation fistulae. (GoR D)

Whilst diversion is used more widely in radiation-associated fistulae of all types as compared to non-radiated fistulae, there is low-level evidence that repair procedures can achieve successful fistula closure and continence in appropriately selected cases. (GoR C)

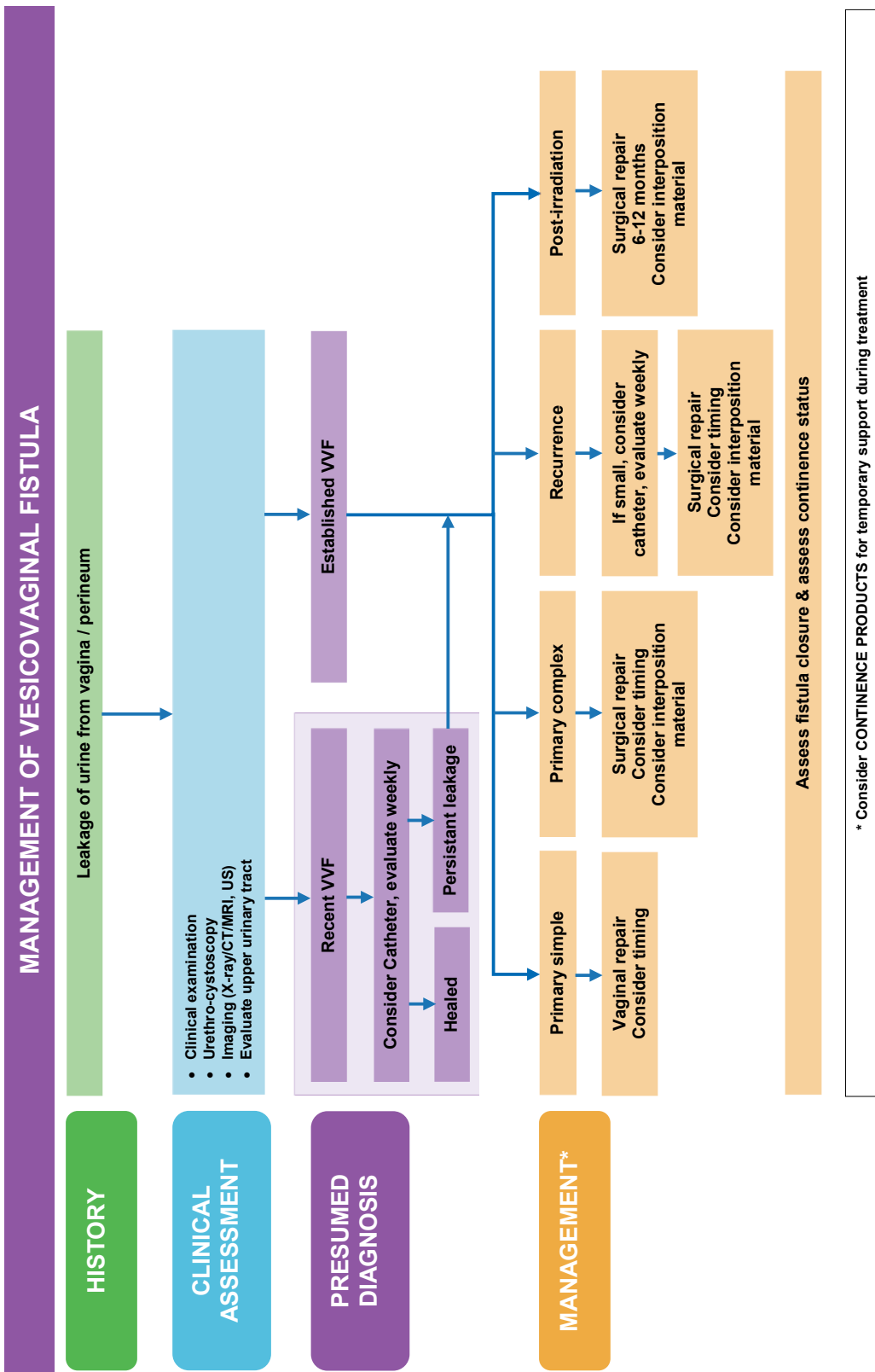
Where urinary and/or faecal diversions are required, attempts should be made to avoid using irradiated tissues wherever possible, and to minimise the potential for anastomotic complications. (GoR C)

There is low-level evidence to support the use of interposition grafts when repair of radiation-associated fistulae is undertaken. (GoR C)

4. MANAGEMENT OF THE COMPLICATIONS OF VVF

The complications of vesico-vaginal fistulae are many but include:

- Persistence or recurrence of urinary incontinence
- Persistence of lower urinary tract symptoms or occurrence of new lower urinary tract symptoms, including overactive bladder
- Urinary tract infections
- Upper urinary tract symptoms, including loin pain
- Dyspareunia and sexual dysfunction
- Infertility
- Neurological symptoms
- Psychological problems and mental illness



1. MANAGEMENT OF FISTULAE INVOLVING BOWEL

- There is limited evidence to support a non-surgical or conservative surgical approach in colo-vesical fistulae where there are minimal symptoms or evidence of limited bowel involvement. (GoR C)
- A one-stage approach to surgery for intestino-vesical fistulae is appropriate in many cases, but should be limited to those patients whose nutritional state is good, and where there is no evidence of additional intra-abdominal pathology (e.g. severe inflammation, radiation injury, advanced malignancy, intestinal obstruction) or major co-morbidity. (GoR B)
- A laparoscopic/robotic approach to one-stage management is feasible, although there is no high level evidence to allow comparison of outcomes with open surgery. (GoR D)

2. MANAGEMENT OF URETERIC FISTULAE

- Surgeons undertaking complex pelvic surgery should be competent at identifying, preserving and repairing the ureter. (GoR D)
- Ureteric stents are not required as prophylaxis against injury during routine gynaecological surgery, while their role in more extensive surgery remains to be established. (GoR B)

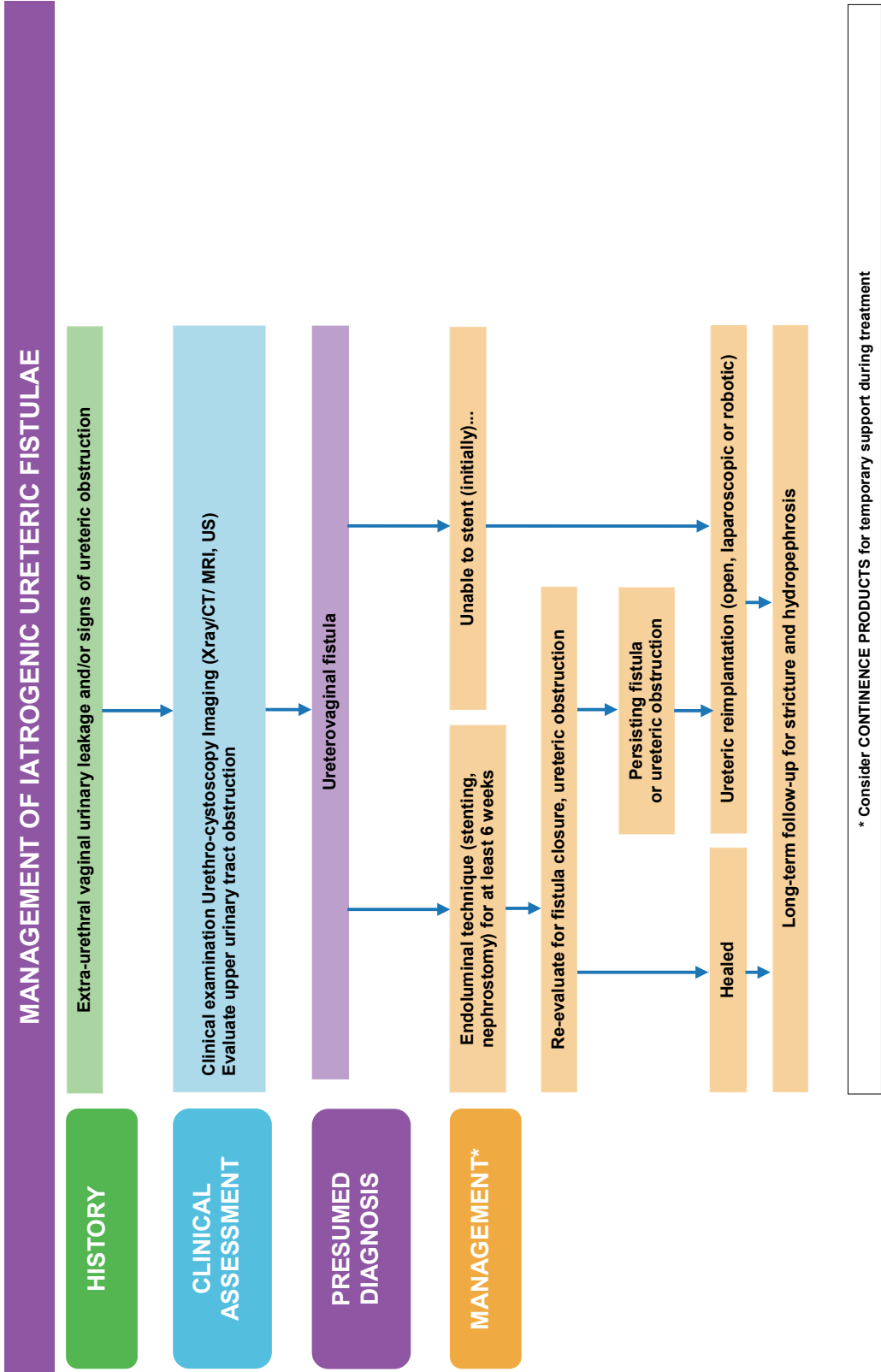
- Most upper urinary tract fistulae should be initially managed by conservative or endoluminal techniques where such expertise and facilities exist. (GoR B)
- Persistent ureterovaginal fistulae should be repaired by an abdominal approach using open, laparoscopic or robotic techniques according to availability and competence. (GoR D)

- For patients with ureteric fistulae associated with advanced pelvic cancer and poor performance status, palliation by nephrostomy tube diversion and endoluminal distal ureteric occlusion is an option. (GoR C)

3. MANAGEMENT OF URETHRO-VAGINAL FISTULAE

Recommendations

- Urethrovaginal fistulae are preferably treated by a vaginal approach. (GoR C)
- A variety of autologous tissue interposition techniques have been described, but their value remains uncertain. (GoR C)
- Urethrovaginal fistulae repair may be complicated by stress incontinence, urethral stricture and urethral shortening necessitating long-term follow-up. (GoR C)



V. PELVIC ORGAN PROLAPSE

1. INTRODUCTION

Pelvic organ prolapse includes vaginal and rectal prolapse. Treatment of pelvic organ prolapse is generally reserved for symptomatic prolapse. Clinicians should recognise that coexistent pelvic floor symptoms are frequently present and that these symptoms may or may not be related to the prolapse. Women with prolapse require a careful and detailed initial assessment not only of the prolapse but associated bladder, bowel and sexual function.

2. ASSESSMENT

Symptom assessment preferably with a validated pelvic floor questionnaire that assesses bladder, bowel, vaginal and sexual function and bothersomeness is required. (Grade C).

Physical examination should:

- Report the most distal site of vaginal descent in relation to a fixed point such as the hymen and include an assessment of the anterior posterior and apical vagina. While standardised reporting utilising tools such as the Pelvic Organ Prolapse Quantification (POP-Q) are encouraged. The system used to measure the extent of the prolapse should be documented.
- Be undertaken in the standing position to evaluate the full extent of the prolapse.
- Determine if coexistent pelvic pathology is present on careful bimanual examination. Cytological screening of the cervix should be undertaken if required.
- The prolapse should be reduced to document the presence of occult stress urinary incontinence (see chapter for prolapse and urinary incontinence pathway).
- Assess pelvic floor muscle function (see chapter for full review).
- Determine if epithelial/ mucosal ulceration is present.
- Evaluate anal sphincter tone and or the presence of rectal prolapse in those with bowel symptoms (refer to chapter for pelvic organ prolapse and bowel symptom pathway).

When examination findings of the extent of the prolapse are not consistent with the history the examination can be repeated in a few weeks' time. (GoR C).

Post void residual should be measured; while most elevated post-void residual urines (150mls) resolve with treatment of the prolapse, a specialist consultation is required.

3. MANAGEMENT

Observation is appropriate when medically safe (GoR C).

Lifestyle interventions include weight loss, treating constipation, avoiding straining at stool and heavy lifting (GoR C).

Pelvic floor muscle training:

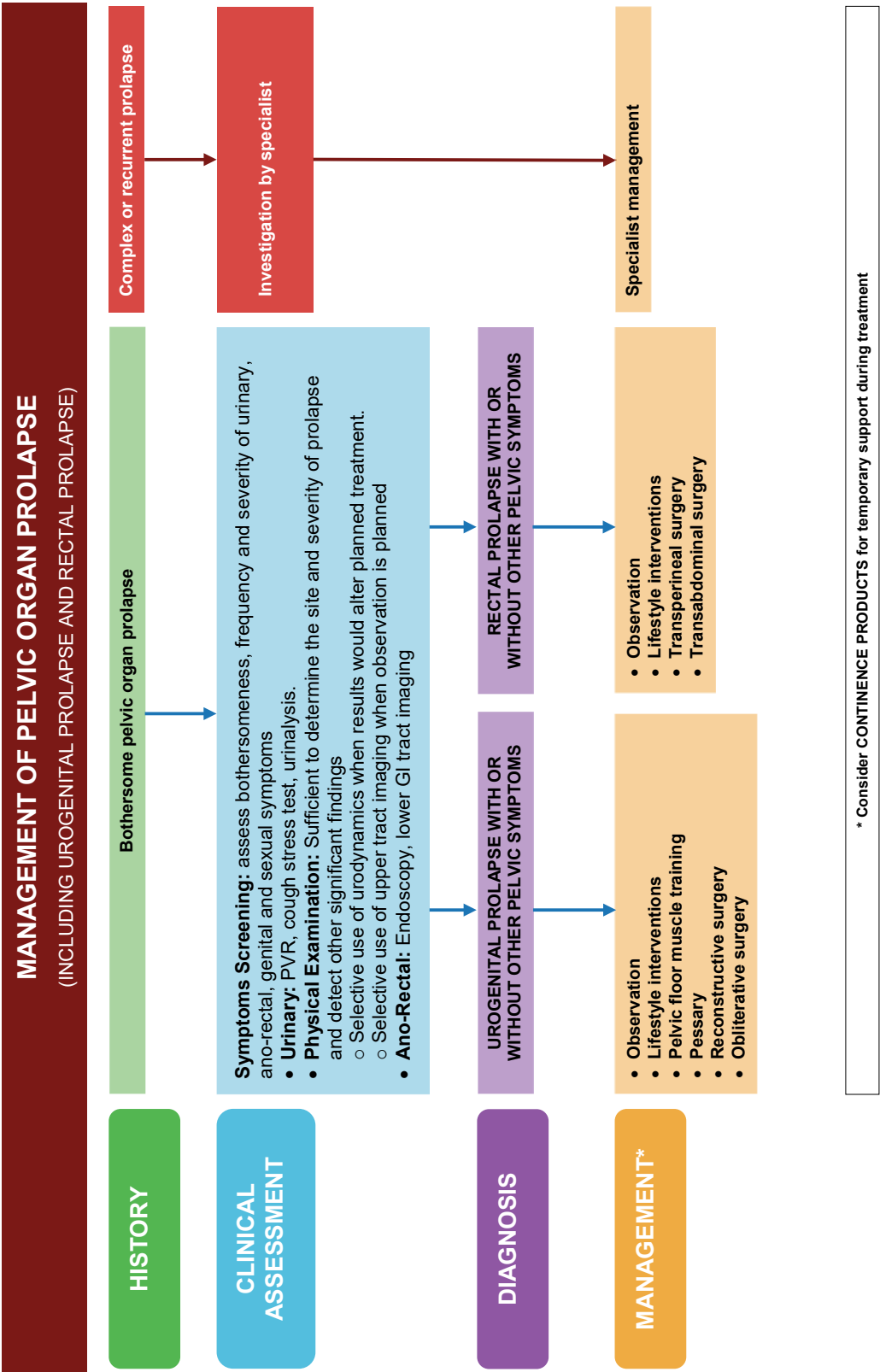
- Reduces associated pelvic floor symptoms (GoR A).
- May reduce the symptom of vaginal bulge (GoR C).
- Does not reduce extent of prolapse on examination based on POP-Q stage (GoR B).

Vaginal Pessary: when successfully fitted

- May reduce prolapse symptoms (GoR B)
 - Need to be regularly reviewed (GoR C)
 - Have high rates of discontinuation (GoR C)
- Local Oestrogens* are recommended in those with hypo-oestrogenic symptoms and in those with urethral prolapse or vaginal ulceration (GoR B)

Reconstructive surgery is reserved for those with symptomatic prolapse and is aimed at correcting the vaginal topography and functional pathology. Please see text for full recommendations.

Obliterative surgery is an important and effective treatment option in those who are happy to sacrifice coital activity. (GoR C)



PATHWAY FOR THE SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE

The pelvic organ prolapse (POP) surgery pathway was designed to provide an evidence based guide for both clinicians and women for the surgical management of pelvic organ prolapse. Within the pathway green lines highlight the preferred option and yellow lines indicate reasonable options.

An early option in the treatment pathway for women not wanting to preserve sexual function is obliterative surgery (colpocleisis) which is an efficacious intervention that has low morbidity (LoE 3).

The majority of women will enter the reconstructive pathway. Apical suspension procedures should be considered in all cases with 10-year re-operation rates for prolapse being significantly reduced if apical suspensions are performed concomitantly with both anterior and posterior colporrhaphy as compared to those performed without apical support.

In those undergoing anterior and posterior colporrhaphy the evidence is supportive of traditional native tissue suture plications (LoE 1). In the anterior compartment permanent mesh could be considered for recurrent cases when the patient understands the risk benefit profile for these interventions and that the data for their use is scant. Evidence is not supportive of biological grafts in the anterior compartment (LoE 2).

In the posterior compartment, fascial plication is superior to site specific native tissue repair (LoE 2) and levatorplasty should be avoided due to higher rates of dyspareunia (LoE3). Data are not supportive of biological or permanent mesh grafts. Posterior colporrhaphy is superior to transanal repair of rectocele (LoE 1) and there is no data to support ventral rectopexy with or without vaginal graft for rectocele.

With recognition of the importance of apical vaginal support in minimising the risk of subsequent recurrence, the pathway separates those with post-hysterectomy (vault) prolapse from those with uterine prolapse.

Data are supportive of sacral colpopexy as the preferred intervention for vault prolapse with superior anatomical and functional outcomes when compared to a variety of vaginal based interventions with and without transvaginal mesh (LoE1). This preference is highlighted by a green preferred option arrow in the management pathway. In recognition that not all patients are suitable for sacral colpopexy, a yellow reasonable option is included for vaginal based apical support (uterosacral or sacrospinous colpopexy). Both uterosacral and sacrospinous colpopexy are

equally effective vaginal options (LoE 1) and utilisation of transvaginal permanent mesh apical support is not supported by the data (LoE1).

When performing sacral colpopexy the laparoscopic approach is preferred with reduced peri-operative morbidity and cost when compared to both the open or robotic approach (LoE 2). The yellow reasonable option pathway exists for both open and robotic options in recognition of the longer learning curve associated with the laparoscopic approach (LoE3).

Apical support in those with uterine prolapse can be performed abdominally or vaginally and includes options for both uterine preservation (hysteropexy) and hysterectomy, with not insignificant relative contraindications for uterine preservation listed in Table 6. In post-menopausal women undergoing hysterectomy, bilateral salpingo-oophorectomy (BSO) significantly reduces the rate of ovarian cancer without increased morbidity. In those retaining ovaries at hysterectomy, bilateral salpingectomy also reduces rate of subsequent ovarian cancer.

Vaginal hysteropexy is equally effective as vaginal hysterectomy with apical suspension and is associated with reduced blood loss and operating time as compared to hysterectomy (LoE 1). Vaginal hysterectomy with apical support has a lower re-operation for prolapse than abdominal sacrohysteropexy (LoE1). Sacrohysteropexy has a higher re-operation for prolapse than sacral colpopexy with hysterectomy however sacral colpopexy with hysterectomy is not recommended due to the high rate of mesh exposure (LoE2). Supra-cervical hysterectomy at sacral colpopexy reduces the rate of mesh exposure associated with hysterectomy and sacral colpopexy however in a single retrospective study, recurrent prolapse was more common in the supracervical hysterectomy group. Although those data is not complete, vaginal based hysterectomy and hysteropexy with apical support should generally be considered as preferred options for uterine prolapse with sacral colpopexy reserved for vault prolapse.

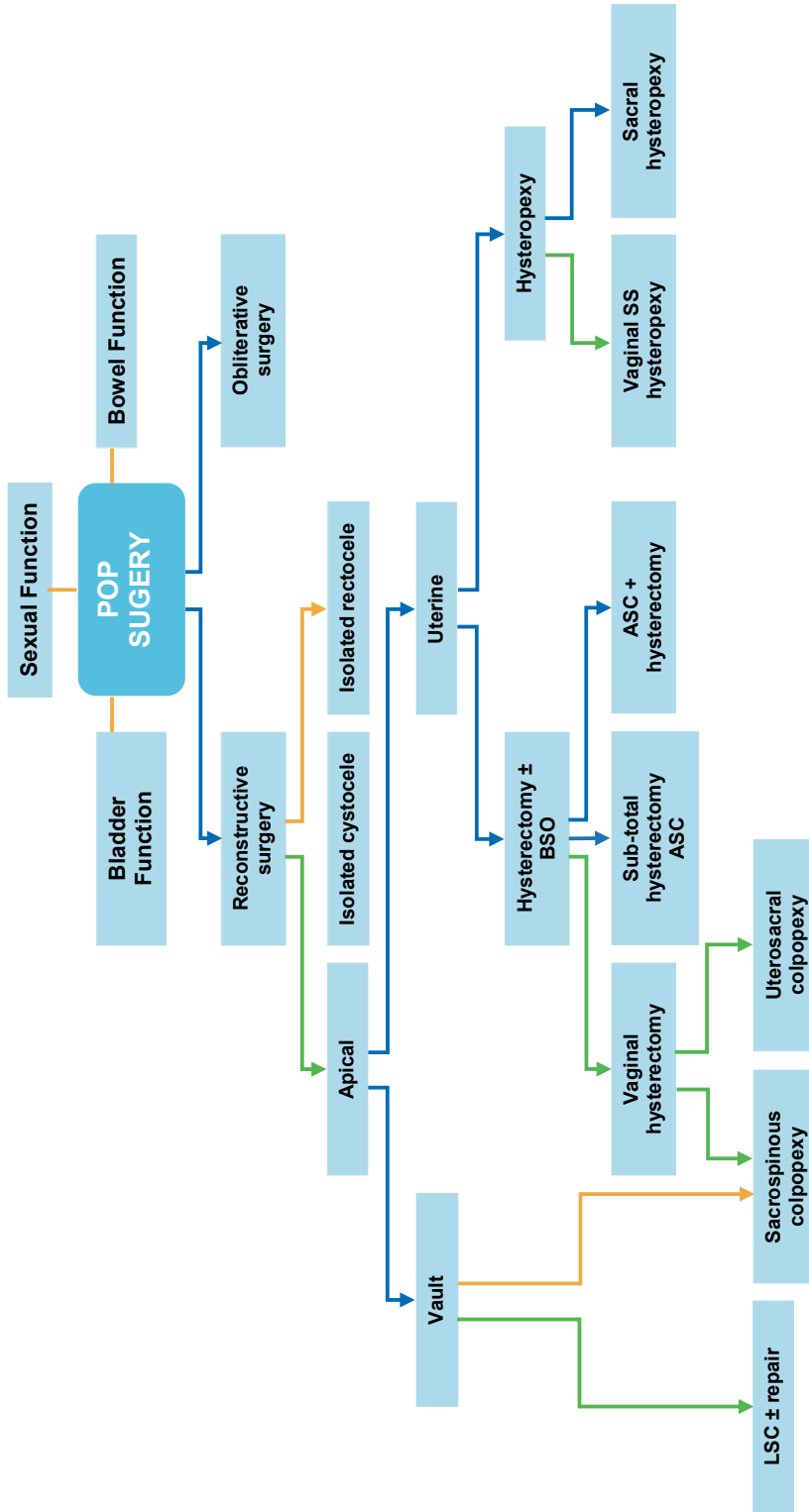
Those undergoing prolapse surgery with stress urinary incontinence (SUI) and occult SUI should generally have continence surgery performed at the time of prolapse surgery (LoE1). Those with prolapse without SUI or occult SUI should not undergo continence surgery at time of prolapse surgery (LoE1).

Based largely upon expert opinion (LoE3) those with prolapse without bowel symptoms and those with impaired defaecation with rectocele should undergo prolapse surgery as per the above pathway. Those with POP and impaired defaecation without rectocele, and those with faecal incontinence require colorectal assessment. If

rectal prolapse exists, these patients may benefit from combined colorectal and gynaecological interventions. Those with significant constipation and prolapse should be approached cautiously and may benefit from gastroenterology assessment prior to entering the POP surgery pathway.

Those undergoing POP surgery generally have improved sexual function post-operatively but a small number undergoing any POP surgery will experience painful intercourse post-operatively that may require subsequent intervention (LoE 1).

PATHWAY FOR THE SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE



Consider CONTINENCE PRODUCTS for temporary support during treatment

VI. URINARY INCONTINENCE IN NEUROLOGICAL PATIENTS

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A. INITIAL MANAGEMENT

1. STRONG GENERAL RECOMMENDATIONS

- Patients with known neurological disease often need evaluation to exclude bladder dysfunction, not only if symptoms occur, but as a standard assessment as neurogenic bladder has a high prevalence in the particular disease (for prevalence figures see chapter)
- A possible neurological cause of "idiopathic" incontinence should always be considered. Diagnostic steps to evaluate this include basic assessments, such as history and physical examination, urodynamics and specialised tests.
- Incontinence in neurological patients does not necessarily relate to the neurologic pathology. Other diseases such as prostate pathology, pelvic organ prolapse, might have an influence. These factors should be evaluated as potential primary or contributory causes.
- Extensive diagnostic evaluation is often useful and necessary to tailor an individual treatment based on complete neurofunctional data. This may not be needed in every patient e.g. patients with suprapontine lesions or in patients where treatment will consist merely of bladder drainage when the person is frail or has limited life expectancy.
- There is often a need to manage both bladder and bowel dysfunction simultaneously

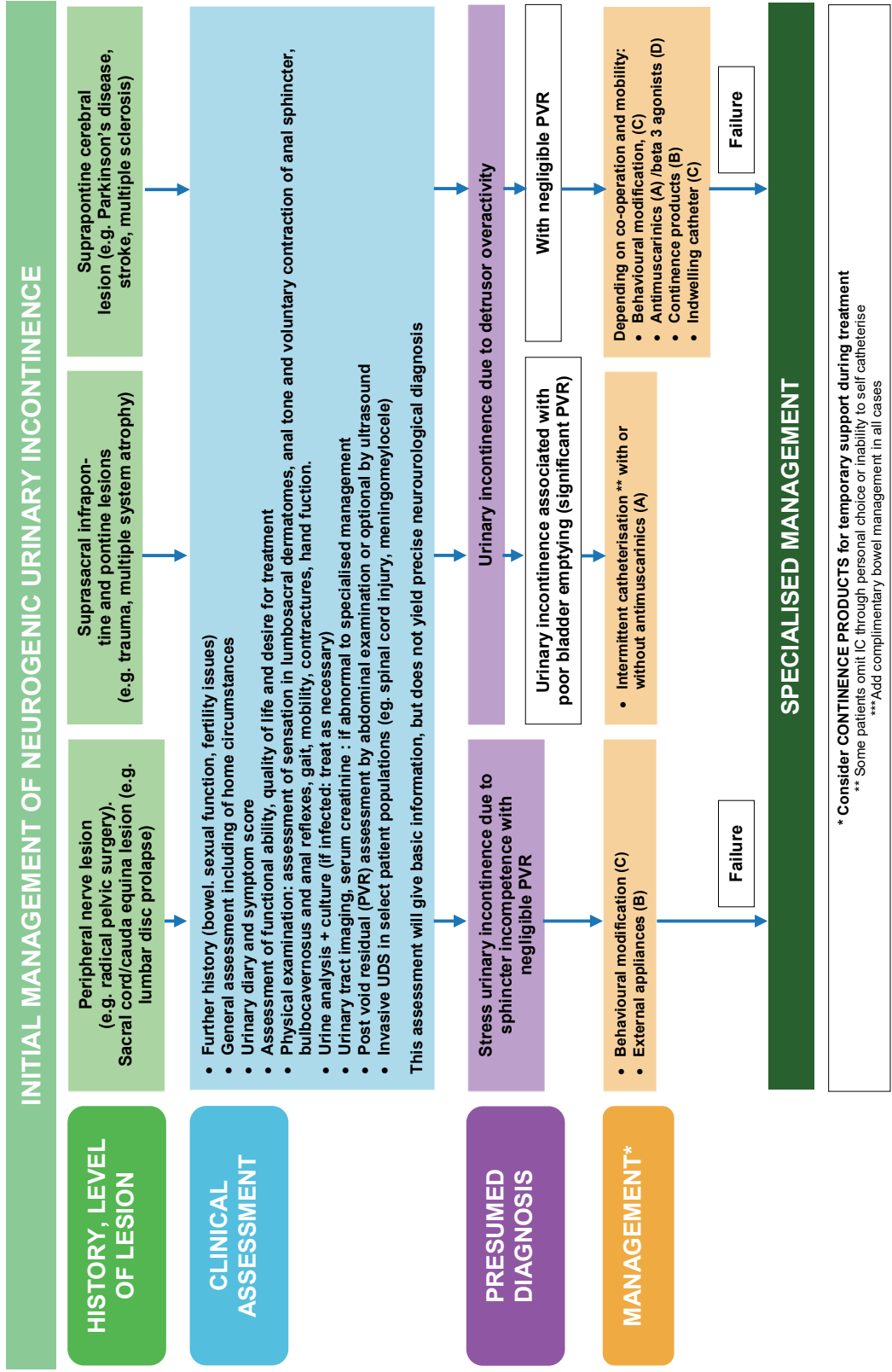
2. INITIAL ASSESSMENT

- The management of neurological urinary incontinence depends on an understanding of the likely mechanisms producing incontinence. This can in turn depend on the site and extent of the nervous system abnormality.
- Under current classifications, neurogenic incontinence patients can be divided into four groups. History and physical examination are important in helping distinguish these groups:

- peripheral lesions (as after major pelvic surgery) including those with lesions of the cauda equina (eg. lumbar disc prolapse);
- sacral spinal cord lesions involving the sacral micturition centre
- suprasacral spinal cord lesions (suprasacral infrapontine spinal cord lesions);
- central lesions of the brain or brain stem (stroke, Parkinson's disease).
- Assessment should be made using Questionnaires, urinalysis, bladder diary, uroflowmetry with assessment of PVR, and imaging of the urinary tract (ultrasoundography); all provide basic data for the initial assessment of the NLUUD.
- Invasive urodynamics should be used as part of the initial assessment in select patient populations (SCI, meningomyelocele)
- Due to increasing data on organ cross-sensitisation and the debilitating effect of faecal incontinence on QoL, a history of bowel function should be also included

3. INITIAL TREATMENT

- Patients with peripheral nerve lesions (e.g. denervation after pelvic surgery) and patients with spinal cord lesions (e.g. traumatic spinal cord lesions) should receive specialised urological management (GoR A).
 - Initial treatment for patients with incontinence due to suprapontine pathology, like stroke: need to be assessed for degree of mobility and ability to cooperate. Initial recommended treatments are behavioural therapy (GoR C) and antimuscarinic drugs for presumed detrusor overactivity (GoR A). If incontinence persists and if operative procedures are not indicated then continence products (GoR B) or catheters (GoR C) may be necessary on a long-term basis. These can also be necessary in non-cooperative or less mobile patients.
- Pharmacological detrusor relaxation and/or antibiotics may be useful in cases of persistent bypass leakage and/or recurrent UTI (patients with continuous drainage)
- In all cases, bowel management should complement management of NLUUD



VI. URINARY INCONTINENCE IN NEUROLOGICAL PATIENTS

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B. SPECIALISED MANAGEMENT

1. ASSESSMENT

- Most patients with neurogenic urinary incontinence require specialised assessment: Invasive urodynamic studies should be used with videourodynamics if available when surgical interventions are planned or when the "bladder may be unsafe".
- Upper tract imaging is needed in some patients and more detailed renal function studies will be desirable if the upper tract is considered in danger: high bladder pressure, upper urinary tract dilation, recurrent or chronic upper tract infection, (major) stones, (major) reflux.
- In patients with peripheral lesions, clinical neurophysiological testing may be helpful for better definition of the lesion

2. TREATMENT

For specialised management, conservative treatment is the mainstay (GoR A). Management of neurogenic urinary incontinence has several options. The algorithm details the recommended options for different types of neurological dysfunction of the lower urinary tract. The dysfunction does not necessarily correspond to one type/level of neurological lesion and is defined best by urodynamic studies. One should always ascertain that the management ensures a safe lower urinary tract (storage at low pressure and complete emptying)

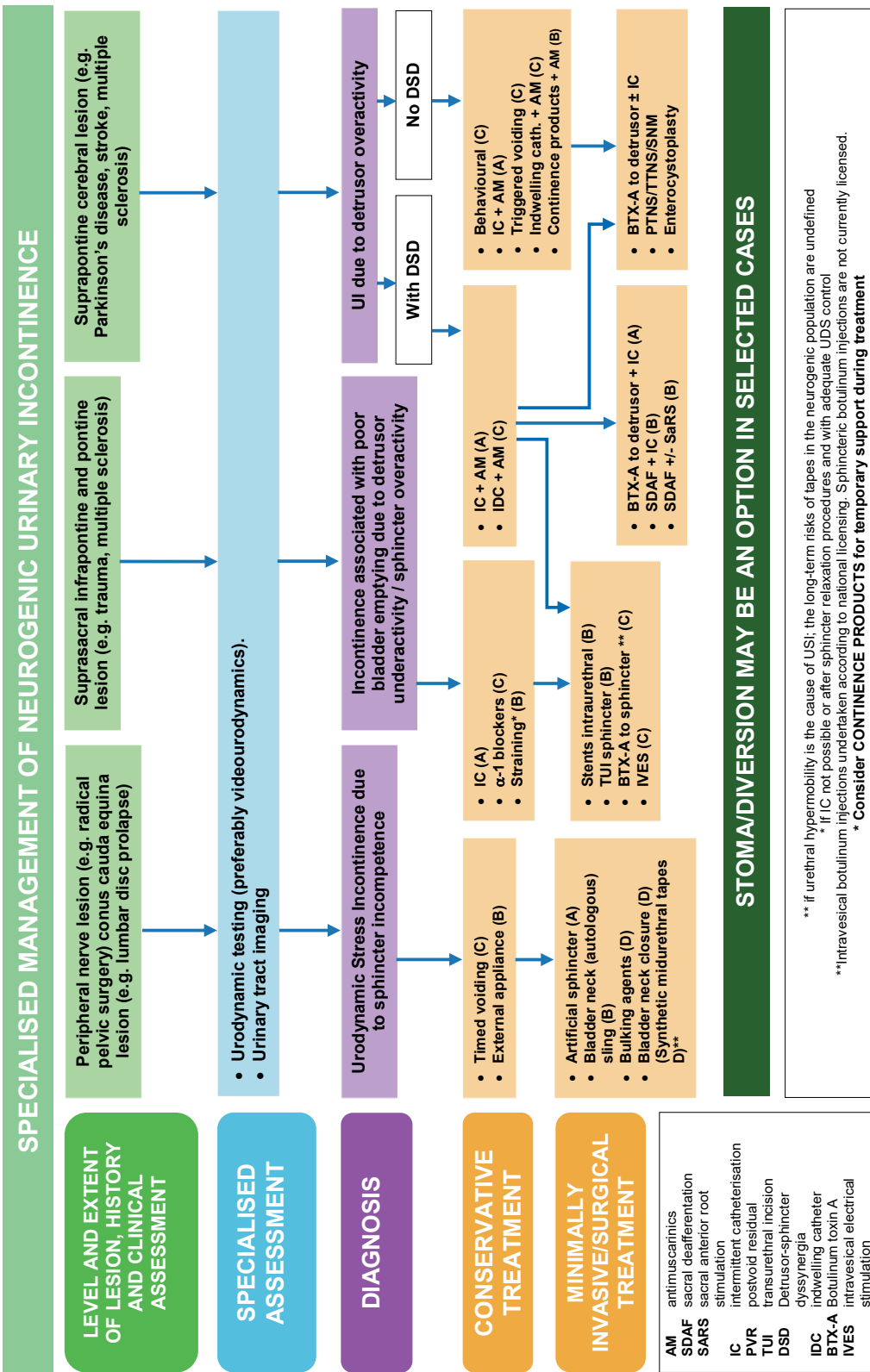
Both urinary and bowel function should be assessed together if both systems are affected, as symptoms and treatment of one system can influence the other, and *vice versa* (GoR A).

As therapeutic approaches can differ in various neurological diseases, the most prevalent diseases are discussed separately in the chapter

3. TREATMENT MODALITIES (OFTEN IN COMBINATION)

- Conservative
 - Intermittent catheterisation (GoR A)
 - Behavioural treatment (GoR C)
 - Timed voiding (GoR C)
 - Continence products (GoR B)
 - Antimuscarinics (GoR A)
 - Alpha-1-adrenergic blockers (GoR C)
 - Oral cannabinoid agonists (MS) (GoR C)
 - Beta-3-agonist alone or as an add-on to AM (GoR D)
 - Bladder expression (GoR B)
 - Triggered voiding (GoR C)
 - Indwelling catheter (GoR C)
- Minimally invasive treatments
 - Botulinum toxin for: sphincter (C) detrusor (A)
 - Intravesical electrical stimulation (C)
 - PTNS/TTNS (C)
 - SNM (stable disease only) (C)

- Surgical treatment
 - Artificial sphincter (A)
 - Bladder neck sling (B)
 - Sub-urethral tapes (D)
 - Bulking agents (D)
 - Bladder neck closure (D)
- Stents intraurethral (B)
- TUI sphincter (B)
- Sacral deafferentation (B)
- Sacral anterior root stimulator (B)
- Enterocystoplasty (B)



VII. BLADDER PAIN SYNDROME

Definition

Bladder Pain Syndrome (BPS): in the absence of a universally agreed definition, the International Society for the Study of Interstitial Cystitis – ESSIC definition is given (1).

ESSIC: Chronic pelvic pain, pressure or discomfort of greater than 6 months duration perceived to be related to the urinary bladder, accompanied by at least one other urinary symptom like persistent desire to void or urinary frequency. Confusable diseases as the cause of the symptoms must be excluded.

There are no published data as to what duration of symptoms indicates that early spontaneous resolution of symptoms is unlikely. While ESSIC arbitrarily uses a 6 month duration, the American Urological Association Guideline suggests that a 6 week history is long enough to initiate diagnosis and treatment of BPS (2). Without further data, the Consultation cannot make a recommendation and believes that it is up to the discretion of the physician and patient as to the proper interval between symptom onset and evaluation and diagnosis of a chronic condition.

1. NOMENCLATURE

The scientific committee of the International Consultation voted to use the term “bladder pain syndrome” for the disorder that has been commonly referred to as interstitial cystitis (IC). The term painful bladder syndrome was dropped from the lexicon. The term IC implies an inflammation within the wall of the urinary bladder, involving gaps or spaces in the bladder tissue. This does not accurately describe the majority of patients with this syndrome. Painful Bladder Syndrome, as defined by the International Continence Society, is too restrictive for the clinical syndrome.

Properly defined, the term Bladder Pain Syndrome appears to fit in well with the taxonomy of the International Association for the Study of Pain (IASP) (see below), and focuses on the actual symptom complex rather than what appears to be long-held misconception of the underlying pathology.

Bladder Pain Syndrome (XXIII-2) (per IASP)

Bladder pain syndrome is the occurrence of persistent or recurrent pain perceived in the urinary bladder region, accompanied by at least one other symptom, such as

pain worsening with bladder filling and day-time and/or night-time urinary frequency. There is no proven infection or other obvious local pathology. Bladder pain syndrome is often associated with negative cognitive, and behavioural, sexual, or emotional consequences, as well as with symptoms suggestive of lower urinary tract and sexual dysfunction.

The Consultation believes that, based on the pathology and endoscopic finding characteristics of the Hunner lesion, the epidemiological pattern that distinguishes it from bladder pain syndrome, the clinical response to local treatment of the lesion by resection, fulguration, or steroid injection, the response to cyclosporine, and the

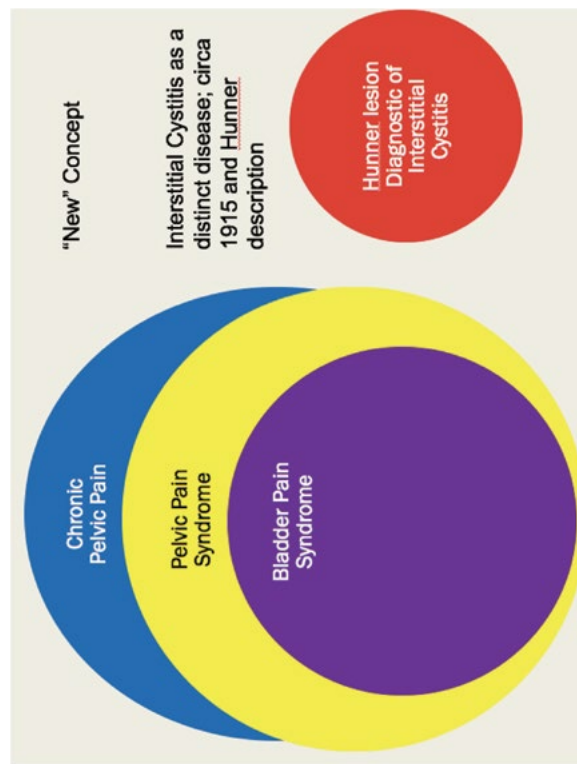


Figure 1

absence of reports in the literature that non-Hunner patients go on to develop Hunner lesions (ie, the finding of a Hunner lesion does not represent a continuum in the natural history of bladder pain syndrome), that the presence of a Hunner lesion should be considered a distinct disease. It therefore should drop out of the bladder pain syndrome construct, much like we do not consider other painful conditions like radiation cystitis, ketamine cystitis, or urinary tract infection a part of bladder pain syndrome.

The Consultation concludes that it would be reasonable to designate the Hunner lesion in symptomatic patients with the term "interstitial cystitis", thus indicating a true interstitial inflammation. It would be defined much as Hunner defined it 100 years ago, and harmonise the largely Asian, European, and North American concepts of interstitial cystitis. The Consultation will continue to refer to the symptom complex as "bladder pain syndrome". Hunner lesion will be considered a distinct phenotype, but in the future may be classified as a separate disorder entirely, albeit with local symptoms that are difficult to differentiate from bladder pain syndrome in the absence of endoscopy. In other words, we may be coming full circle in the historical perspective Figure 1.

2. HISTORY / INITIAL ASSESSMENT

Males or females whose symptoms meet the requirements of the definition of bladder pain syndrome should be evaluated. The presence of commonly associated disorders including irritable bowel syndrome, chronic fatigue syndrome, and fibromyalgia in the presence of the cardinal symptoms of bladder pain syndrome also suggests the diagnosis. Abnormal gynaecological findings in women and well-characterised, confusable diseases that may explain the symptoms must be ruled out.

The initial assessment consists of a bladder diary or frequency/volume chart, focused physical examination, urinalysis, and urine culture. In the absence of confusable disorders (uncomplicated disease), a diagnosis can be made and treatment instituted. Urine cytology, cystoscopy, and urodynamic evaluation are recommended if clinically indicated and/or the diagnosis is in doubt (complicated disease). Patients with urinary infection should be treated and reassessed. Those with recurrent urinary infection, abnormal urinary cytology, and microscopic or gross haematuria are evaluated with appropriate imaging and endoscopic procedures, and only if the findings are unable to explain the symptoms, are they diagnosed with BPS. GoR C

3. INITIAL TREATMENT

- Patient education, (GoR B)
- Dietary manipulation, (GoR B)
- Nonprescription analgesics,
- Stress reduction,
- Pelvic floor relaxation techniques comprise the initial treatment of BPS. In the patient with findings suggesting pelvic floor dysfunction, pelvic floor physical therapy with myofascial trigger point release and intravaginal Thiele massage is often an effective therapeutic intervention. The treatment of pain needs to be addressed directly, and in some instances referral to an anaesthesia/pain centre can be an appropriate early step in conjunction with ongoing treatment of the syndrome. (GoR A)

When conservative therapy fails or symptoms are severe and conservative management is unlikely to succeed,

- Oral medication (GoR B) or
- Intravesical treatment can be prescribed. It is recommended to initiate a single form of therapy and observe results, adding other modalities or substituting other modalities as indicated by the degree of response or lack of response to treatment. (GoR B)

4. SECONDARY ASSESSMENT

If initial oral or intravesical therapy fails, or before beginning such therapy based on clinician judgment, it is reasonable to consider further evaluation which can include urodynamics, pelvic imaging, and cystoscopy with bladder distention and possible bladder biopsy under anaesthesia.

- Findings of detrusor overactivity suggest a trial of antimuscarinic or beta-3-agonist therapy.
- The presence of a Hunner lesion suggests therapy with transurethral resection, fulguration of the lesion, or direct steroid injection into the lesion. (GoR B)

- Bladder distention itself can have therapeutic benefit in 30-50% of patients, though benefits rarely persist for longer than a few months. (GoR C)

5. REFRACTORY BPS

Those patients with persistent, unacceptable symptoms despite oral and/or intravesical therapy are candidates for more aggressive treatment modalities. Many of these are best administered within the context of a clinical trial if possible. These may include

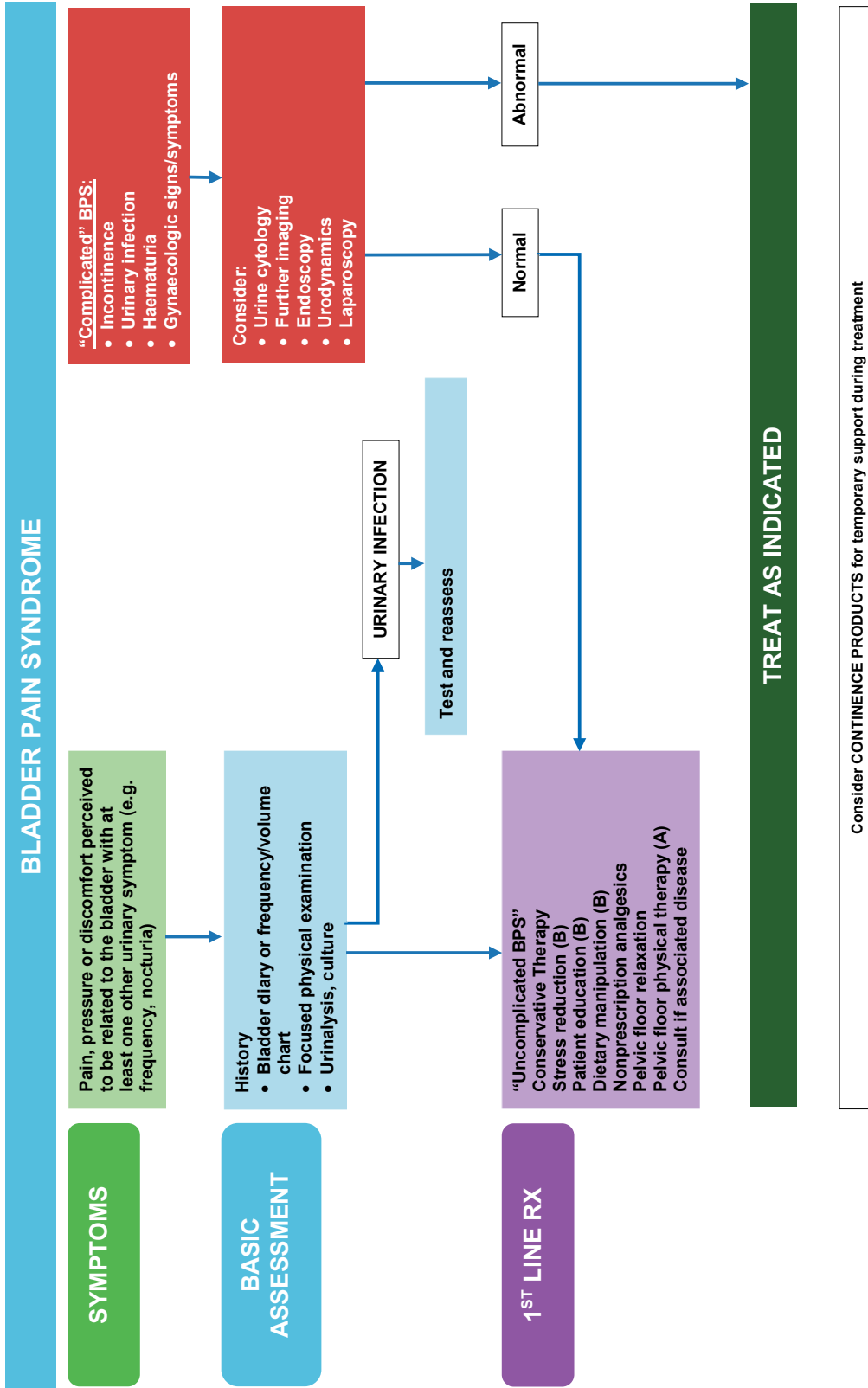
- Sacral nerve stimulation, (GoR B)
- Intradetrusor botulinum toxin, (GoR B)

- Oral cyclosporine A (GoR C), or
- Clinical trials of newly described pharmacological management techniques. At this point, most patients will benefit from the expertise of an anaesthesia pain clinic.

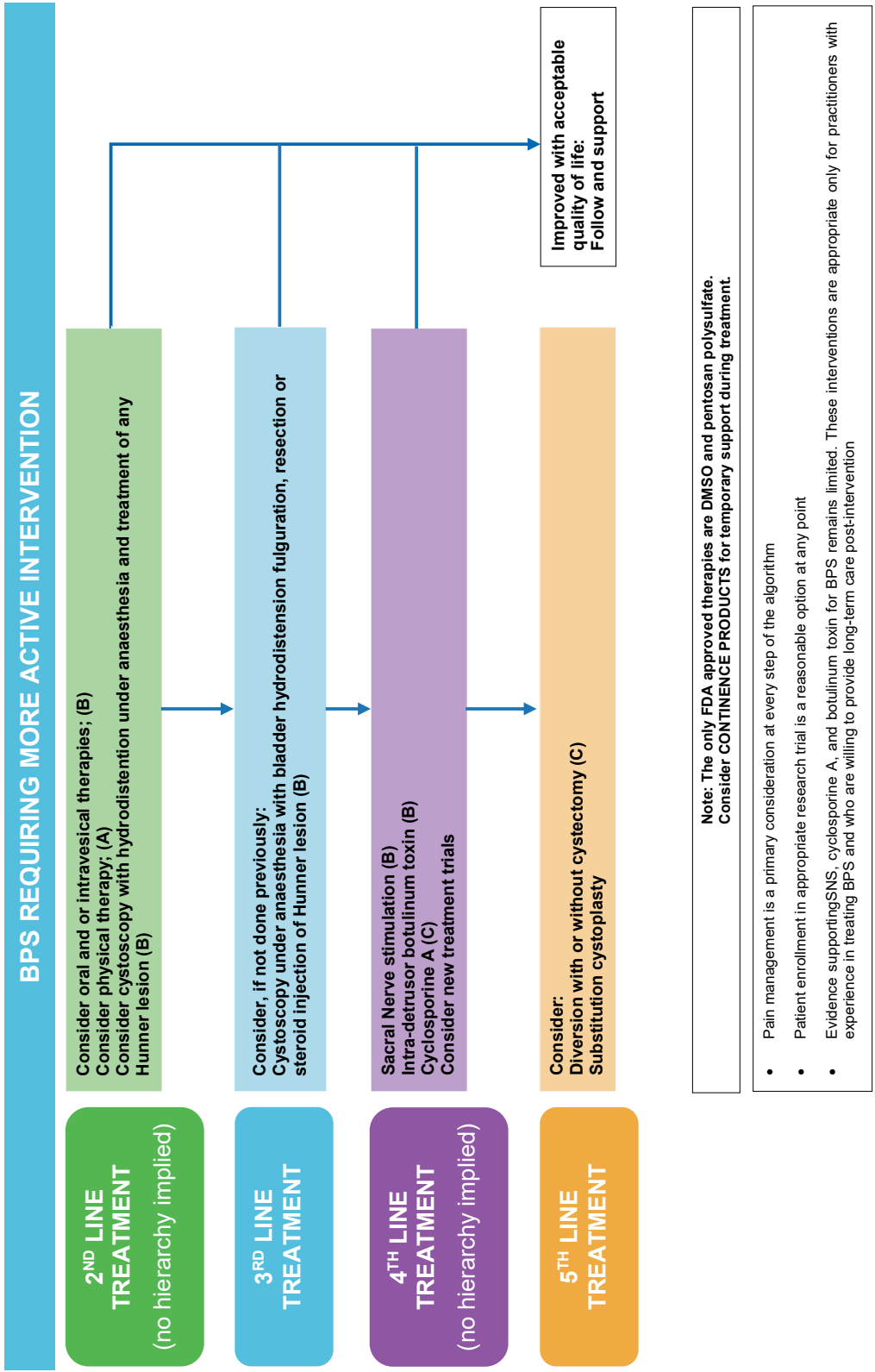
The last step in treatment is usually some type of surgical intervention aimed at increasing the functional capacity of the bladder or diverting the urinary stream.

- Urinary diversion with or without cystectomy has been used as a last resort with good results in selected patients. Cystectomy and urethrectomy do not appear to add any additional efficacy to diversion alone.

Augmentation or substitution cystoplasty seems less effective and more prone to recurrence of chronic pain in small reported series (GoR C)



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VIII. FAECAL INCONTINENCE IN ADULT PATIENTS

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ASSESSMENT AND MANAGEMENT

1. INITIAL CLINICAL ASSESSMENT

Adult patients with faecal incontinence present with a variety of symptom complexes. As many people are reluctant to admit to having faecal incontinence, it is important to proactively enquire about it, especially in known high risk groups (such as older community-living individuals, post partum women who might have had an obstetric injury and patients with loose stools).

History will include symptoms such as loose stools and urgency; the type and severity of bowel incontinence, systemic disorders, neurological disorders, and ano-rectal surgeries (e.g., haemorrhoidectomy), obstetric history for women, medications, diet, chronic straining, cognitive status, and effects of symptoms on quality of life.

2. INITIAL INTERVENTIONS

- Assessing the type of bowel incontinence may help identify an aetiology. Types of bowel incontinence: Anal incontinence is the involuntary loss of faeces and/or flatus and/or mucus). Faecal incontinence is the involuntary loss of faeces. Flatus incontinence is the involuntary loss of rectal gas, which may indicate rectal sensory impairment and/or anal sphincter dysfunction. Mucus incontinence is the involuntary loss of mucus only (See Figure 1).
 - Some subtypes of faecal incontinence are urgency faecal incontinence, which is the involuntary loss of faeces due to an inability to defer defaecation, once the desire is perceived, for long enough to reach a toilet. Urgency faecal incontinence is often a symptom of external anal sphincter dysfunction. The symptom of urgency does not necessarily result in urgency faecal incontinence. Functional faecal incontinence is due to limitations in mobility or toileting ability or delayed assistance. Passive faecal incontinence, incontinence without forewarning, is typically related to internal anal sphincter dysfunction or poor closure of the external sphincter due to rectal prolapse or stage III/IV haemorrhoids.

- Physical examination will include anal inspection, abdominal palpitation, a brief neurological examination, digital rectal examination and usually procto-sigmoidoscopy or colonoscopy.
 - Further diagnostic testing needs to be considered if the patient has symptoms such as an unexplained change in bowel habit, weight loss, anaemia, rectal bleeding, severe or nocturnal diarrhoea, or an abdominal or pelvic mass and bowel pathology when organic conditions such as cancer, inflammatory bowel disease (IBD), a recto-vaginal fistula, full thickness rectal prolapse, or cloacal deformity are suspected. Condition specific management is indicated for these patients.
 - Reversible factors (such as inadequate access to toilets and side effects of medications resulting in loose stools) should be assessed and addressed at the outset.
- Some initial management can often be performed in primary care. After environmental factors and local or systemic pathology have been excluded, initial interventions include:
- Discussion of options and goals of management with the patient
 - Provision of patient or caregiver information and education (GoR A)
 - Adjustment of diet and fluid advice, fibre intake (GoR A)
 - Establishing a regular bowel habit (GoR C) or urgency training if relevant (GoR C)
 - Anti-diarrhoeal medication can help if stools are loose (GoR B)
 - Use of continence products including various types and sizes of absorbent pads, briefs, etc., to contain leaked faeces and prevent skin damage
 - Provide advice on practical coping skills when incontinence occurs (GoR C)

3. SECONDARY INTERVENTIONS

- If initial interventions fail to improve symptoms after 8-12 weeks, consideration should be given to referral to an incontinence specialist (e.g., gastroenterologist, continence nurse, advisor physiotherapist, or colorectal surgeon) for other interventions or further assessment.
- Pelvic floor muscle training (PFMT) – contraction of pelvic floor muscles, multiple times per day to improve strength of contraction and increase awareness of anorectal muscle function. (GoR C)
- Biofeedback therapy – behavioural treatment designed to enhance the strength of sphincter contraction and improve rectal sensation using specialised equipment. Biofeedback therapy can be combined with PFMT to improve strength. (GoR B)
- Transanal Irrigation to maximise bowel emptying and minimise faecal incontinence primarily in patients with incomplete elimination, passive faecal incontinence, or faecal incontinence with defaecation difficulty. (GoR C)

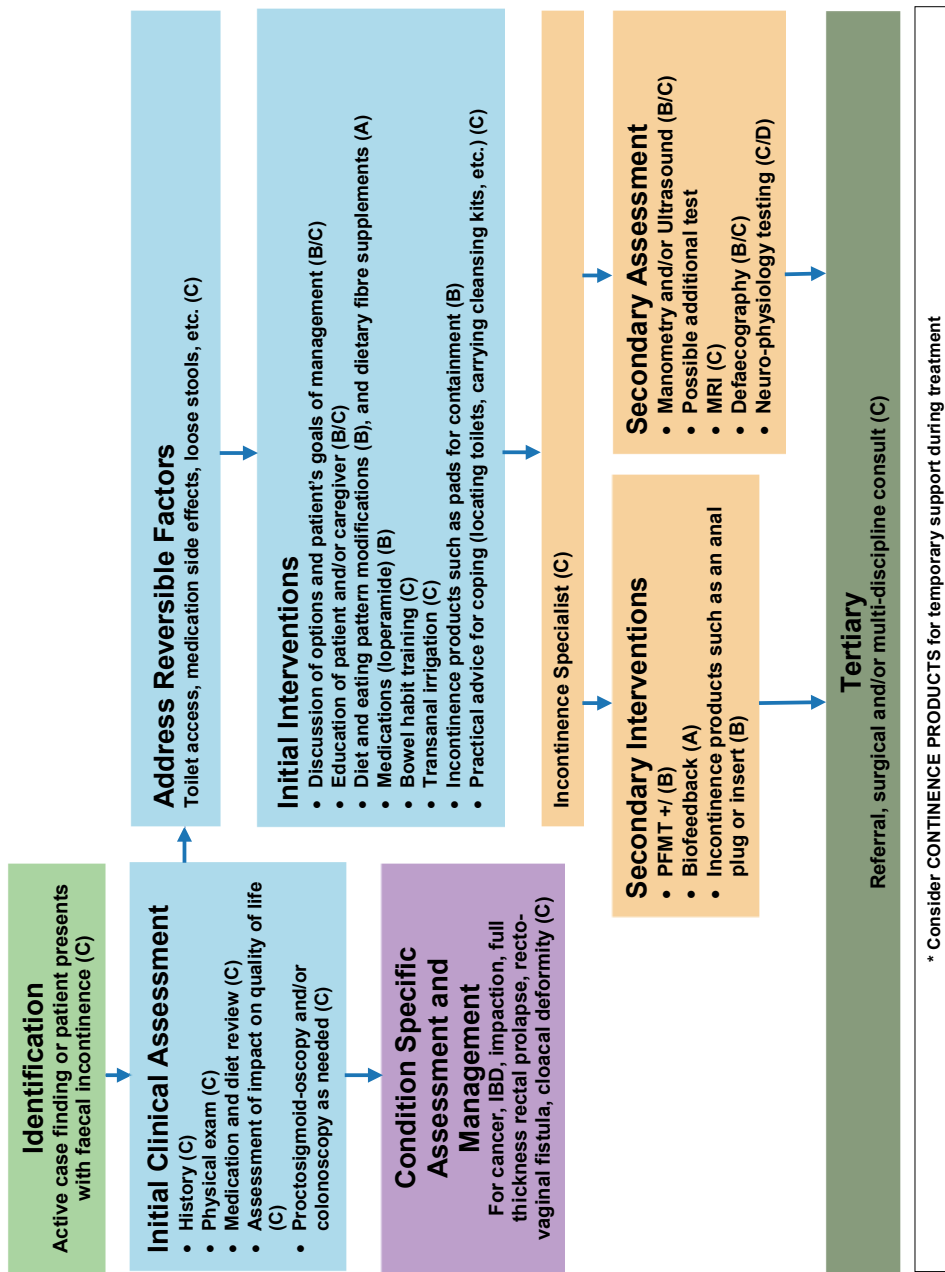
4. SECONDARY ASSESSMENT

- A variety of anorectal investigations, including manometry, anal ultrasound, and possibly MRI, defaecography, and neurophysiological testing can help to define structural or functional abnormalities of anorectal function and guide management if initial and/or secondary interventions are ineffective

5. TERTIARY REFERRAL, SURGICAL OR MULTIDISCIPLINARY CONSULTATION

- Faecal incontinence that fails to respond to initial and secondary management requires specialised consultation by a gastroenterologist, colorectal surgeon, urogynaecologist, and/or a multi-disciplinary team

ASSESSMENT AND CONSERVATIVE MANAGEMENT OF FAECAL INCONTINENCE



* Consider CONTINENCE PRODUCTS for temporary support during treatment

VIII. FAECAL INCONTINENCE IN ADULT PATIENTS

SURGERY FOR FAECAL INCONTINENCE

1. PATIENT ASSESSMENT

- The reader is referred to the relevant chapter sections in “Dynamic Testing” and “Conservative Treatment for Faecal Incontinence.” In general, patients referred for surgical management of faecal incontinence must either have failed conservative therapy or not be candidates for conservative therapy due to severe anatomic or neurological dysfunction.
- Prior to surgical management of faecal incontinence, the integrity of the anal sphincter complex should be assessed. This assessment is best performed with endoanal ultrasound, though pelvic MRI may also be useful. Ancillary tests include anal manometry, electromyography, and defaecography.
- If the patient has persisting faecal incontinence, he or she should undergo repeat assessment, including endoanal ultrasound.

2. SPECIALISED MANAGEMENT

- The surgical approach is influenced by the presence and magnitude of an anatomical anal sphincter defect. If no defect is present, or if the sphincter defect is minimal, options include SNS and biomaterial injection therapy.
- Acute anal sphincter repair is usually required following obstetric or direct trauma. End to end or overlapping repair may be performed. When possible the internal anal sphincter should be separately repaired. (GoR C)
- Patients with rectal prolapse, rectovaginal fistula or cloacal deformity often have associated faecal incontinence. Initial therapy should be directed at correction of the anatomical abnormality. (GoR C)
- For patients with moderate sphincter defects, sphincteroplasty, SNS or biomaterial injection therapy can each be considered. For patients with large sphincter defects (>120 degrees), sphincteroplasty is likely to be the best option, though a PNE trial for SNS can be considered. (GoR C)

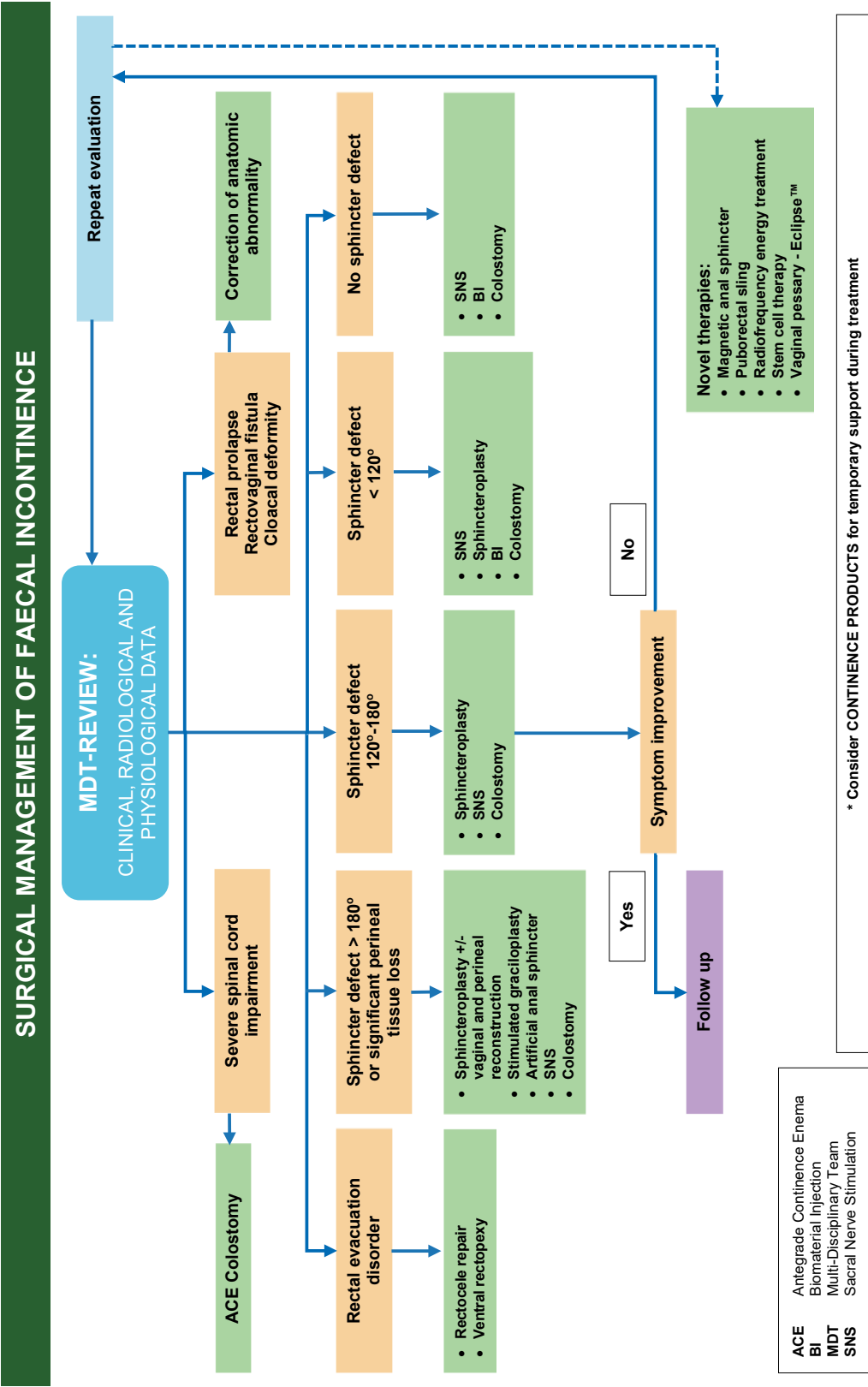
- Patients with sphincter defects of greater than 180° or major perineal tissue loss require individualised treatment. In some cases, initial reconstruction can be performed. Should incontinence persist, alternatives include stimulated muscle transposition (usually graciloplasty) artificial anal sphincter implantation, or SNS. (GoR C)

3. SALVAGE MANAGEMENT

- For patients who remain incontinent following sphincteroplasty, repeat endo-anal ultrasound should be undertaken to reassess the status of the repair. If no defect is present, or if the sphincter defect is minimal, options include SNS and biomaterial injection therapy. If there is a large persisting sphincter defect, repeat sphincteroplasty can be considered. (GoR C)
- Patients who have failed SNS can be considered for biomaterial injection therapy or sphincteroplasty if a sphincter defect is present. Other alternatives include stimulated graciloplasty and implantation of an artificial anal sphincter. (GoR C)
- Patients who fail surgical therapy for faecal incontinence, or who do not wish to undergo extensive pelvic reconstruction, should consider placement of an end sigmoid colectomy. (GoR C) While this procedure does not restore continence, it does restore substantial bowel control and appears to improve social function and quality of life. Novel therapies can also be considered under protocol: PTNS, the magnetic anal sphincter, SECCATM, vaginal pessary (EclipseTM) and sling procedures. (GoR D)

4. SPECIAL SITUATIONS

- Individuals with congenital abnormalities may be amenable to surgical repair. Often this will involve both laparoscopic abdominal and perineal approaches. Poor functional outcomes may be treated by an Antegrade Continence Enema (ACE) procedure or colostomy. Patients with cauda equina type neurological disorders, either congenital or acquired, should be considered for an ACE procedure or colostomy. (GoR C)



IX. FAECAL INCONTINENCE IN NEUROLOGICAL PATIENTS

A. INITIAL MANAGEMENT

➤ Patients with known neurological disease may present with symptoms related to neurological bowel dysfunction, such as; difficulty in defaecation, constipation and faecal incontinence which disturb their activities of daily living and impair quality of life. Many have permanent impairments and functional limitations and disabilities, which are due to neurological deficits and complications

- Functional assessment:
 - Hand and arm use, fine hand use, mobility – maintaining body position, transfer and walking ability.
 - Environmental factors assessment:
 - toilet accessibility, devices for bowel care and mobility; caregiver support and attitude;

1. INITIAL ASSESSMENT

- The history should include:
 - Neurological diagnosis and functional level
 - Previous and present lower gastrointestinal (LGIT) function and disorders
 - Severity of neurogenic bowel dysfunction
 - Current bowel care and management including diet, fluid intake, medications affecting bowel functions
 - Co-morbidity / complication e.g., urinary incontinence, autonomic dysreflexia, pressure ulcers, sexual dysfunction
 - Patient's satisfaction, needs, restrictions and quality of life
 - Environmental factors and barriers and facilitators to independent bowel management.
- Physical examination:
 - Cognitive function; motor, sensory and sacral reflexes – voluntary anal sphincter contraction, deep perianal sensation, anal tone, anal and bulbo-cavernosus reflexes
 - Spasticity of the lower limbs
 - Abdominal palpation for faecal loading and rectal examination

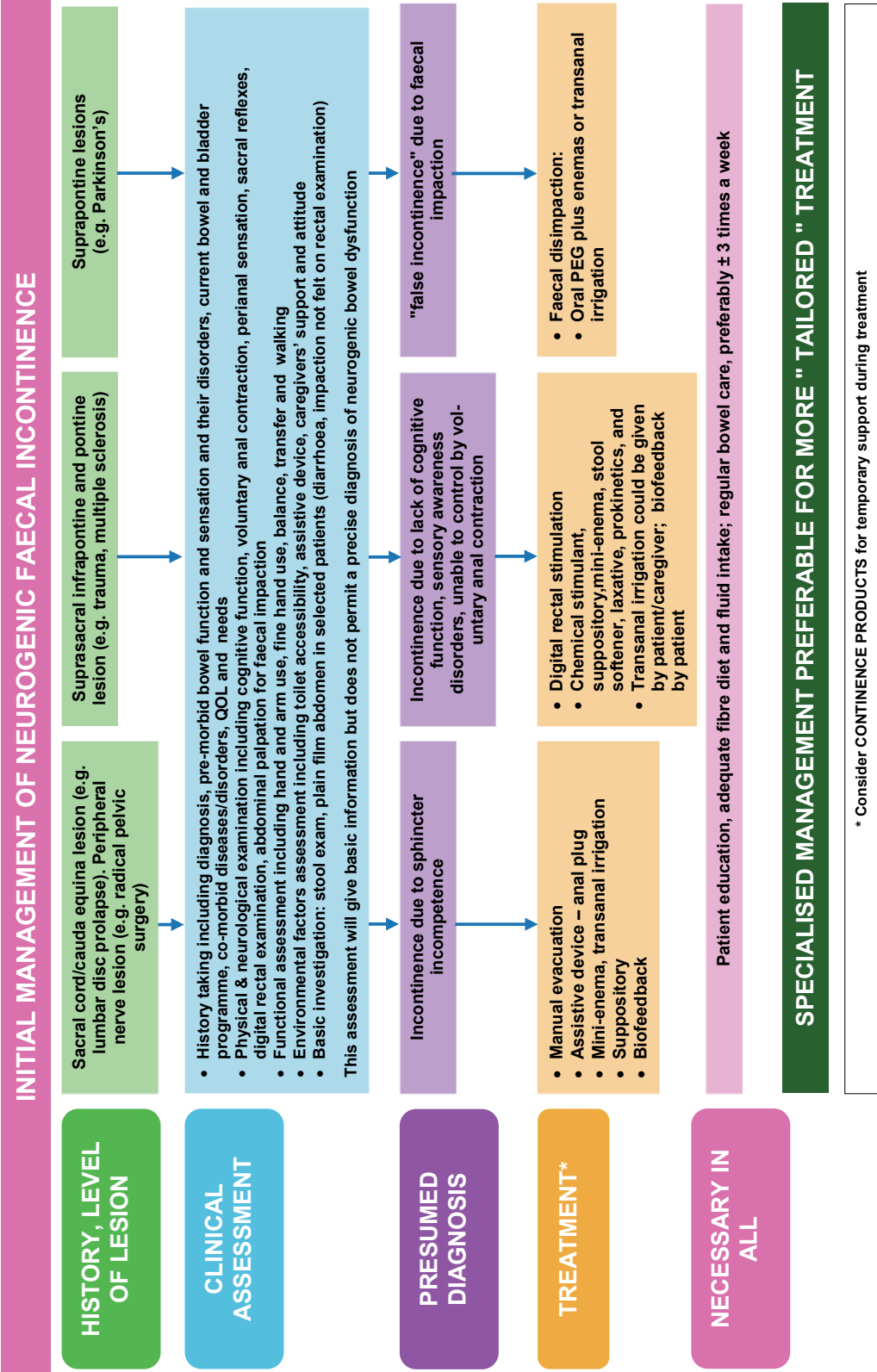
2. BASIC INVESTIGATIONS

Stool examination, plain abdominal X-Ray

3. INITIAL TREATMENTS

- Patient education and goals-setting to achieve complete defaecation on a regular basis and faecal continence based on right time, right place, right trigger and right consistency
- Adequate fibre diet and fluid intake; appropriate trigger according to preservation of sacral (anorectal) reflex – digital rectal stimulation (GoR C); suppository and enema (GoR B); if no anorectal reflex, manual evacuation (GoR B); abdominal massage (GoR C) can also be helpful
- Prescribe medications – stool softener, laxative, prokinetic agents, anti-diarrhoeal drugs as necessary
- Assistive techniques may be necessary for
 - Defaecation – transanal irrigation (GoR A)
 - For incontinence – anal plug (GoR C)

The algorithm does not apply to management in acute neurological patients that need regular bowel emptying.



IX. FAECAL INCONTINENCE IN NEUROLOGICAL PATIENTS

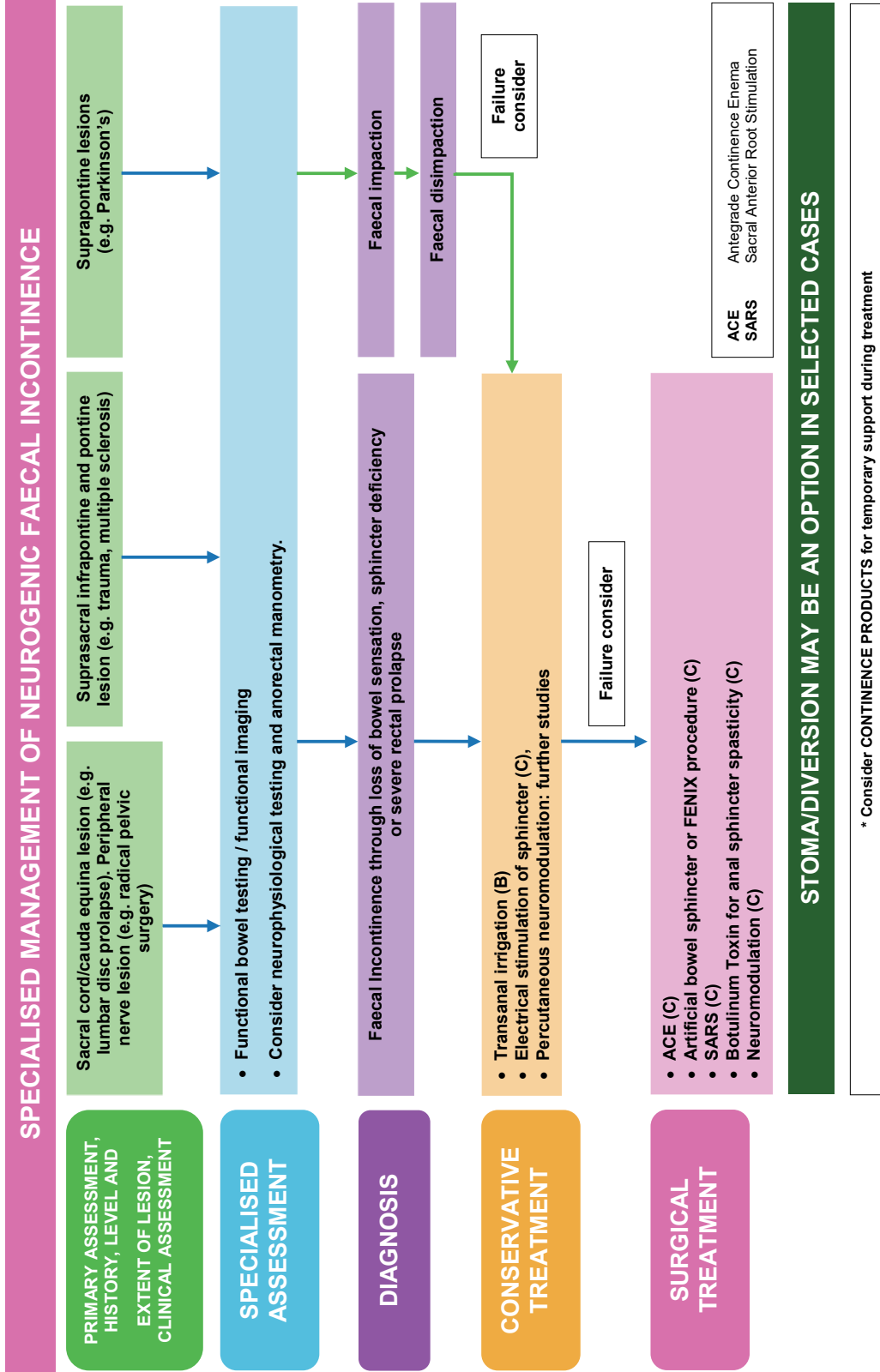
B. SPECIALISED MANAGEMENT

1. ASSESSMENT

- Some patients with neurogenic faecal incontinence will need specialised assessment, especially if initial management is unsuccessful to look for comorbidity and certainly before performing invasive treatment
- Do not assume that all symptoms are due to neuropathy, e.g. women with neurological pathology might have had childbirth injury to the sphincter
- Special investigations: manometry, endoanal ultrasound, (dynamic) MRI, (needle) EMG. These specific bowel functional tests and electro-diagnostic tests must be considered optional, as their value in neurological pathology is not sufficiently demonstrated so far.

2. TREATMENTS

- Conservative treatment for neurological faecal incontinence is also the mainstay for specialised management, (GoR C).
 - Management of neurological incontinence does not include very extensive treatment modalities and many conservative interventions are still empirical.
 - Transanal irrigation (GoR B).
- Electrical stimulation sphincter, (GoR C).
 - Percutaneous neuromodulation and sacral nerve stimulation : further research is required (GoR D).
 - Surgical management of neurogenic faecal incontinence has different options which need a very strict patient selection
 - Antegrade Contenance Enema ACE (GoR C).
 - Artificial bowel sphincter or FENIX procedure (GoR C).
 - Sacral Anterior Root Stimulation SARS (GoR C).
 - Botulinum Toxin (GoR C).
 - Neuromodulation (GoR C).
 - It is recommended that urinary and bowel function are assessed simultaneously if both systems are affected, as symptoms and treatment of one system can influence the other and vice versa (GoR A).
 - As the therapeutic approach can differ in different neurological diseases, the most prevalent diseases are discussed separately in the chapter.



X. URINARY AND FAECAL INCONTINENCE IN FRAIL OLDER MEN AND WOMEN

- There is no reason to suspect why interventions which have proven efficacy in the community dwelling elderly should not also be effective in frail older people. Clinicians should, however, take due regard of the practicality, potential benefits and dangers of employing any single intervention in this population.
- Frail older people do require a different approach addressing the potential role of co-morbid disease, current medications (prescribed, over the counter and/or naturopathic), and functional and cognitive impairment in urinary and faecal incontinence.
- The extent of the investigation and management should take into account the degree of bother to the older person and/or caregiver, the goals for care, the degree that the older person is able to undertake any intervention and the overall prognosis and life expectancy.
- Effective management to meet the goals of care should be possible for most frail older people.

1. HISTORY AND SYMPTOM ASSESSMENT

- Active case finding for urinary and faecal incontinence should be done in all frail older people (GoR A).
- History should include comorbid conditions and medications that could cause or worsen incontinence.
- Physical examination should include a rectal examination for faecal loading or impaction (GoR C), functional assessment (mobility, transfers, manual dexterity, dressing and undressing ability, ability to toilet) (GoR A), a screening test for depression (GoR B), and cognitive assessment (to assist in planning and management, (GoR C)).
- The mnemonic DIPPERS (see urinary and faecal incontinence algorithms) covers some of these comorbid conditions. Note that urogenital atrophy does not, in itself, cause urinary incontinence and should not be treated for this purpose (GoR B).
- The patient and / or caregiver should be asked about the degree of bother of urinary incontinence and/or faecal incontinence (GoR B); goals for urinary and

faecal incontinence care (dryness, decrease in specific symptoms, quality of life, reduction of comorbidity, lesser care burden) (GoR B); and likely cooperation with management (GoR C).

- Evaluation for bowel “alarm” symptoms (rectal bleeding, positive blood screening from stool studies, obstructive symptoms, recent onset of constipation, weight loss, and a change in stool calibre) will need more extensive evaluation (GoR A)
- Urinalysis is recommended for all patients, primarily to screen for haematuria (GoR C).
- Treatment of otherwise asymptomatic bacteriuria/pyuria is not beneficial (GoR C), and it may cause harm by increasing the risk of antibiotic resistance and severe adverse effects. e.g., *Clostridium difficile* colitis (GoR C).
- Stool studies may not be needed in all patients with faecal incontinence. Patients with diarrhoea, especially those with more acute onset diarrhoea, may need to be tested for infectious causes of their diarrhoea. Other stool studies could involve testing for malabsorption syndromes.
- The utility of the Clinical Stress test in this population is uncertain (GoR D).
- Wet checks can assess urinary incontinence frequency in long-term care residents (GoR C).
- A post voiding residual volume (PVR) test is impractical in many care settings and there is no consensus for the definition of what constitutes a “high” PVR in any population. A PVR measurement is not recommended in the routine initial assessment of frail older people with urinary incontinence.
- However, there is compelling clinical experiential evidence for PVR testing in selected frail older people with: diabetes mellitus (especially long standing); prior urinary retention or high PVR; recurrent UTIs; medications that impair bladder emptying (e.g., opiates); severe constipation; persistent or worsening urgency urinary incontinence despite antimuscarinic/beta-3-agonist treatment; or prior urodynamics showing detrusor underactivity and/or bladder outlet obstruction (GoR C). Treatment of contributing comorbidity may reduce PVR. Trial with catheter may be considered for PVR > 200-500 ml if the PVR is felt to contribute to UI or urinary frequency (GoR C).

- Nocturia Assessment of frail elders with bothersome nocturia should identify potential underlying causes including nocturnal polyuria (by bladder diary/frequency- volume chart or wet checks; oedema on examination) (GoR C), primary sleep problems (e.g., sleep apnoea); and low voided volumes (e.g., from high PVR).
- Stool impaction/loading. If suspected on digital rectal examination, an abdominal x-ray may be necessary to further evaluate the degree and location of impaction/loading in frail older adults.

2. CLINICAL DIAGNOSIS

The most common types of Urinary Incontinence in frail older people are urgency, stress, and mixed urinary incontinence. Frail older people with urgency urinary incontinence also may have detrusor underactivity during voiding with a high PVR but without outlet obstruction. There is no evidence that antimuscarinics are less effective or cause retention in this situation (GoR D).

The most common types of faecal incontinence in frail older people are related to urgency and passive leakage. Passive leakage can refer to leakage, seepage and staining following bowel movements that are not associated with faecal urgency and may also occur with faecal impaction. Because constipation and impaction often contribute to faecal incontinence in older adults, these are considered separately in the algorithm.

3. INITIAL MANAGEMENT

- Initial treatment should be individualised and influenced by goals of care, treatment preferences and estimated remaining life expectancy, as well as the most likely clinical diagnosis (GoR C). In some frail older persons the only possible outcome may be containment; management with continence products, especially for people with minimal mobility (require assistance of > 2 people to transfer), advanced dementia (unable to state their name), and/or nocturnal urinary and faecal incontinence.
- Conservative and behavioural therapy for UI includes lifestyle changes (GoR C), bladder training for more fit alert persons (GoR B), and prompted voiding for frailer, more impaired older people (GoR A).
- For the select cognitively intact older person with UI or FI, pelvic floor muscle therapy can be considered, but there are few studies (GoR C). Antimuscarinics

may be added to conservative therapy of urgency UI (GoR A-C, depending on agent).

- For the select cognitively intact older with FI, biofeedback may be considered, but few studies exist among frail older adults.
- Alpha-blockers may be cautiously considered in frail men with suspected prostatic obstruction (GoR C). All drugs should be started at the lowest dose and titrated with regular review until either care goals are met or adverse effects are intolerable.
- DDAVP (vasopressin) has a high risk of severe hyponatraemia in frail older persons and should not be used outside specialist centres or without very careful monitoring and long term followup (GoR A).
- Improving stool consistency can be done with dietary fibre and supplemental fibre in older adults (GoR C). In older adults with diarrhoea, loperamide may be considered at low doses to improve stool consistency. However, close monitoring for constipation and impaction is needed.

4. ONGOING MANAGEMENT AND REASSESSMENT

Optimal urinary and faecal incontinence management is usually possible with the above approaches. If initial management fails to achieve the desired goals, the next steps are reassessment and treatment of contributing comorbidity and/or functional impairment.

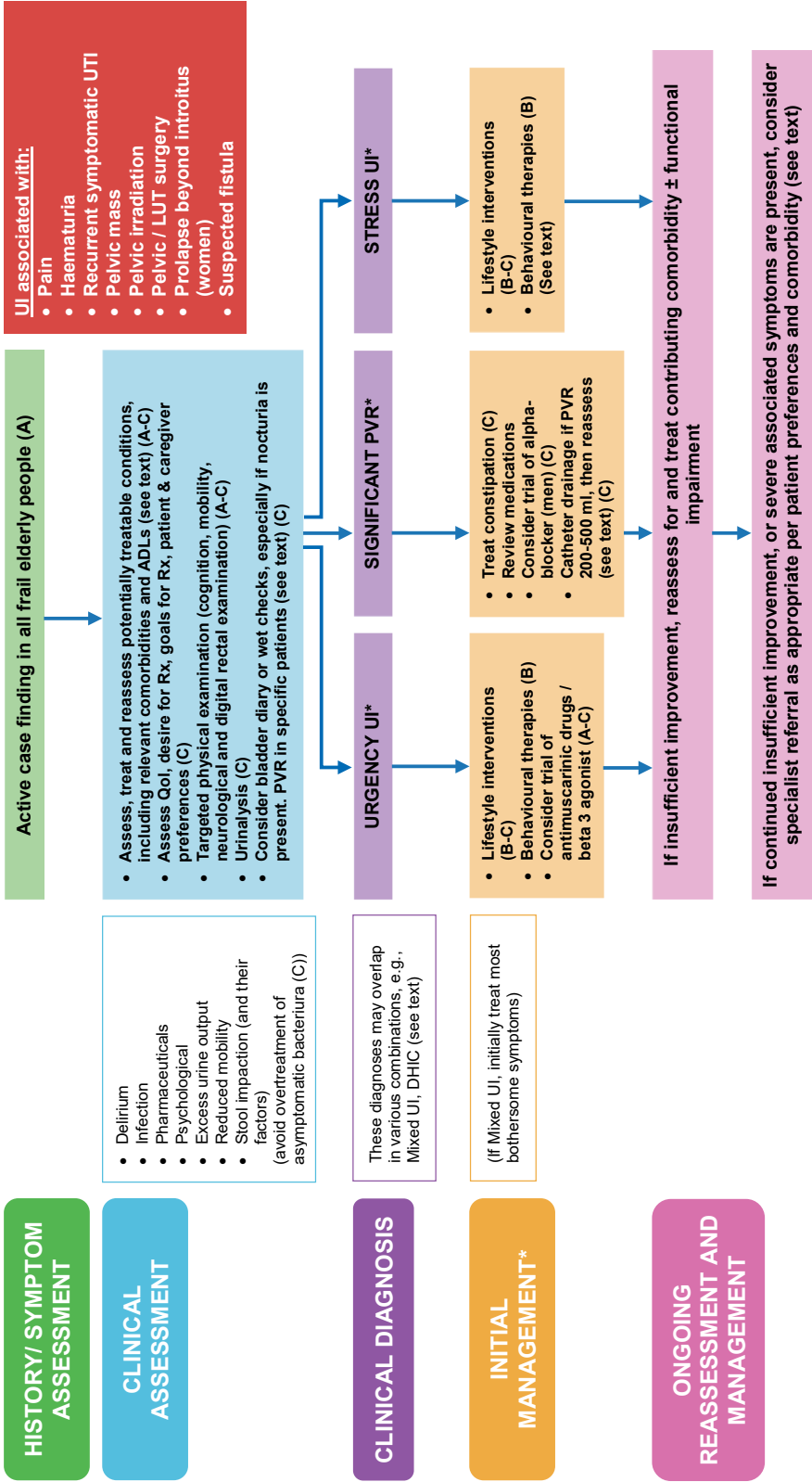
5. SPECIALISED MANAGEMENT

If frail older people have either other significant factors (e.g., pain, haematuria, bowel "alarm" symptoms), UI or FI symptoms that cannot be classified as urgency, stress, or mixed or overflow or other complicated comorbidity which the primary clinician cannot address (e.g. dementia, functional impairment), then specialist referral should be considered. Referral may also be appropriate when there is been insufficient response to initial management. The type of specialist will depend on local resources and the reason for referral: surgical specialists (urologists, gynecologists, colorectal surgeons), gastroenterologists, geriatricians or physical therapist (functional and cognitive impairment); or continence nurse specialists (homebound patients). Referral decisions should consider goals of care, patient/caregiver desire for invasive therapy and estimated remaining life expectancy.

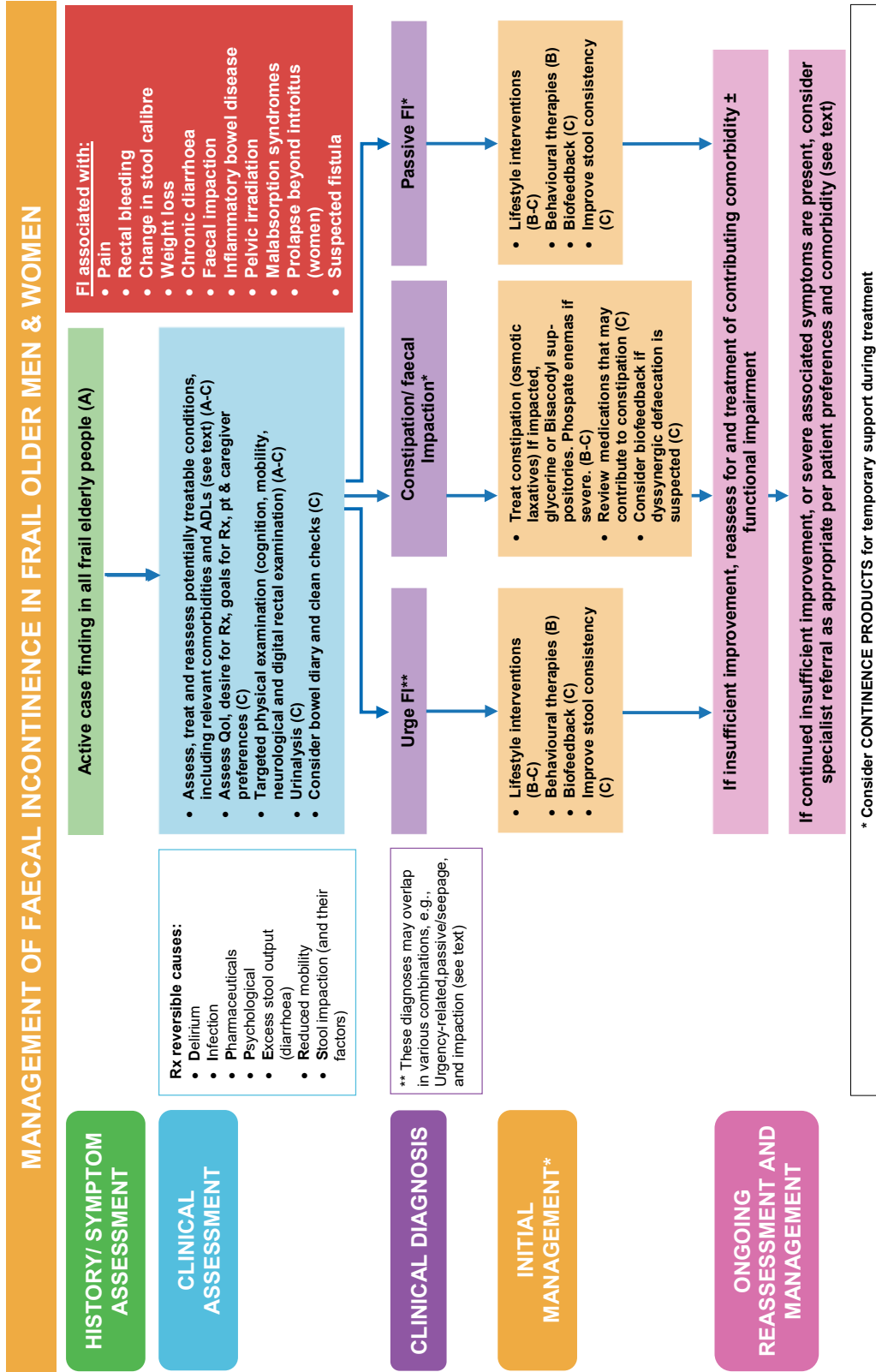
- Age *per se* is not a contraindication to UI or FI surgery (GoR C), but before surgery is considered, all patients should have:
 - Evaluation and treatment for any comorbidity, medications, and cognitive or functional impairments contributing to UI that could compromise surgical outcome (e.g., dementia that precludes patient ability to use artificial sphincter) (GoR C).
 - Adequate trial of conservative therapy, including pharmacological therapies where relevant (GoR C).
- Discussion (including the caregiver) to ensure that the anticipated surgical outcome is consistent with goals of care in the context of the patient's remaining life expectancy (GoR C).
- Urodynamic testing or anorectal manometry, because clinical diagnosis may be inaccurate (GoR B).
- Preoperative assessment and perioperative care to establish risk of, and to minimise the risk of common geriatric post-operative complications such as delirium and infection (GoR A), dehydration and falls (GoR C).

MANAGEMENT OF URINARY INCONTINENCE IN FRAIL OLDER MEN & WOMEN

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* Consider CONTINENCE PRODUCTS for temporary support during treatment



4. RECOMMENDATIONS FOR FURTHER RESEARCH IN EPIDEMIOLOGY

1. Longitudinal study designs are needed to: (i) estimate the incidence and remission rates of urinary incontinence (UI) anal incontinence (AI) and pelvic organ prolapse (POP) and to (ii) describe the natural course of these conditions and (iii) to investigate risk factors and possible protective factors. In addition, similar studies regarding other lower urinary tract symptoms (LUTS) should be initiated.
2. Although there is now more information regarding prevalence, incidence, and other epidemiological data in developing countries, further information is still needed. It is recommended that fundamental research regarding prevalence, incidence and other epidemiological data in developing countries should be encouraged, and tailored to the cultural, economic and social environment of the population under study.
3. Some potential risk and protective factors deserve more attention. For example, the role of pregnancy and childbirth in the development of UI, AI and POP must be studied in a fashion that links population-based methods to clinical assessment of pregnancy, delivery and birth trauma and follows women over many years. Such a design is necessary because the effect of pregnancy and childbirth may become clear only years later when the woman is older and because the woman will not then be able to report the exact nature of the tear, episiotomy, etc.
4. There should be more emphasis on the associations between UI, AI and POP and specific diseases like stroke, diabetes, and psychiatric diseases.
5. The variation of disease occurrence in groups of different racial origin yet similar environmental exposures, lend support to the presumed genetic influence on the causation of UI, AI and POP. This again provides circumstantial evidence for a genetic contribution to pelvic floor muscle disorders since most of these studies have been unable to control for heritability in relation to the complex interaction of environmental factors.

The aetiology of UI, AI and POP is widely recognised to be multifactorial, yet the complex interaction between genetic predisposition and environmental influences is poorly understood. Genetic components require further investigation. Twin studies provide a possible means of studying the relative importance of genetic predisposition and environmental factors. By comparing monozygotic female twins with identical genotype, and dizygotic female twins who, on average, share 50 percent of their segregating genes, the relative proportions of phenotypic variance resulting from genetic and environmental factors can be estimated. A genetic influence is suggested if monzygotic twins are more concordant for the disease than dizygotic twins whereas evidence for environmental effects comes from monozygotic twins who are discordant for the disease.

5. RECOMMENDATIONS FOR FURTHER BASIC SCIENCE RESEARCH

The following proposals for research come from the Committees' work in reviewing the current literature on Basic Science:

1. Integrate data from reductionist experiments to inform the formulation of better systems-based approaches in the investigation of the pathology of the lower urinary tract (LUT), the genital tract (GT) and the lower gastro-intestinal tract (LGIT).
2. Encourage greater emphasis on basic research to characterise tissues receiving relatively little attention: ie the lower gastrointestinal tract; the bladder neck and urethra; the ureter, pelvic floor musculature.
3. Generate research programmes for fetal and neonatal research in LUT and LGIT function.
4. Use genome-wide bioinformatic and population health surveys to generate testable hypotheses regarding the physiological and pathophysiological functions of the LUT, GT and LGIT.
5. Generate improved experimental approaches to investigate the pathophysiology of the LUT and LGIT by:
 - The development of animal models that accurately describe human pathological conditions, including the greater use of large-animal models
 - The better use of reverse translational approaches for linking animal models to the human disease.
 - The use of human tissue from well-characterised patient groups.
 - The development of emerging areas such as: tissue engineering; proteomics and metabolomics
 - Increased collaborations between biological, physical and mathematical sciences.
6. Develop centres of excellence or consortia of excellence in LUT, GT and GIT research
 - Integrate expertise from university departments, academic medical units and industry
 - Encourage translational approaches to research.
 - Develop inter-institutional research-training programmes to allow new researchers the opportunity to better interact and exchange ideas.
7. Bring about a greater emphasis on the importance of research to medical trainees and science graduates through:
 - Establishing research training as a core component of postgraduate clinical development
 - Increased access to support funds, especially scholarships and personal awards
 - Organisation of focused multidisciplinary research meetings, either stand-alone or as dedicated sessions during national and international conferences
 - Greater interaction between medical centres and Higher Education Institutions (HEIs).
 - Allowing researchers-in-training better access to international meetings through reduced registration charges and improved travel grants.
 - Inclusion in clinical meetings of point-counterpoint session(s) with both basic science and clinical viewpoints.
 - Development of research forums for exchange of ideas between active researchers and industry.
 - Lobbying research-funding organisations about the medical and social importance of LUT and LGIT disorders.
8. Increase emphasis on research into LUT and LGIT in HEIs through:
 - Greater representation on grant-funding agencies
 - Encouragement of submission to high impact factor journals and recognition of research published in specialty journals
 - More integrated teaching and training opportunities

6. RECOMMENDATIONS FOR PRIMARY PREVENTION, CONTINENCE PROMOTION, MODELS OF CARE AND EDUCATION

Primary prevention, continence promotion and advocacy, models of care and education involves informing and educating the public and health care professionals that UI and FI are not inevitable, but are treatable or at least manageable. Other bladder disorders such as BPS/IC and POP can also be treated successfully. The committee found information about recent practice and research initiatives in all of these areas but evidence-based research only on primary prevention of UI. Continence promotion and advocacy, and professional and non-professional education, require prioritisation by public health professionals, educationalists, clinicians and researchers to reduce the burden that UI, FI, BPS/IC and POP places on society, healthcare systems, caregivers, and above all, affected adults. As to models of care, the evidence supports nurse-led community services as leading to higher health-related QoL and in some instances, higher cure rates. The multidisciplinary referral settings are also reporting favourable outcomes.

1. PRIMARY PREVENTION

- Pelvic floor muscle exercises can prevent UI in pregnant and postpartum women. (Level of Evidence: 1)
- Education designed for community-dwelling older women can prevent UI. (Level of Evidence: 1)
- No recent RCTs or case-control studies were located for prevention of FI. (Level of Evidence: 4)
- Pelvic floor muscle exercises should be provided for pregnant women. (GoR A)
- Education of older women to prevent UI should be provided. (GoR A)
- Continence promotion is required to address broad gaps in knowledge about incontinence (GoR C)
- Strategies to promote awareness about incontinence and its treatment can be strengthened by the use of evidence based theories and methods from the field of health promotion, including the social determinants of health (GoR D)
- The Internet represents an important source of information about incontinence, however the quality of information is variable (GoR C)
- For help-seeking behaviour, no RCTs or case-control studies were located (Level of Evidence 4)
- Continence promotion programmes need to accommodate varying levels of health literacy and access to health information in different populations (Level of Evidence: 4)
- Public health campaigns about incontinence and other pelvic floor disorders need to use terminology targeted to consumers' understandings (Level of Evidence: 4)
- Satisfaction surveys about continence care could yield relevant and detailed information by using open-ended, rather than closed-ended questions (Level of Evidence: 1)
- Evidence for the use of leaflets or brochures in raising awareness about UI and different treatment options is inconclusive (Level of Evidence: 1).
- Evidence for the impact of continence advocacy worldwide was based on opinion (Level of Evidence: 1)
- Recommendation for help-seeking behaviour: No recommendation was possible based on the level of evidence provided by the available research.
- Worldwide Advocacy (GoR D)

2. MODELS OF CARE

- Effectiveness of service delivery models. (Level of Evidence: 4)
- A care delivery model should be based on the principles as described in the Optimum Continence Service Specification. (GoR C)
- Increased emphasis is needed on non-physician models of care. (GoR C)
- Despite the proliferation of guidelines, there is increasing evidence that practicing clinicians and nurses are not consistently following them. Implementation models should be developed on how to translate guidelines into practice. (GoR C)
- Effectiveness of guidelines in clinical practice has not been determined. (Levels of evidence: 3 to 4).
- There is a continued need for evaluation research to explore impact of guidelines on clinical care both at individual and population levels. This evaluation strategy needs to include impact on a wide range of outcomes, including incidence and prevalence of disease, treatment outcomes, prevention efforts, costs, and health care policy. (GoR: C)
- Effectiveness of public education efforts through various channels including education, public media and mass communications (Levels of Evidence 3-4)

3. EDUCATION

- Professional education of UI, FI, BPS/IC, and POP is not evident as determined by materials reviewed. (Levels of Evidence: 3-4)
- There is a need for additional focused research on methods to enhance patient and public about pelvic disorders, both at an individual and broader public level. (GoR C)
- The role of technology in public education for continence promotion should be examined in more depth. (GoR C)

7. RECOMMENDATIONS FOR TRANSLATIONAL AND CLINICAL RESEARCH

A. RECOMMENDATIONS ON STUDY CONDUCT AND STATISTICAL METHODS

The role of quality RCTs as providing the strongest level of evidence in incontinence research should be fully acknowledged by researchers, journal reviewers, and editors. (GoR A)

Careful attention to the planning and design of all research, especially RCTs, is of the utmost importance. (GoR A)

Appropriate expertise in biostatistics and clinical trial design should be employed at the design phase of a RCT and thereafter on an ongoing basis. For Phase 4, phase 5, and implementation trials, health economists should be included in trial design to support questions of value (cost-effectiveness). (GoR A)

The design, conduct, analysis and presentation of RCTs must be fully in accordance with the CONSORT Statement. (GoR A)

The design, conduct, analysis and presentation of observational studies should follow STROBE guidelines. (GoR A)

The design, conduct, analysis and presentation of meta-analyses should follow QUORUM guidelines. (GoR A)

Reporting studies of diagnostic tests, including urodynamics, should follow the STARD statement guidelines. (GoR A)

B. RECOMMENDATIONS ON RESEARCH CONDUCT

1. RECOMMENDATIONS FOR CONSERVATIVE TREATMENT TRIALS

Use correct terminology to describe the intervention. (GoR A)

Report details of ability to perform correct contraction, dose-response issues and adherence. (GoR A)

Use recommended outcome measures with high responsiveness, reliability and validity. (GoR A)

Compare new methods with the best available intervention. (GoR A)

Use power calculation in planning of the study. Avoid large sample sizes and weak (ineffective dosages) interventions. (GoR A)

For long-term follow-up studies report cross-over, co-interventions, recurrent and competing events, adherence in the follow-up period and loss to follow-up. (GoR A)

2. RECOMMENDATIONS FOR SURGICAL AND DEVICE TRIALS

- The safety and serious side effects of new operations must be completely defined with adequate follow-up so that risks can be weighed against efficacy. At a minimum, this requires more use of large scale, independent, prospective, multicentre cohort studies when RCTs are not practical. (GoR A)
- Safety and serious side effects of incontinence devices must be completely defined with adequate follow-up, especially for use of implantable devices and biological materials, so that risks can be weighed against efficacy. (GoR A)
- Valid informed research consent is required in all trials of surgical interventions, which is separate from the consent for surgery. (GoR A)
- We recommend ongoing research into the usefulness of pre- and post-operative predictive testing (such as urodynamics, ultrasound, MRI, etc) in surgical trials. (GoR A)
- Reports of successful treatment should be limited to subjects with a minimum (not mean) of one-year follow-up and should include a patient perspective measure. Specific assumptions about subjects lost to follow-up should be stated. (GoR A)

- Randomisation for surgical trials should occur at the time of surgery to minimise drop-outs and switch of procedure (GoR A)
- Long-term follow-up of RCT cohorts in an observational cohort is recommended (GoR A)

3. RECOMMENDATIONS ON COST ANALYSIS IN INCONTINENCE

- Cost analysis should be incorporated into clinical studies whenever possible (137). (GoR A)
- Cost analysis should describe the perspective of the analysis and analyses using the societal perspective and the payer perspective are useful. (GoR A)

C. RECOMMENDATIONS FOR SPECIFIC PATIENT GROUPS

1. MEN AND WOMEN WITH LUTS

1.1. Men with LUTS

- Measurement of prostate size should be performed before and after treatment (at the same time as continence outcome measures where possible) whenever prostate size is considered to be a variable, or to change during the intervention and follow up. (GoR A)
- Maximum free flow rate and measurement of post-void residual urine should be recorded pre-treatment and the effect of therapy on these parameters should be documented simultaneously with assessment of the primary outcome variables. (GoR A)
- Participants should be stratified by prostate size at randomisation when size is considered to be a potentially important determinant of treatment outcome. (GoR C)

1.2. Women with LUTS

- Specific information about menopausal status, hysterectomy, parity/obstetric history, and hormonal status should be included in baseline clinical trial data and controlled for in specified analyses in the research protocol. (GoR A)
- High quality, symptom and bother scores (e.g., ICIQ-FLUTS, ICIQ-SF, ICIQ-QoL(KHQ), PISQ, ICIQ-FLUTSsex) validated in women should be employed when assessing outcomes. (GoR A)
- Standardised assessment of pelvic organ prolapse should be performed before treatment and at the time of other outcome assessments in all

research where prolapse and continence outcomes are being assessed. (GoR A)

- Criteria for cure/improvement/failure from incontinence treatment should be defined in the protocol based on patient perception as well as objective and semi-objective instruments such as validated questionnaires, diaries and pad tests. (GoR A)
- Assessment of the impact of treatment on sexual function should be performed with other outcome assessment when appropriate. (GoR B)

2. CHILDREN

- Long-term follow-up is of critical importance in the paediatric population in order to ascertain the effect of a treatment on normal growth and development. (GoR A)
- Research is needed to develop standardised outcome measures including validated, age-specific symptom and disease-specific quality of life outcome measures. (GoR B)

3. NEUROGENIC POPULATIONS

- Detailed urodynamic studies are recommended for classification of neurogenic lower urinary tract disorders in research studies because the nature of the lower tract dysfunction cannot be accurately predicted from clinical data. Videourodynamic studies are preferred but are not mandatory. (GoR C)
- An area of high priority for research is the development of a classification system to define neurogenic disorders. Relevant features could include the underlying diagnosis, the symptoms, a precise documentation of the neuromuscular lesion by clinical neurophysiologic testing, and the nature of the urodynamic abnormality. (GoR C)

4. POPULATIONS AFFECTED BY BLADDER PAIN SYNDROME (INCLUDING INTERSTITIAL CYSTITIS)

- Broader entry criteria should be used to reflect the full spectrum of the BPS/IC patient population. (GoR B)
- The primary endpoint of BPS/IC trials should be patient driven and the Global Response Assessment is recommended. A wide spectrum of secondary endpoints will be useful in defining the effect of treatments. (GoR B)

5. POPULATIONS AFFECTED BY PELVIC ORGAN PROLAPSE

- A validated standardised assessment of prolapse (eg POP-Q) should be used for baseline and outcome assessments. (GoR A)
- Complete reporting of outcomes including a validated assessment of anatomy, functional status, and complications is essential. (GoR A)
- Complications/adverse events (especially for mesh) must be explicitly and completely reported in any research. (GoR A)
- Long term outcomes (> 2 years) of intervention studies are needed. (GoR A)

D. RECOMMENDATIONS FOR ETHICS IN RESEARCH

The GoR for this section is A.

Continuity in clinical direction from design through authorship is mandatory. Investigators should be involved in the planning stage and a publications committee should be named at the beginning of the clinical trial. The Uniform Requirements for Manuscripts

Submitted to Biomedical Journals, from the International Committee of Medical Journal Editors should be followed. Authorship requires:

- Substantial contributions to conception and design or acquisition of data or analysis and interpretation of data,
 - Drafting the article or revising it critically for important intellectual content,
 - Final approval of the version to be published
- Authors should provide a description of what each contributed and editors should publish that information.
- Authors should have access to all raw data from clinical trials, not simply selected tables

Clinical trial results should be published regardless of outcome. The sponsor should have the right to review manuscripts for a limited period of time prior to publication but the manuscript is the intellectual property of its authors, not the sponsor.

- All authors should be able to accept responsibility for the published work and all potential conflicts of interest should be fully disclosed

8. INTERNATIONAL CONSULTATION ON INCONTINENCE MODULAR QUESTIONNAIRE (ICIQ): QUESTIONNAIRES AND BLADDER DIARY

A. INTERNATIONAL CONSULTATION ON INCONTINENCE MODULAR QUESTIONNAIRE (ICIQ)

The scientific committee which met at the end of the 1st ICI in 1998 supported the idea that a universally applicable questionnaire should be developed, that could be widely applied both in clinical practice and research and should reflect the patients' perspective of their situation.

The hope was expressed that such a questionnaire would be used in different settings and studies and would allow cross-comparisons, for example, between a drug and an operation used for the same condition, in the same way that the IPSS (International Prostate Symptoms Score) has been used.

An ICIQ Advisory Board was formed to steer the development of the ICIQ and met for the first time in 1999. The project's early progress was discussed with the Board and a decision made to extend the concept further and to develop the ICIQ Modular Questionnaire to include assessment of urinary, bowel and vaginal symptoms(1). The first module to be developed was the ICIQ Short Form Questionnaire for urinary incontinence: the ICIQ-UI Short Form (2) (Fig 1). The ICIQ-UI Short Form is now widely used globally and since 2004 its use or further development has been reported in almost 100 publications.

Given the intention to produce an internationally applicable questionnaire, requests were made for translations of the ICIQ-UI Short Form at an early stage, for which the Advisory Board developed a protocol for the production of translations of its modules. The ICIQ modules have been translated into over 40 languages to date across the various modules.

Since the fifth consultation a further two modules have been published and are available for use: the ICIQ Bladder Diary (3,4) and ICIQ-LTCqol(5). The bladder diary is the first fully validated bladder diary, which notably incorporated patient and clinician input during its development. The ICIQ-LTCqol questionnaire provides an assessment of symptoms, impact and bother associated with indwelling catheter use. This brings the total number of available modules to sixteen.

With increasing demand for electronic versions of questionnaires, a study has been conducted by the ICIQ group to evaluate the equivalence of the ICIQ's psychometric properties in alternative formats (6). With equivalence demonstrated, app development for the eICIQ is underway.

www.ICIQ.net provides details of the validation status of the modules under development for urinary symptoms, bowel symptoms and vaginal symptoms and provides information regarding the content of existing modules. Information regarding production of translations and the ICIQ development protocol is also available for those interested in potential collaborations to continue development of the project.

Initial number

ICIQ-UI Short Form

CONFIDENTIAL

DAY MONTH YEAR

Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth:

DAY MONTH YEAR

2 Are you (tick one): Female Male

3 How often do you leak urine? (Tick one box)

never 0

about once a week or less often 1

two or three times a week 2

about once a day 3

several times a day 4

all the time 5

4 We would like to know how much urine you think leaks.
How much urine do you usually leak (whether you wear protection or not)?
(Tick one box)

none 0

a small amount 2

a moderate amount 4

a large amount 6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all a great deal

ICIQ score: sum scores 3+4+5

6 When does urine leak? (Please tick all that apply to you)

never – urine does not leak

leaks before you can get to the toilet

leaks when you cough or sneeze

leaks when you are asleep

leaks when you are physically active/exercising

leaks when you have finished urinating and are dressed

leaks for no obvious reason

leaks all the time

Thank you very much for answering these questions.

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Figure 1: ICIQ-UI Short Form

Table 1: Fully validated ICIQ modules and derivation

MODULES AVAILABLE FOR USE	
ICIQ-MLUTS(7) (ICS <i>male</i> Short Form)	Urinary symptoms (male)
ICIQ-FLUTS(8) (BFLUTS Short Form)	Urinary symptoms (female)
ICIQ-VS(9)	Vaginal symptoms and quality of life
ICIQ-B(10,11)	Bowel symptoms and quality of life
ICIQ-UI Short Form(2)	Urinary incontinence short form
ICIQ Bladder diary(3,4)	Bladder events and fluid intake
ICIQ-N(12,13) (ICS <i>male</i> /BFLUTS)	Nocturia symptoms
ICIQ-OAB(12,13) (ICS <i>male</i> /BFLUTS)	Overactive bladder symptoms
ICIQ-MLUTS Long Form(12) (ICS <i>male</i>)	Urinary symptoms long form (male)
ICIQ-FLUTS Long Form(13) (BFLUTS)	Urinary symptoms long form (female)
ICIQ-LUTSqol(14) (KHQ)	Urinary symptoms quality of life
ICIQ-Nqol(15) (N-QoL)	Nocturia quality of life
ICIQ-OABqol(16) (OABq)	Overactive bladder quality of life
ICIQ-LTCqol(5)	Long term catheter symptoms and quality of life
ICIQ-MLUTSsex(12) (ICS <i>male</i>)	Sexual matters related to urinary symptoms (male)
ICIQ-FLUTSsex(13) (BFLUTS)	Sexual matters related to urinary symptoms (female)

B. ANNEX 1 BLADDER CHARTS AND DIARIES

The ICS defines three types of Bladder Charts and Diaries which can be used to collect data:

MICTURITION TIME CHART

- times of voiding and
- incontinence episodes

FREQUENCY VOLUME CHART

- times of voiding with voided volumes measured,
- incontinence episodes and number of changes of incontinence pads or clothing

BLADDER DIARIES

- the information above, but also
- assessments of urgency,
- degree of leakage (slight, moderate or large) and descriptions of factors leading to symptoms such as stress leakage, eg. running to catch a bus. It is important to assess the individual's fluid intake, remembering that fluid intake includes fluids drunk plus the water content of foods eaten. It is often necessary to explain to a patient with LUTS that it may be important to change the timing of a meal and the type of food eaten, particularly in the evenings, in order to avoid troublesome nocturia.

The recent development and publication of the ICIQ Bladder Diary provides the first fully validated bladder diary that incorporated patient, clinician and statistical

input during its development (3,4). This rigorous development methodology has ensured the provision of a psychometrically robust tool that reflects the key issues from a patient's and clinical perspective to enable the gathering of required information to treat patients with LUTS (Fig 1). The diary is intended to be a standalone tool that provides instructions and an example to guide completion. The diary is intended for completion over three days and fits onto two sides of A4 to optimise administration and completion. Data collected are:

- Fluid intake
- Urine output
- Leakage episodes
- Time of sleep and waking
- Pads used
- Optional bladder sensation scale

The bladder sensation scale is intended to be an interchangeable variable that can be replaced with a more pertinent measure for an intended use, for example, a pain scale. It is advised that any scale used in this manner should be validated.

INSTRUCTIONS FOR USING THE BLADDER DIARY

This diary helps you and us to understand why you get trouble with your bladder. The diary is a very important part of the tests we do, so that we can try to improve your symptoms. On the chart you need to record:

9. When you get out of bed in the morning, show this on the diary by writing 'GOT OUT OF BED'.
10. During the day please enter at the correct time the drinks you have during the day, eg. 8.00am – two cups of coffee (total 400 ml).
11. The time you pass your urine, eg. 7.30am. Do this every time you pass urine throughout the day and night.
12. Each time you pass urine, collect the urine in a measuring jug and record the amount (in mls or fluid ozs) next to the time you passed the urine, eg. 1.30pm/320ml.
13. Each time you pass your urine, please write down how urgent was the need to pass urine:
 - 'O' means it was not urgent.
 - + means I had to go within 10 minutes.
 - ++ means I had to stop what I was doing and go to the toilet.
14. If you leak urine, show this by writing an 'W' on the diary at the time you leaked.
15. If you have a leak, please add 'P' if you have to change a pad and 'C' if you have to change your underclothes or even outer clothes. So if you leak and need to change a pad, please write 'WP' at the time you leaked.
16. If you have a leakage please write in the column called 'Comments' whether you leaked a small amount or a large amount and what you were doing when you leaked, eg. 'leaked small amount when I sneezed three times'.
17. Each time you change a pad or change clothes, please write in the 'Comments' column.
18. When you go to bed at the end of the day show it on the diary - write 'Went to Bed'.

ICIQ-BLADDER DIARY (12/13)

YOUR NAME: _____

DAY 1 DATE: ____/____/____

Please complete this **3 day** bladder diary. Enter the following in each column against the time. You can change the specified times if you need to. In the time column, please write **BED** when you went to bed and **WOKE** when you woke up.

Drinks Write the amount you had to drink and the type of drink.

Urine output Enter the amount of urine you passed in millilitres (mls) in the urine output column, day and night. Any measuring jug will do. If you passed urine but couldn't measure it, put a tick in this column. If you leaked urine at any time write **LEAK** here.

Bladder sensation Write a description of how your bladder felt when you went to the toilet using these codes

0 - If you had no sensation of needing to pass urine, but passed urine for "social reasons", for example, just before going out, or unsure where the next toilet is.

1 - If you had a normal desire to pass urine and no urgency. "Urgency" is different from normal bladder feelings and is the sudden compelling desire to pass urine which is difficult to defer, or a sudden feeling that you need to pass urine and if you don't you will have an accident.

2 - If you had urgency but it had passed away before you went to the toilet.

3 - If you had urgency but managed to get to the toilet, still with urgency, but did not leak urine.

4 - If you had urgency and could not get to the toilet in time so you leaked urine.

Pads If you put on or change a pad put a tick in the pads column.

Here is an example of how to complete the diary:

Time	Drinks		Urine output	Bladder sensation	Pads
	Amount	Type			
6am	WOKE		350ml	2	
7am	300ml	tea			
8am			✓	2	
9am					
10am	cup	water	Leak	3	✓

Time	Drinks		Urine output (mls)	Bladder sensation	Pads
	Amount	Type			
6am					
7am					
8am					
9am					
10am					
11am					
Midday					
1pm					
2pm					
3pm					
4pm					
5pm					
6pm					
7pm					
8pm					
9pm					
10pm					
11pm					
Midnight					
1am					
2am					
3am					
4am					
5am					

Figure 2: ICIQ-Bladder Diary (page 1)

ICIQ-BLADDER DIARY (12/13)

YOUR NAME: _____

DAY 2 DATE: ____/____/____					DAY 3 DATE: ____/____/____						
Time	Drinks		Urine output (mls)	Bladder sensation	Pads	Time	Drinks		Urine output (mls)	Bladder sensation	Pads
	Amount	Type					Amount	Type			
6am						6am					
7am						7am					
8am						8am					
9am						9am					
10am						10am					
11am						11am					
Midday						Midday					
1pm						1pm					
2pm						2pm					
3pm						3pm					
4pm						4pm					
5pm						5pm					
6pm						6pm					
7pm						7pm					
8pm						8pm					
9pm						9pm					
10pm						10pm					
11pm						11pm					
Midnight						Midnight					
1am						1am					
2am						2am					
3am						3am					
4am						4am					
5am						5am					

Bladder sensation codes

- 0** - No sensation of needing to pass urine, but passed urine for "social reasons"
- 1** - Normal desire to pass urine and no urgency
- 2** - Urgency but it had passed away before you went to the toilet
- 3** - Urgency but managed to get to the toilet, still with urgency, but did not leak urine
- 4** - Urgency and could not get to the toilet in time so you leaked urine

Figure 3: ICIQ-Bladder Diary (page 2)

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4. ICS CONSENSUS AND COMMITTEE DOCUMENTS

A 'medical consensus' is defined by the Council of Europe as "a public statement on a particular aspect of medical knowledge that is generally agreed upon as an evidence-based, state-of-the-art knowledge by a representative group of experts in that area".

The document is usually developed by a multidisciplinary independent panel of experts convened either by a medical association or by a governmental authority to review and summarise the scientific literature in order to:

1. Advance the understanding of an issue, procedure, or method;
2. Outline standards of care and good practice;
3. Provide guidance to health care professionals, especially on controversial or poorly understood aspects of care;
4. Support and promote good clinical practice in the best interest of the patient;
5. Improve the quality and effectiveness of health care.

The consensus documents by summarising the published literature on a specific topic should be considered as a comprehensive summary of the opinions and the expression of the general opinion of the panel of experts that does not necessarily imply unanimity. Since they provide a "snapshot in time" they must be re-evaluated periodically.

There are different ways of producing a consensus document. The Delphi method is a useful process that involves sending out questionnaires of statements; collating and anonymizing feedback; sharing them in a number of cycles within the experts who can adjust their answers in subsequent rounds. It allows to avoid bringing experts together for a physical meeting, to facilitate interaction between experts and to reduce individual bias. However, consensus documents do not provide algorithms or guidelines for practice that are usually issued by any organization for healthcare providers and commissioners to promote best care for patients.

In this e-book we will describe how the International Continence Society consensus documents are developed. These are usually commissioned by the Board of Trustees or by ICS committees and aim to set out the organisation's position or philosophy about a specific topic.

We will also describe the criteria that Working /Committee groups which wish to produce a consensus document for the ICS should adhere to.

Finally, we will discuss the Standard Operating Procedure that has been compiled by the International Continence Society. This includes a Proposal Stage, a Preparatory Stage, a Review Stage, a Publication Stage and a Implementation Stage. A set of step-by-step instructions for the creation of the consensus documents will be described in detail including: creation of a working group and appointment of a chair; submission of the proposal sent to ICS Office; review and approval of the proposal by Board of Trustees and Editor of NeuroUrology & Urodynamics Journal (NUUJ); preparation of the consensus document; review of the content by relevant committees and Board of Trustees; submission of the consensus document NUUJ; publication of the consensus document on the ICS website and advertised."



Alex Digesu
ICS Trustee



Good urodynamic practice adaptations during the COVID-19 pandemic

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Abstract

Urodynamics testing forms the cornerstone of investigations when it comes to lower urinary tract dysfunction. It has to be done to the highest standards by following the International Continence Society Good Urodynamics Practice protocols. However, with the COVID-19 pandemic, certain adaptations to the urodynamics procedure need to be considered especially when it comes to quality control. This article aims to define these adaptations to help urodynamicists in their daily practice.

KEYWORDS

adaptations, COVID-19, International Continence Society, urodynamics

1 | INTRODUCTION

Urodynamics (UDS) forms the cornerstone investigation to assess the function and dysfunction of the lower urinary tract (LUT) and good urodynamics practice (GUP) guidelines have been published by the International Continence Society (ICS)^{1,2} and the United Kingdom Continence Society.³

The spread of COVID-19 across the world has obviously affected the delivery of healthcare services. Female and functional urology (FFU) has probably been the hardest hit subspeciality in urology with massive cut down (Figure 1) in outpatient urological investigations and procedures and urological operations.⁴ Most, if not all, guidelines have categorized FFU procedures into low priority with possibility of delaying such procedures beyond 3 months⁵⁻⁷ unless there is an infected prosthetic device causing individuals to become unwell. Healthcare professionals have also been redeployed to help in other services and maintaining emergency care for COVID-19 patients.

To that effect, several guidelines have been published prioritizing surgeries and suggested converting face-to-face consultations to telephone or video consultations to reduce person-to-person contact.⁸ However, none of these guidelines cater for adaptations of an invasive UDS test during the COVID-19 pandemic which obviously involves coming into close contact with patients and patients coughing during the investigation to check for quality control or effort/stress leakage. Below we describe the adaptations necessary in an UDS investigation during the COVID-19 pandemic to reduce the risk of infection to patients and urodynamicists while maintaining GUP.

2 | ADAPTATIONS OF PRIORITISING UDS TESTING

It is reasonable to suppose that in several centers the availability of UDS services (in terms of human resources, offices availability, and reduction of the executable examinations per day, due to social distancing) will

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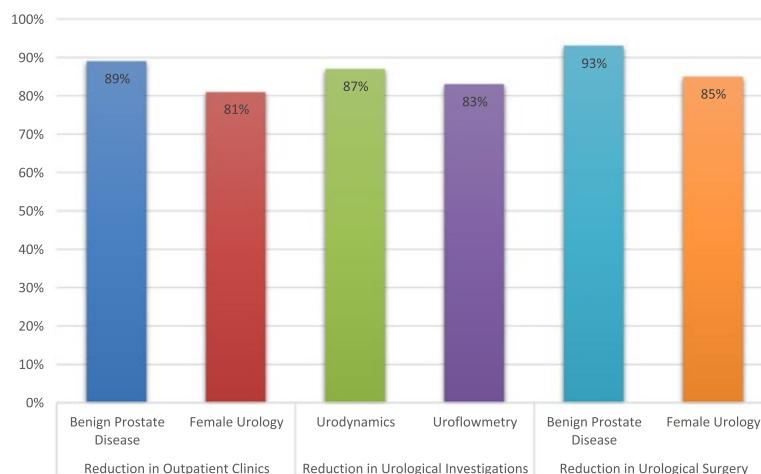


FIGURE 1 Overall percentage reduction in female and functional urology activity worldwide

be reduced while the pandemic subsides. In this case, centers should consider different priorities for different cases. The priority criteria used for surgical procedures (Table 1) could also be used to prioritize urodynamic studies.⁹ The main considerations would be whether performing the UDS test would alter the current treatment of the patient and also when after the UDS test will an operation be performed. There are no P1 (Emergency/Urgent) priority indications for invasive UDS that we have identified.

2.1 | High priority (P2)

Neurogenic patients at risk for upper urinary tract deterioration (eg, spinal cord injury or spinal dysraphism patients and some multiple sclerosis patients¹⁰⁻¹²) should be given the higher priority.¹² Same priority may be given to patients with suspected poor compliance (eg, affected

by radio-cystitis) in which a urinary diversion or bladder augmentation is or could be planned as a P2 priority or those due for a kidney transplant.

If UDS is considered necessary or useful in patients waiting for second stage surgery for sacral neuromodulation (eg, implant of the pulse generator) then they should be investigated as soon as possible before the surgical procedure and ideally within 4 weeks of the advanced timed lead implant.

2.2 | Intermediate priority (P3)

Male patients with benign prostatic obstruction have low priority for surgery unless they have an indwelling urinary catheter which is getting blocked with calcifications or needing regular changes; in this case, urodynamic investigation, if indicated, should be performed just before the surgical procedure which needs to be planned as soon as possible after the acute phase of the pandemic.^{5,12} These patients may be considered in the intermediate priority group, thus not to be postponed more than 3 to 4 months. The same priority may be given to female patients with pelvic organ prolapse and hydronephrosis or vaginal ulcers.

2.3 | Low priority (P4)

All other indications for urodynamic investigation (overactive bladder, urgency or stress urinary incontinence, male

TABLE 1 Prioritization of urological procedures

Priority level (P)	Type	Timing of operation/procedure
P1a	Emergency	Needed within 24 h
P1b	Urgent	Needed with 72 h
P2	High	Can be deferred up to 4 wk
P3	Intermediate	Can be delayed for up to 3 mo
P4	Low	Can be delayed for more than 3 mo

LUTS, neurogenic bladder without risk for the upper urinary tract) may be given a low priority.

3 | ADAPTATIONS PRIOR TO UDS TESTING

3.1 | Patient risk assessment

When deliberating the order of patient bookings, a basic risk assessment may be beneficial. Clinical need is the priority (as above), but subsequent to this there should be a consideration of patient risk. An assessment based on reported risk criteria¹³ may allow departments to identify low, moderate, and high-risk patients. The latter of which requires careful consideration and elevated levels of COVID-19 risk management.

3.2 | Preurodynamic appointment

Departmental variation is common for urodynamic procedures, but for those who perform an in-depth patient history, it is recommended that this is conducted via a telephone consultation before the hospital-based appointment. This ensures that exposure time is minimized for both staff and patients.

A comprehensive patient history should also ensure the appropriateness of the referral, guaranteeing patient appointments are well utilized. On consultation, it is also advisable to outline the precautions the department is taking to reduce the COVID-19 risk; allowing patients the opportunity to postpone investigations should they wish.

3.3 | Number of cases

In accordance with Public Health England guidance,¹⁴ urodynamic tests are not considered to be aerosol-generating procedures. As such, there is no current need for full air change in the room and thus no regulations pertaining to the period of time between patients. This said, there are a number of factors which will dictate the volume of patients that are seen safely. These include sufficient time to perform an intensive room clean as agreed by local infection control, as well as the overall volume of patients within waiting areas and transiting corridors, where 2 m distancing is problematic. The risk of patients crossing in confined areas can be mitigated by introducing one-way systems. However, it is important to be mindful of patients' mobility and the distance they are requested to walk especially from reception to the UDS suite.

3.4 | Route into the department

Independent travel to the hospital should be encouraged, with patients using personal forms of transport rather than public transport where possible. Upon arrival at the department, they should be promptly collected from general waiting areas and escorted to a Personal Protective Equipment (PPE) station, where they can be assessed in private. Current symptoms (fever, new-onset cough, loss of taste/smell etc) can be enquired about (see GOV.UK for up to date symptom list), patient temperature performed (>37.8°C need to be rebooked), and basic preventative measures such as hand-gel and face masks can be administered. Staff should be encouraged to take responsibility for their own safety and PPE outside of the clinical rooms. Face masks may be an appropriate measure, but local agreement on the use of PPE is recommended. Patients should be escorted in and out of the department in a timely fashion, ensuring their hospital visit is as short as possible. The UK government has now suggested that anyone going into hospital, including staff, should use a face covering.

4 | ADAPTATIONS DURING UDS TESTING

Guidelines for preventing infection transmission carried by airborne or surface droplets will clearly have an impact on urodynamic procedures.

4.1 | Personal protective equipment

In addition to the normal use of single-use gloves and aprons by the urodynamicist, single-use surgical face masks are recommended for both patients and staff.¹⁵ Given that body fluids, contact and coughs are conducted in UDS procedures, eye protection in the form of a face visor is also recommended.¹⁵ Standard UDS clinic rooms are acceptable, since negative pressure rooms are not required and positive pressure rooms are not recommended,¹⁵ however a period for cleaning the room is needed between each patient. There is no need for patients to wear gloves as per advice from infection control staff but patients will either use hand-gel or wash their hands for 20 seconds before entering and leaving the UDS room. We recommend that local and national guidelines are adhered to with regard to PPE.

4.2 | Physical distance

Wherever possible, a distance of 2 m should be maintained between staff and patient. Clearly, for procedures

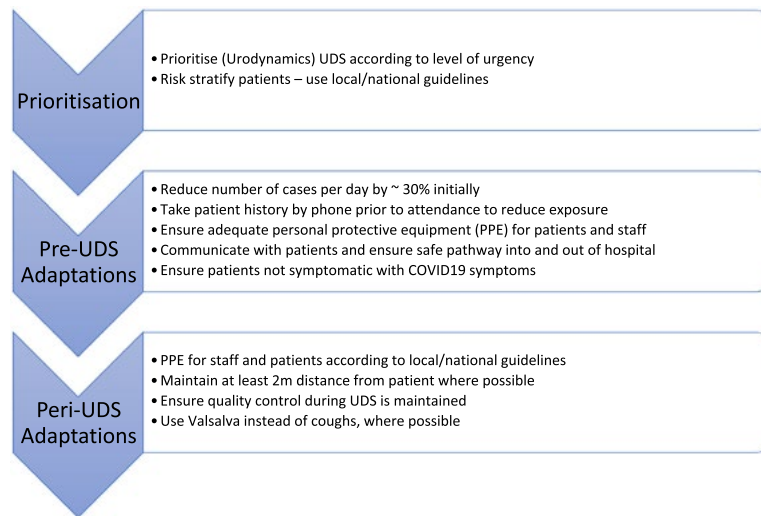


FIGURE 2 Summary of adaptations for urodynamic testing

such as catheterization and examination of the patient this is impossible. Precautions must, therefore, be taken in the form of PPE as above and adjusting elements of the test to allow observation from a distance of at least 2 m. Where urinary leakage needs to be observed, especially in women, the patient should be asked to stand or squat over a pad on the floor, rather than sit on the flow-meter, in order that leakage can be seen from further away. During video UDS, fluoroscopic screening can provide evidence of urethral leakage and will be sufficient for a diagnosis of urodynamic stress incontinence (USI).

4.3 | Coughing and Valsalva

A key test for signal quality and for USI is coughing by the patient. As this will result in airborne particles being generated, coughing should be kept to an absolute minimum and always with a mask in place. Quality control can be carried out effectively by a Valsalva manoeuvre¹⁶ or even by gentle external pressure on the abdomen by the patient, thus coughing is not needed in this case. For stress testing, again a Valsalva manoeuvre or other physical provocations can be attempted first, and only then if required, the patient be asked to cough. In that case, the cough must be directed away from others in the room and shielded by an elbow or by a handheld tissue that is then discarded, since the mask itself must not be touched during use.¹⁵ The patient is then given a hand-gel to use. For the same reason, if the patient is unable to push against a closed glottis to perform a Valsalva,

they can again use a tissue over the mask to close their nose and mouth while raising lung pressure.

5 | CONCLUSION

Urodynamic tests are crucial diagnostic tests in FFU. It is, therefore, imperative that these tests are carried out according to the ICS GUP guidelines. However, in view of the COVID-19 pandemic, certain adaptations need to be followed to maintain good quality testing and obtaining meaningful results (Figure 2).

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Technology-based management of neurourology patients in the COVID-19 pandemic: Is this the future? A report from the International Continence Society (ICS) institute

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Abstract

Coronavirus disease-2019 (COVID-19) pandemic significantly altered our daily life as well as our professional practice. COVID-19 has disrupted our lives both professionally and personally. We know the urological management in a neurogenic patient needs to be tailored to the individual circumstances, this is even more pertinent during these uncertain times. International Continence Society is the premier international organization in functional urology. Lately, it has established an institute to facilitate teaching and training opportunities all over the world. The School of Neurourology teamed with the School of Modern Technology and set up a Webinar—"How to manage the neurourological patients in the current pandemic." This was set up as a case-based discussion to deliberate the management of our patients in the present climate and examine the role of modern technology in overcoming the current barriers.

KEYWORDS

COVID-19, neurourology, technology, telemedicine

1 | CURRENT STATUS OF COVID-19 DISEASE AROUND THE GLOBE: THE ROLE OF ICS SCHOOLS IN THIS PERIOD—WEBINAR-BASED TEACHING

We are living in an unprecedented time. Coronavirus disease-2019 (COVID-19) has disrupted our lives both professionally and personally. In these challenging times, the demand on health care has put enormous pressure on all of us. We not only have to look after patients with COVID-19 but additionally have to provide ongoing care to our existing patients, quite a significant proportion of them have challenging health care needs. We know the urological management in a neurogenic patient needs to be tailored to the individual circumstances, this is even more pertinent during these uncertain times.

International Continence Society (ICS) is the premier international organization in functional urology. Lately, it has established an Institute to facilitate teaching and training opportunities all over the world. The ICS Institute brings together experts from around the globe. The directors of the institute feel at this time of international crisis to utilize ICS platform to share the challenges we are all facing in managing our patients. We feel in the current environment that our colleagues need support with some recommendations that can not only help to keep our patients safe but also alleviate apprehensions in both health care givers and patients which we are still looking after our neurogenic patients in the current climate in the best way possible, in addition to, playing our part in supporting the wider efforts to control the crises facing us.

The School of Neurourology teamed with the School of Modern Technology and set up a Webinar—"How to manage the neuro-urological patients in the current pandemic." This was set up as a case-based discussion to deliberate the management of our patients in the present climate and examine the role of modern technology in overcoming the current barriers.

2 | COMMENTS AND QUESTIONS FROM DELEGATES IN WEBINAR AND OUR COMMENTS

Institute Directors Rizwan Hamid (School of Neurourology) and Emre Huri (School of Modern Technology) conducted a live case-based discussion on Friday, 24th April 2020. The experts discussed the challenges in current management of neurogenic bladder with a case of multiple sclerosis as a reference. The main aim was how to use modern technology, alternative management strategies, and how functional urologists and neuro-urologists can manage their patients in the current pandemic with COVID-19.

The webinar was very well attended, and there were 25 comments from the participants. As one would expect, the comments reflected the varying practice from different parts of the world. However, there was a common theme that all physicians have stopped elective surgery and face to face consultations for neurogenic patients. There appeared to be an increasing use of modern technology with telemedicine and apps to communicate with patients. There was some concern with regard to the patients with high pressure bladders, it was felt that without adequate follow-up and not performing botulinum toxin A (BTX-A) injections, the upper tracts may be at risk. It was also suggested to carry out local anesthesia procedures with adequate personal protection to ensure the patients at risk continue to receive the treatment they require.

3 | EVALUATION OF GUIDELINES FOR MANAGEMENT OF NEUROUROLOGY PATIENTS

There has been a variety of recommendations and guidelines from various international organizations during this pandemic. This includes European Association of Urology,¹ ICS,² British Association of Urological Surgeons,³ and National Institute for Health and Care Excellence.⁴ All organizations acknowledge that most of these are recommendations based on expert opinion and need to be tailored to local health care systems and needs.

In addition, it must be emphasized that different countries are at different points of the pandemic. All have unique set of challenges that need to be taken into account whilst adjusting services in these uncertain times.

Accepting these limitations, most of the organizations have proposed the following recommendations in the management of a neurourological patient.

1. All planned surgical procedures for neurourological indications should be postponed (except as listed below).
2. All face to face out-patients appointments should be cancelled.
3. Encourage clinicians to undertake telephone and video consultations where possible. This will not only help alleviate patients concerns that they have not been forgotten but can also identify those patients in need for urgent consultations.
4. The patients already admitted to rehabilitation units and neurology wards would have ongoing neuro-urological issues. These patients need to be provided with urological input but adequate personal protection equipment should be worn as per local protocols to minimize the risks to health care professionals.
5. No elective surgical procedures should be undertaken (except as below).
6. All urodynamic studies should be postponed both on in-patients and out-patients.

3.1 | Emergencies

These would continue to be managed as per existing protocols. The specific indications for our patients would be: problems with catheter blockage, urosepsis requiring hospitalization, and patient is going into renal failure

3.2 | Modern technology

We feel modern technology and telemedicine have acquired a central role at this time. Many of our neuro-urological patients are young and "tech savvy" and with recent modifications can use smart phones.

4 | NEUROUROLOGY PATIENTS CHALLENGES IN COVID-19 OUTBREAK

Patients with neurogenic bladder dysfunction are challenging because of their potential susceptibility to COVID-19 infection. All scheduled elective surgeries and

office visits were cancelled by many national health authorities.⁵ As patients cannot be diagnosed with urodynamic evaluation or treated with invasive therapies like BTX-A, we have to devise alternative ways to keep patients safe and provide reassurance. During this unprecedented period, when there can be problems with patient safety due to the recommendation for deferring even minimally invasive surgery. The possible overlap of COVID-19 clinical syndrome with different conditions, such as urosepsis in neurourology patients, should be recognized and merits appropriate investigation. Regular follow-up with telemedicine or phone calls for preservation of continent status, avoidance of urinary tract infection, upper urinary tract safety, preservation of quality of life, and evaluation of economic and social circumstances should be considered. In high risk patients with maximum detrusor pressure greater than 40 cm H₂O, low bladder compliance, risk of autonomic dysreflexia, recurrent urinary tract infections, and recent changes in the upper urinary tract, it is probably advisable to undertake intradetrusor BTX-A injections under local anesthesia where possible.⁶ Though, this would be dependent on local protocols and the changing situation in the country.

5 | TECHNOLOGY-BASED TOOLS IN PANDEMIC: TELEMEDICINE, 3D PRINTING TECHNOLOGY, AI-BASED APPLICATIONS AND DIGITAL HEALTH

The use of modern technology by health care professionals is not only dependent on the availability of the technological services in a country but also related to cultural, economical, and social values. This results in varied utilization of technology from country to country during COVID-19 outbreak. However, a number of neurourology patients are young and tech savvy and keen to use various platforms to get more information regarding diagnosis and treatment of their condition. The health care professional should encourage the neurological patients to use technology to identify the urological problems and discuss with health care givers to formulate appropriate management strategies during this COVID-19 epidemic.

Telemedicine is the main technology-based tool to keep neurourological patients out of hospital environment. It is bridging the gap between people, physicians, and health systems, enabling everyone, especially symptomatic patients, to stay at home and communicate with physicians through virtual ways, helping to decrease the spread of the virus to populations and the medical staff

on the frontlines. For patients on medication, to continue the prescriptions, official software approved by local regulators will be helpful to the patients that need topping up of long-term medication.

Telemedicine use has increased 10-fold after the outbreak. However, it should be kept in mind that this enhanced usage of telemedicine for patient communication raises a number of medicolegal issues, concerns about informed consent, adherence to data protection and security law, and the technical support to run these systems. Some of these can be minimized by use of self-control system like Chatbot. This can help the patients in getting information about one's own situation by inputting the required data and following the computer-generated advice. The simplest telemedicine application is phone call or videoconference. It is recommended to use a licensed product and that would not only be reliable but would also have adequate safeguards for data protection. The appointments can be scheduled as routine but in place of face to face the patient would have a telephone consultation. In addition the physiotherapy and teaching session like self catheterization can be taught and monitored over video consultations.

We need to advise the patients for using artificial intelligence-based smartphone applications for prevention and follow-up for COVID-19. Giving instruction to the relatives of patients is the most important issue that we should take into account. On the other hand, 3D medical printing for production mask and shield, or small useful medical apparatus, is another technology-based solution for health care professionals.

COVID-19 can negatively effect to mental health of the population as people are forced to stay indoors for many days. In these trying times, digital health apps are providing help. On the other hand, with over 3 billion social media users worldwide, social media has a good tool outreach across all age groups.⁷

6 | SUMMARY

The aim is to keep our neurourological patients out of the hospital environment as much as possible. A significant proportion would be considered a high risk group in the current circumstances. However, we need to reassure them, probably with virtual clinics, that their urgent issues (as mentioned above) need to be dealt with in the most safe and effective manner. It would be imperative to follow the local protocols and guidelines in the ever changing fight against this pandemic so the management can be tailored to the individual needs in the context of local available resources. Telemedicine provides face to face communication better than phone calls providing

the evaluation of patient environment, patient physical status, and is also helpful for solving catheterization problems. Virtual channels, including contact tracing systems, wearables, and AI-based applications, should be used by patients to increase the awareness of COVID-19 risks.

7 | FUTURE DIRECTIONS

There is a lot of evidence^{8,9} that the patients and health care physicians feel quite comfortable with the use of telemedicine, AI-based apps, and modern technology to deliver at least some aspects of health care. This is even more relevant for our neurourology patients who want to keep in touch with health care providers and want reassurance that they are safe but quite often do not want to make the long journey to the hospital with their complex needs.

It is envisaged that there will be a significant use of modern technology to communicate with neurourology patients even after the COVID-19 pandemic is over. Telemedicine will be used to evaluate the patients and carry out follow-up consultations. This can keep the most vulnerable patients out of the hospital and help to fast track patients that need to be seen for necessary investigations and offered appropriate treatment.

We wish the best to all our colleagues and patients.

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SOUNDING BOARD



Assessment of patients with lower urinary tract symptoms where an undiagnosed neurological disease is suspected: A report from an International Continence Society consensus working group

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Abstract

Aim: Lower urinary tract symptoms (LUTS) are a common urological referral, which sometimes can have a neurological basis in a patient with no formally diagnosed neurological disease ("occult neurology"). Early identification and

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specialist input is needed to avoid bad LUTS outcomes, and to initiate suitable neurological management.

Methods: The International Continence Society established a neurological working group to consider: Which neurological conditions may include LUTS as an early feature? What diagnostic evaluations should be undertaken in the LUTS clinic? A shortlist of conditions was drawn up by expert consensus and discussed at the annual congress of the International Neurourology Society. A multidisciplinary working group then generated recommendations for identifying clinical features and management.

Results: The relevant conditions are multiple sclerosis, multiple system atrophy, normal pressure hydrocephalus, early dementia, Parkinsonian syndromes (including early Parkinson's Disease and Multiple System Atrophy) and spinal cord disorders (including spina bifida occulta with tethered cord, and spinal stenosis). In LUTS clinics, the need is to identify additional atypical features; new onset severe LUTS (excluding infection), unusual aspects (eg, enuresis without chronic retention) or "suspicious" symptoms (eg, numbness, weakness, speech disturbance, gait disturbance, memory loss/cognitive impairment, and autonomic symptoms). Where occult neurology is suspected, healthcare professionals need to undertake early appropriate referral; central nervous system imaging booked from LUTS clinic is not recommended.

Conclusions: Occult neurology is an uncommon underlying cause of LUTS, but it is essential to intervene promptly if suspected, and to establish suitable management pathways.

KEYWORDS

incontinence, lower urinary tract symptoms, neurology, neurourology, overactive bladder, overactive bladder

1 | INTRODUCTION

Lower urinary tract symptoms (LUTS) are highly prevalent and a major cause of urological referral. The majority reflect uncomplicated presentations, such as overactive bladder (OAB) or benign prostate enlargement. LUTS are also a significant feature in neurological disease.¹ Notably, there are some neurological conditions where LUTS can be an early symptom in the presentation of the disease. Consequently, a situation can arise where LUTS assessment might be requested and the underlying neurological disease is still undiagnosed. Two major dangers inherent in failing to identify an undiagnosed neurological etiology are risks of deterioration of the neurological conditions, and of poor outcomes for LUTS treatment, potentially due to inappropriate surgery or symptom deterioration. Suitable neurological management for the underlying condition is needed

- to establish a correct diagnosis and prognosis,

- to actively manage the neurological condition by obtaining early specialist input,
- to minimize disease progression through early treatment (especially for multiple sclerosis [MS]),
- to avoid predictable adverse events during invasive diagnostics and after surgical therapy,
- for the maintenance of a patient-centered approach to management, and
- for patients to adapt their life according to prognosis.

Healthcare professionals (HCPs) from various disciplines, notably doctors, nurses, continence advisors, and physiotherapists, may be responsible for initial assessment of these patients. Accordingly, these HCPs need to remain alert to patients with subtle symptoms and clinical signs that should be further explored and who might need an additional referral to exclude or identify an, as yet, undiagnosed neurological condition. For this to be effective, they must be aware of potential pathways

of evaluation, to ensure the possibility is appropriately addressed.

This consensus considers situations where LUTS could be a presenting complaint preceding the identification of an underlying neurological disease,² hereafter referred to as “occult neurology.” This consensus document gives brief outlines of neurological conditions in which LUTS arise relatively early in the disease course, and presents an approach to assessment of a patient where the receiving clinician suspects there could be an undiagnosed neurological condition.

2 | METHODS

The International Continence Society (ICS) established a working group whose remit was to consider:

1. Which neurological conditions may include LUTS as an early feature?
2. What diagnostic evaluations should be undertaken in the LUTS clinic, and which should be left to specialist expertise?

The qualitative method of nominal group technique was utilized to generate initial content (key relevant conditions) in response to the remit. An iterative group dialogue for a panel of neurological and neurosurgical specialists was used to draw up a shortlist of conditions, with two rounds of blind voting to finalize the list. The list was then presented for open discussion at the annual congress of the International Neurourology Society, Istanbul, 2020. The ICS then established a multidisciplinary working group to generate recommendations for identifying clinical features and management, which worked remotely due to the widely dispersed international representation.

3 | RESULTS

3.1 | Neurological conditions where LUTS can be an early feature

The following conditions may present for LUTS assessment before a neurological condition has been recognized, because LUTS are potentially an early feature in the disease course. The underlying processes commonly involve demyelination, neurodegeneration, or developmental abnormality, for which some archetypal conditions are listed in Table 1. The main conditions responsible include the following.

3.1.1 | MS and related neuroinflammatory disorders

The most common progressive neurological disease affecting younger people with onset around 20 to 40 years of age. It is more common in women than men. It can impair function of any part of the central nervous system by demyelination and axonal loss (Table 1). It is a progressive condition, but the rate and pattern of progression varies (the progressive clinical course usually becoming evident after 10-20 years after diagnosis). Commonly, there is abrupt deterioration (relapse) lasting days to weeks as a new demyelination event starts, followed by (often incomplete) improvement. Neurological symptoms are typically monocular loss of vision, double vision, sensory loss, weakness, and ataxia. A variety of disease-modifying medications are available. The exact pattern of LUTS is diverse, while severe incontinence is mainly seen in the late stages of the disease.

Transverse myelitis due to other inflammatory causes can occasionally present as urinary retention with few neurological signs because of predilection for conus involvement, particularly when associated with antibodies against Myelin oligodendrocyte glycoprotein (MOG antibody transverse myelitis); persisting urogenital and bowel dysfunction is common despite motor recovery at followup.¹⁵

3.1.2 | Multiple system atrophy

A progressive sporadic adult-onset neurodegenerative disorder (Table 1). Prevalence is 8 per 100 000 among people older than 40 years of age. It affects men and women equally and has an average age onset of approximately 55 to 60 years. The mean life expectancy is 6 to 10 years following diagnosis. Clinical symptoms are subdivided into extrapyramidal, pyramidal, cerebellar, and autonomic symptoms (notably postural hypotension). Extrapyramidal symptoms include bradykinesia, rigidity, and postural instability, resembling Parkinson's disease (PD). Nonmotor symptoms, such as sleep and cognitive disorders, respiratory problems, and emotional/behavioral symptoms, might also occur during disease development. The different symptoms can be used to categorize multiple system atrophy (MSA) into the Parkinsonian subtype (MSA-P) and the cerebellar subtype (MSA-C). MSA-P predominates in Western countries, while MSA-C is more common in Japan. The condition may initially present with bladder dysfunction, particularly urinary retention.^{16,17} For men, erectile dysfunction (ED)¹⁸ is commonly an earlier feature than LUTS; the

TABLE 1 Archetypal neurological conditions, which may include lower urinary tract symptoms as an early feature

Classification (mechanism)	Archetypal condition	Early urological features	Early neurological features	Epidemiology	Similar conditions
Demyelinating disorder	Multiple sclerosis	Urinary urgency (62%-65%), frequency (50%), UUI (45%), nocturia (33%), ^{3,4} SUI 31%, ED 53%. UDS; DO with DSD, detrusor underactivity.	May report unilateral painful loss of vision, paraesthesias or motor deficit ⁶	Peak onset: 30-40 y. Rare before puberty and in the elderly. Estimated incidence (Europe) <20 - >200/100 000 ⁷	Transverse myelitis. Neuromyelitis optica
Focal CNS white matter demyelination		Fecal incontinence and/or constipation (40%) ⁵		Median time to death 30 y from onset depending on subtype ⁶	
Neurodegenerative disorder	Multiple system atrophy	Difficulty voiding/nocturia are most common, also urgency and UUI ⁸ ED is an early feature	Postural hypotension and incoordination are common presenting symptoms. Slow movement, slurred speech, poor balance, and fainting (syncope) also commonly occur	Mean age of onset is 54 y, with survival 7-9 y. UK prevalence 4.4/100 000 ⁹	Alzheimer's dementia. Parkinson's disease. Progressive supranuclear palsy
Extrapyramidal, autonomic, and cerebellar progressive degeneration		In cerebellar MSA, 83% have ED at diagnosis, 58% have urinary incontinence and 50% have OAB		Slight male preponderance	
Developmental disorder	Occult spinal dysraphism, including SBO and tethered cord	Variable features. SBO, OAB, ¹⁰ incontinence, enuresis. With tethered cord, urgency and UUI are common. UDS; DO 42%, low compliance 67%. ¹¹ DSD and sensory abnormalities can occur ¹²	SBO often asymptomatic. Dimple/hair tuft on the back. Maybe posture changes, with altered spinal curvature. Tethered cord can include impaired lower limb or bowel function ¹³	Congenital, reducing prevalence. ¹⁴ Unlikely to influence survival	Syringomyelia (developmental or acquired)

Abbreviations: CNS, central nervous system; DO, detrusor overactivity; DSD, detrusor sphincter dyssynergia; ED, erectile dysfunction; MSA, multiple system atrophy; NPH, normal pressure hydrocephalus; OAB, overactive bladder; SBO, spina bifida occulta; SUI, stress urinary incontinence; UDS, Urodynamics; UUI, urgency urinary incontinence.

reviewing HCP considering this possibility needs to enquire about ED, since men commonly do not report the symptom unless the topic is raised.

3.1.3 | Parkinson's disease

A neurodegenerative condition with the key motor symptoms of tremor, rigidity, and bradykinesia affecting motor control, which is also associated with prominent nonmotor symptoms. Early PD can cause storage LUTS, and motor symptoms may be mild. A useful feature to look out for is a unilateral low frequency pill-rolling tremor affecting the upper limb (or leg). Established PD manifests obvious motor features (shaking, rigidity, slowness of movement, and difficulty with walking); once it has reached this stage, PD will generally have been diagnosed.

PD patients usually report nocturia, urgency, and difficulty voiding and present with detrusor overactivity (DO) on urodynamics.^{19,20} Voiding dysfunction increases with neurological disability (for men and women), correlating with the extent of dopamine depletion.^{21,22} In some male patients, benign prostatic obstruction can occur concomitantly with PD, and therefore selection of patient for possible prostate surgery should be done with great care to avoid possible urinary incontinence.

3.1.4 | Normal pressure hydrocephalus

Normal pressure hydrocephalus (NPH) is characterized by communicating enlargement of cerebrospinal fluid (CSF) ventricles, with normal intraventricular pressures. The enlargement is associated with stretching of periventricular fibers of the corticospinal tract in the brain, which impairs bladder control. DO is a typical finding on urodynamics. As it is substantially underdiagnosed, the actual worldwide incidence and prevalence have not been defined; in Japan it was estimated at around 1% of older adults (over 65).²³ The classic triad is abnormal broad-based shuffling gait, urinary incontinence and dementia (short term memory impairment), but about half present with gait abnormality only as the initial feature. There may be only mild cognitive impairment at the time the patient starts to experience urinary symptoms. Treatment is with placement of a ventriculoperitoneal shunt by a neurosurgeon and can lead to symptom resolution/prevention of progression.

3.1.5 | Dementia

A group of neurodegenerative conditions (including Alzheimer's disease, vascular dementia, dementia with

Lewy bodies and frontotemporal dementia), with wide-ranging effects on memory, cognition, and personality. LUTS are more common in people living with dementia than those without dementia.²⁴ In certain forms of dementia, such as dementia with Lewy bodies, LUTS are more likely to be an early feature of the disease. LUTS tend to be a later feature in Alzheimer's disease.²⁵

3.1.6 | Spinal cord conditions

A range of situations may affect the spinal cord directly (Table 1), while degenerative spine conditions may affect the spinal cord secondarily, for example, by causing lumbar spinal stenosis or cervical myelopathy. There may be little in the way of localizing symptoms. The archetypal condition is spina bifida occulta (SBO) and tethered cord, in which a developmental abnormality fixes the lower part of the spinal cord, placing it at risk by stretching and distortion as the person grows. Affected patients are often asymptomatic until late childhood or adulthood, then presenting with back pain and LUTS. Syringomyelia is a problem with the central CSF canal in the spinal cord, which can lead to compression of the surrounding spinal cord tracts; this can occur in SBO.

Other conditions include:

- a tumor of the spinal cord or vertebral column and
- spinal stenosis, leading to claudication and LUTS.

Prolapsed intervertebral disc (lumbar disc prolapse) is usually easily diagnosed from the association of urinary retention (painless) with severe back pain, nerve root pain (eg, sciatica), loss of range of movement, and bowel dysfunction. However, back pain is sometimes not prominent, notably where there is central disc prolapse with little impingement on the spinal roots.

3.2 | Evaluation where there is a possible occult neurological mechanism

For the HCP, the fundamental issue is to identify a situation where LUTS are present alongside other unexplained symptoms, which are atypical for a LUTS presentation. This must then trigger an onward referral to an appropriate specialist (neurology or neurosurgery), or an alert to the patient's primary care physician. HCPs in the LUTS clinic are not required to make the neurological diagnosis, but they must remain vigilant to the possibility of a neurological disorder and seek relevant expertise (neurological consultation) where needed.

Situations in which HCPs should suspect possible occult neurology:

- New onset severe LUTS not caused by urinary tract infection.
- Association with unusual features not typically seen in LUTS presentations.
- Presence of other “suspicious” symptoms, such as altered speech, vision, or balance.

3.2.1 | History and examination

All consultations on LUTS involve a basic assessment undertaken according to the relevant guidelines.^{18,26,27} The details of basic LUTS assessment are not given in detail here, but guidelines include assessment of:

- Evaluation of the severity and bother associated with each LUTS.
- Consideration of possible pathophysiology and differential diagnosis.

- Exclusion of features, which are possible indicators of serious underlying mechanism, for example, infection/inflammation, or malignancy.
- Concomitant bowel or sexual dysfunction.

Any neurological feature might, but not necessarily, have a similar time course to the LUTS. If the initial impression suggests there could be an occult neurological problem, the practitioner should evaluate key indicators that may increase the index of suspicion. A summary is presented in Figure 1. This assessment includes looking for:

1. Urological symptoms or findings
 - (a) Severe/rapid onset OAB maybe with urgency incontinence.
 - (b) Difficulty initiating voiding and prolonged duration. Flow rate test may suggest straining, and there may be a post void residual.
 - (c) Changes in bladder sensation, including reduced or absent bladder sensations.
 - (d) Dysuria in the absence of urinary tract infection (this may indicate detrusor sphincter dyssynergia).

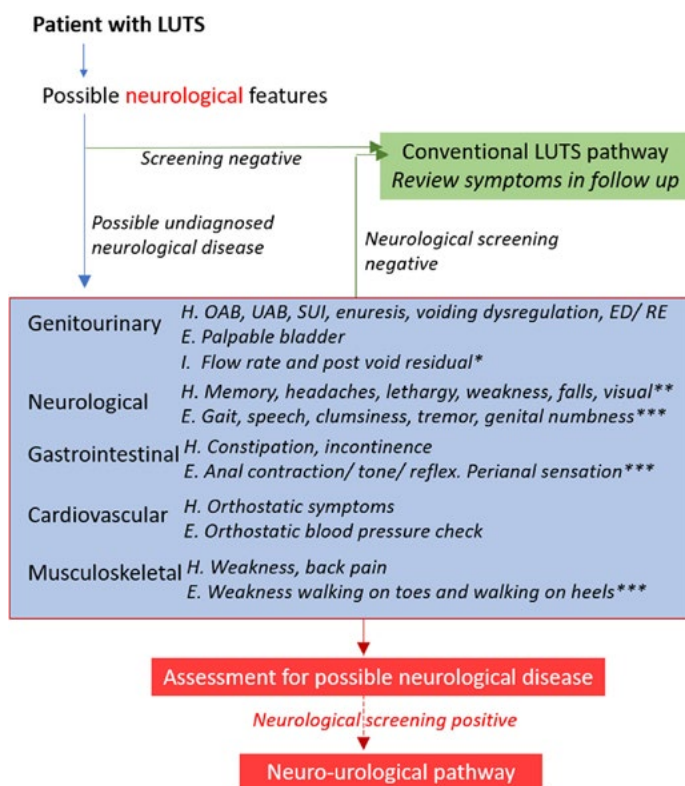


FIGURE 1 Summary of key clinical evaluations in LUTS clinic in the event of a possible undiagnosed neurological disease. E, examination; ED, erectile dysfunction; H, history; I, investigation; LUTS, Lower urinary tract symptoms; RE, retrograde ejaculation. *Flow rate test may suggest straining/post void residual. **Double vision/loss of acuity. Multiple sclerosis can cause transient unilateral loss of vision some years previously. ***Nerve supply is from the sacral spinal cord, and is a consequence of weak plantar flexion and dorsiflexion

2. Unusual urological symptoms or examination findings
 - (a) Enuresis.
 - (b) Voiding dysregulation, that is, urination in situations, which are generally regarded as socially inappropriate, such as while still fully dressed, or in a public setting away from toilet facilities.²⁸
 - (c) Involuntary voiding, that is, sporadic bladder emptying when awake, without intention to void.²⁸
3. Indicators of lower urinary tract muscle weakness
 - (a) Abdominal straining for voiding.
 - (b) Stress urinary incontinence (and possibly fecal incontinence), particularly in nulliparous women and younger men with no previous lower urinary tract surgery.
 - (c) Retrograde ejaculation.
4. Symptoms or findings in other organ systems, which are heavily dependent on neurological control or likely to be affected by a relevant condition
 - (a) Gastrointestinal, for example gastroparesis, constipation, reduced anal tone.
 - (b) Cardiovascular for example orthostatic hypotension.
 - (c) Musculoskeletal.
 - (d) Autonomic, for example loss of salivation, loss of sweating, and impaired thermoregulation. In PD and MSA there may be drooling (sialorrhoea).
5. Features of one of the neurological conditions listed above
 - (a) MS; motor or sensory deficit, transient unilateral visual disturbance (previous optic neuritis).
 - (b) MSA; ED, orthostatic hypotension, unilateral tremor, slow movement, postural instability.
 - (c) PD; Stooped posture, lack of facial expression, quiet and hoarse speech, slowness of movement especially visible during walking, and shaking (tremor)—more often seen unilaterally in the hand while walking or at rest and classically “pill-rolling” in nature.
 - (d) NPH; gait disturbance, urinary incontinence, cognitive impairment.
 - (e) Dementia; memory and personality changes.
 - (f) Spinal cord problem; limb weakness, sensory changes, back pain.

Observation of or assessment for gait, tremor, speech, and clumsiness can easily be made in clinic. It is worth noting any history of essential tremor, as this might be confused with a parkinsonian tremor, but does not need neurology referral. Essential tremor typically presents with bilateral postural hand tremor and can also affect the head and voice, has a family history, and improves with beta blockers or alcohol.

3.3 | Additional assessment for possible neurological disease

In the event that history and examination are consistent with the possibility of occult neurological disease, the responsible practitioner needs to consider the following.

1. Steps to confirm or exclude the neurological diagnosis:
 - (a) The HCP treating LUTS should refer for a formal specialist opinion. Direct referral is preferable, for reliable and prompt assessment.
 - (b) The consensus panel does not recommend the use of MRI scanning or other imaging modality from the LUTS clinic. This is best arranged from the neurology clinic, in consultation between the neurology and neuroradiology services, because it is crucial that the correct part of the neuraxis is scanned and the appropriate settings are used.
 - (c) The referral should be made immediately, without waiting for the results of urodynamic testing (due to the potential delay). If urodynamics have already been done, the results can be included in the referral. Subsequent urodynamic tests can be forwarded when available.
 - (d) Neurological consultation and investigation following referral may not necessarily attain a confirmatory diagnosis; urological follow up is nonetheless appropriate, and re-referral to neurology may be needed in the event of subsequent change in symptoms or apparent deterioration.
2. Adaptations of the urological assessment pathway:
 - (a) The role of urodynamic testing should be re-evaluated; if not already done, they may be delayed pending receipt of the neurological evaluation, to decide how the test should be run. In this situation, it is appropriate that the test is directly overseen by the urologist.
 - (b) Definitive LUTS management should be delayed until the result of neurological assessment is available. If the neurological finding is positive, the patient should be moved to a neuro-urological care pathway for example.^{1,29} If negative, standard LUTS pathways can be followed, but this should be reconsidered if new symptoms subsequently emerge.

3.4 | Additional considerations

In several situations, factors affecting lower urinary tract function may be suggested by features in the medical history or physical examination:

1. Functional neurological disorder (FND)³⁰ is suggested by symptoms such as limb weakness and nonepileptic attacks, particularly in women with chronic idiopathic urinary retention. FNDs may be accompanied by psychological comorbidities such as affective disorders (eg, depression and anxiety) and other functional syndromes, such as fibromyalgia or irritable bowel syndrome. Screening tools are available for evaluating psychological/psychiatric morbidities in adults.³⁰
2. Centrally active medications may cause urinary retention (eg, opioids, antipsychotics, antidepressant agents, anticholinergic respiratory agents, alpha-adrenoceptor agonists and benzodiazepines³¹) or enuresis (eg, choline esterase inhibitors (such as rivastigmine or, donepezil) and antipsychotics³²).
3. Scrutiny of medical history and current medication, to consider conditions that may already be diagnosed in the patient, but whose implication for LUTS has not been recognized. Potentially relevant conditions include (list not complete):
 - (a) Previous pelvic or retroperitoneal surgery (in case of damage to peripheral lower urinary tract nerves). This may make the patient reliant on abdominal straining for bladder emptying.
 - (b) Delayed second stage of labor (pudendal nerve damage).
 - (c) Previous traumatic brain injury.
 - (d) Previous spine hyperextension without fracture.
 - (e) Neuropathies for example vitamin B₁₂ deficiency, diabetic neuropathy (but not uncomplicated diabetes mellitus), systemic lupus erythematosus, Sjogren's syndrome, amyloid, myasthenia gravis, or Guillain Barre syndrome. Severe peripheral neuropathies can cause gait disturbance with sensory ataxia.
 - (f) Herpes zoster infection of sacral dermatomes with shingles (this is very rare).
 - (g) Active genital herpes affecting sacral levels.

If any of these is identified, they should be considered in case they represent a contributory factor underlying LUTS. If they appear to be causative:

- The possibility of occult neurological disease is reduced, and the priority of neurological assessment should be reviewed accordingly.
- The urological assessment should be designed to reflect the complexity of the LUTS mechanisms.

4 | CONCLUSIONS

There is a large catalog of neurological diseases, but relatively few affect urinary tract function early in their

course. MS, MSA, PD, NPH, some types of dementia or specific spinal cord pathologies are particularly relevant. Thus, an HCP seeing a patient with LUTS should remain alert to features indicating the possibility of an underlying neurological condition. If suspected, specialist input should be sought before requesting diagnostic imaging, and the LUTS management pathway should be adapted.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Consensus statement on bladder training and bowel training

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Abstract

Aim: This consensus statement synthesizes evidence to guide healthcare professionals on promoting consistent, cohesive and achievable bladder training for people with overactive bladder/urgency urinary incontinence and bowel training for those with urgency fecal incontinence.

Methods: The Consensus Statement on Bladder and Bowel Training was developed by a sub-group of the International Continence Society Nursing Committee and an expert panel, who formed a virtual Consultation Group. Review of published research, expert opinion articles, policy statements, and voluntary professional group information identified existing recommendations, from which statements were formulated and organized. A modified Delphi process was used to reach consensus on each statement, involving three rounds of virtual consultation. Consultation Group members indicated agreement/disagreement with each statement. Statements, or changes, were accepted when consensus was reached, defined as agreement by 80% of the Consultation Group.

Results: No universal definition of bladder training or bowel training was found, therefore a consensus definition was developed and agreed for each. Limited high quality studies of bladder training were identified and no studies investigating the use or effectiveness of bowel training for urgency fecal incontinence in adults. Broad-ranging evidence suggests both types of training should include four elements, personalized to individual need and situation: information and education; a prescribed voiding/evacuation regimen based on individually identified patterns of bladder or bowel functioning; progression of voiding/evacuation regimen; ongoing support and reinforcement.

Conclusions: These consensus statements will support healthcare practitioners to design and deliver consistent bladder and bowel training. Improved evidence on mechanisms and effectiveness is needed to inform practice.

KEYWORDS

behavior therapy, bladder training, bowel dysfunction, bowel training, urinary incontinence

1 | INTRODUCTION

Clinical guidelines across the world recognize bladder training¹⁻⁴ as a first line intervention for lower urinary tract symptoms, including urgency urinary incontinence and bowel training as a first line intervention for urgency fecal incontinence in adults.^{5,6} Healthcare practitioners involved in promoting continence and managing bladder/bowel dysfunction recommend these interventions regularly in practice. Bladder and bowel training are considered to be safe forms of therapy^{1,3,7,8} and may be implemented in a variety of care settings including community-based clinics, home care, and rehabilitation and aging care institutions based on patient ability and motivation and symptom-reports, without the need for extensive or invasive diagnostic investigations.^{2,3} Evidence for effectiveness of bladder training suggests it may be helpful for treatment of urinary incontinence^{2,3,9} and that overactive bladder symptoms (urinary urgency and commonly frequency, nocturia, urgency incontinence) improve in 57% to 87% and resolve in 12% to 73% of cases.¹⁰ There is currently no robust evidence on the effectiveness of bowel training for urgency fecal incontinence although observational studies have examined effects of individual parts of a bowel training program (ie, diet advice, methylcellulose fiber) on urgency fecal incontinence¹¹ and differences in anorectal manometry and endoanal ultrasound measures in women with urgency versus passive fecal incontinence.¹² In practice, protocols vary considerably¹³ and published reports provide only limited descriptions of the actual intervention content and delivery methods used.^{14,15} Therefore, healthcare practitioners may find it challenging to access information on how to support people with these types of bladder or bowel dysfunction and effectively implement bladder training or bowel training programs.

2 | AIM

This statement synthesizes evidence from a range of sources to offer practical guidance to promote consistent, cohesive and achievable bladder training for people with overactive bladder syndrome/urgency urinary incontinence or bowel training for those with urgency fecal incontinence or defecation urgency.

3 | METHOD OF STATEMENT DEVELOPMENT

The Consensus Statement was developed by a Project Working Group, a sub-group of the ICS Nursing

Committee and a virtual Consultation Group. The ICS Nursing Committee was the overseeing steering group. The five members of the Project Working Group (JB, DB, JO, KH, SE) conducted a narrative review of published research evidence, expert opinion articles, clinical guidelines, policy statements, and information from voluntary professional groups. The information used was gathered from a broad range of sources to identify existing or previous practice recommendations from initiatives at local and national levels, incorporating qualitative as well as quantitative work. Structured searches for relevant research were conducted in PubMed, CINAHL, EMBASE, Cochrane Library, using Cochrane Incontinence Group topic search terms including: urinary incontinence, bladder instability/irritability/hyperreflexia, overactive bladder, behavioral intervention and bladder (re)training. Due to the challenge of identifying studies when a low yield was expected, the search for bowel training was conducted by a biomedical librarian. Search terms included ((anal or anorectal* or bowel* or fecal* or fecal* or rectal* or stool*) adj4 (continen* or incontinen*)).mp., (bowel and (habit* or management or program* or training or re-training)).mp. Given the anticipated low number of returns, there were no date limits applied, but searches were limited to adults and articles published in English. Searches for guidelines included relevant societies such as the European Urological Association, American Urological Association, Wound, Ostomy and Continence Nurses Society, American Society of Colon and Rectal Surgeons, American Gastroenterological Association, NICE Guidance, and the International Continence Society. The most recent International Consultation on Incontinence 6th Edition^{2,5} was consulted. Other sources were identified in gray literature using search engines such as Google, OpenGrey and relevant charity/voluntary organization websites. Documents and materials used in practice by members of the Nursing Committee were also collated.

One member of the Project Working Group (JB) took the role of reading, sifting and formulating the evidence into statements, which the other members of the Project Working Group refined to construct the first version of the consensus statements to be sent to the virtual Consultation Group. The organization of the statements was modeled according to steps of the nursing process^{16,17}: assessment, planning, intervention and evaluation (See Appendixes A and B). A similar process is used as a healthcare approach by other types of healthcare practitioners. The statements are derived from the best available evidence, including expert opinion at the time they were produced, recognizing that levels and types of evidence vary.

The procedure used to reach consensus about each statement was based on the Delphi method and is outlined in the flowchart below (See Figure 1). In brief, 20 nurse members of ICS were recruited by the ICS office staff to serve as the virtual Consultation Group. The Consultation Group submitted curriculum vitae that were reviewed to support their expertise on the topic. The Consultation Group reviewed the statements developed by the Project Working Group and emailed suggested changes to the ICS office staff. Staff removed information identifying the person proposing the change, before forwarding the information to the Project Working Group. The Project Working Group incorporated the suggested changes to the statements into the document that was returned to the Consultation Group by the ICS staff. The Consultation Group emailed their votes for agreeing or disagreeing with statements or changes to the ICS office staff. This procedure was repeated three times. Statements or changes were accepted when consensus was

reached, defined as agreement by 80% of the Consultation Group. For information, a glossary of the standardized ICS definitions used in constructing these consensus statements is provided as a Supporting Information file.

4 | CONSENSUS STATEMENT ON BLADDER TRAINING

4.1 | Definition of bladder training

Bladder training is a broad term, encompassing bladder retraining, bladder discipline, bladder re-education and bladder drill.² There is currently no universally agreed definition of bladder training for adults, although the 2016 International Consultation on Incontinence describes bladder training (Chap 12, p.86) as ‘a program of patient education, along with a scheduled voiding regimen with gradually adjusted voiding intervals. Specific

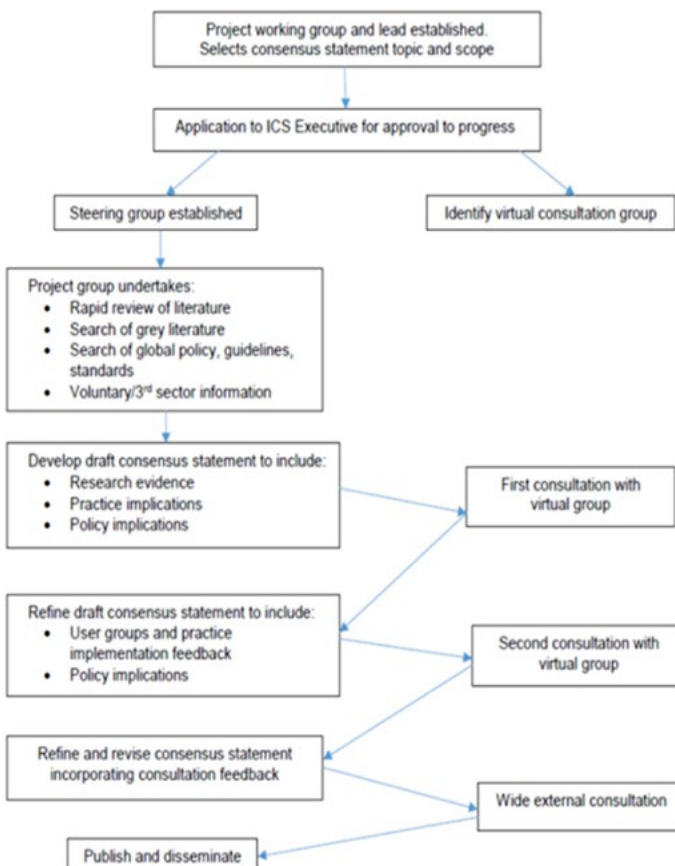


FIGURE 1 Consensus statement development flowchart

goals are to correct faulty habit patterns of frequent urination, improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes and restore patient confidence in controlling bladder function'.² Bladder training is considered to be a form of behavior modification, (defined by the International Continence Society (ICS) as 'the analysis and alteration of the relationship between the patient's symptoms and his or her environment for the treatment of maladaptive voiding patterns, which may be achieved by modification of the behavior and/or environment of the patient'¹⁸). However recent bladder training developments have placed increasing emphasis on the importance of cognitive and psychological aspects that target beliefs and perceptions to impact behavior.¹⁹

Based on the literature reviewed for the purposes of this Consensus Statement the following definition of bladder training was developed:

Bladder training is an intervention that actively supports a motivated person, without significant cognitive or physical impairment, with an overactive bladder or urgency urinary incontinence, to make lifestyle and behavioral changes to regain bladder control through education, progressively increasing voiding intervals, use of urgency suppression techniques and positive reinforcement of effort and success.

5 | HOW BLADDER TRAINING WORKS

The mechanism of action of bladder training is not fully understood.² It arose from the theoretical premise that abnormal voiding habits could be altered by modifying an individual's behavior. The purpose of bladder training is to restore a normal voiding pattern by progressively lengthening the interval between voids. People with bladder dysfunction are taught to void at regular intervals throughout the day and to otherwise suppress the urge to void using strategies such as distraction and relaxation.¹⁴ It is hypothesized that by repeatedly suppressing the urge to void, the person's functional bladder capacity will increase and this, in turn, will lead to a reduction in urinary frequency and the urge to void.^{2,19} Urgency suppression techniques help the person achieve bladder control by diverting their attention away from the urgency sensation using competing mental activities. Relaxation techniques aim to reduce anxiety and feelings of panic. It is hypothesized that deep breathing reduces the intensity of

the urgency sensation and relaxes the detrusor muscle.¹⁹ Together these urge suppression techniques are thought to enable improved cortical bladder control by inhibition of involuntary detrusor contractions; improved urethral closure during bladder filling and control of afferent sensations.

To perform bladder training, patients need to have the mental and physical capacity to (a) identify the urge to void; (b) understand how the bladder functions, (c) rapidly contract their pelvic floor muscles; and/or (d) apply distraction techniques to suppress the urge to void and (e) defer voiding.^{2,14} Thus, education and coaching are key components of the intervention. Additionally, since positive outcomes rely on active client participation, motivation and the cognitive/physical ability to adhere to a progressive schedule are also essential.²⁰

Bladder training differs from scheduled voiding programs, such as timed voiding or prompted voiding in so far as it includes cognitive and psychological components.^{21,22} It is thought that bladder training, through operant learning techniques, improves cortical control over the lower urinary tract.^{23,24} Operant learning is brought about by the positive feedback created by successful urge suppression and longer voiding intervals and conscious recognition by the person of their improved bladder control. However, based on the idea that frequency is a habit that becomes a precursor to urgency and drives it, the role of emotion in the development of urgency is increasingly becoming the target of intervention.²⁵ The roles of other cognitive contributors, including self-monitoring, education/information, positive reinforcement, follow up, as well as health behavioral change theories are recognized, but have yet to be fully explored in light of bladder training theories.

The Consensus Statement on Bladder Training is presented in Table 1, however, the full document, which includes supporting evidence for each statement, as well as suggestions on demonstrating its use in practice, is provided as Appendix A.

6 | CONSENSUS STATEMENT ON BOWEL TRAINING

6.1 | Definition of bowel training

The term bowel training encompasses bowel retraining and bowel re-education, a form of behavior modification designed to restore bowel continence by changing a person's behavior and/or environment.¹⁸ There is currently no universally agreed definition of bowel training so based on the literature reviewed for this Consensus

TABLE 1 Consensus statement on bladder training**Consensus statement on bladder training****Assessment**

- Adults with urinary incontinence or other lower urinary tract dysfunction are assessed by a healthcare practitioner for lifestyle, risk factors and quality of life to ensure the type of bladder dysfunction is identified:
 - a. urinary incontinence (UI) – urgency UI, mixed UI
 - b. overactive bladder (OAB) or other storage lower urinary tract symptoms

and that the person:

- is suitable for bladder training and potentially will benefit.
- has the functional ability to use the toilet either independently or with assistance
- is cognitively able to participate
- is motivated to undertake and adhere to a personalized bladder training program
- has realistic expectations of treatment
- has ability to voluntarily contract pelvic floor muscles

Planning

- The person's goals for bladder training are established with the healthcare practitioner. For example, a reduction in the frequency and severity of symptoms, the ability to sleep at night without going to the toilet, the ability to go out and socialize, reduced carer impact, etc.
- The practitioner develops or structures the person's bladder training program in collaboration with them, taking into account their personal goals and the following factors, before commencing the program:
 - the frequency of voiding and voiding intervals
 - duration of bladder training the person will practice before attempting to increase the voiding interval
 - whether the person prefers a standardized bladder training schedule or one that is individually tailored
 - how long the person will attempt to suppress the urge to void when urgency is experienced (eg, 5, 10, 15 or 30 min, or until urgency subsides)
 - the duration of the full bladder training program in weeks
 - the indicators of improvement and readiness to progress (eg, reduction in number of incontinence episodes, urge reduction, demonstrated commitment to the schedule)
 - the types of urgency suppression techniques the person will use
 - the method the person will use to self-monitor their progress, for example bladder diaries, measured voided volumes

Intervention

- The healthcare practitioner ensures the bladder training program is structured and supervised.
- The bladder training program duration will vary according to the person's progress and goals but should be at least 6 wk.
- Healthcare practitioners should review clients on a regular basis and adjust the mode and frequency of contact according to their professional judgment and the person's goals and preferences. The degree of reinforcement (coaching) patients require will vary.
- Follow-up support to maintain effects of bladder training should be provided, in accordance with the person's goals and preferences.
- The healthcare practitioner provides adults undertaking bladder training with verbal and written information and education on:
 - a. what constitutes a healthy bladder, including its function, anatomy and potential susceptibility to dysfunction
 - b. what happens to the bladder in overactive bladder syndrome/urinary incontinence
 - c. their individual bladder function and patterns, including anticipatory/'just in case' voiding habits and incontinence episodes (based on bladder diary)
 - d. effects of current medication, diet, fluids and caffeine on bladder function
 - e. how to self-monitor symptoms and interpret their bladder diary
 - f. purpose of bladder training
 - g. how bladder training works
 - h. the rise and de-escalation of the sensation of urgency, sometimes known as the 'urge wave'²⁶
 - i. the staged approach to bladder training
 - j. the need for active involvement, commitment and ongoing motivation
 - k. psychological strategies to support success
 - l. realistic expectations about the efforts required and the potential challenges
 - m. expected outcomes

(Continues)

- An initial bladder training program and voiding intervals are agreed and implemented based on the person's baseline voiding diary information and individual goals.
- Bladder training is usually implemented during waking hours only
- Voiding intervals are set in accordance with the person's preference for a standardized bladder drill or individually tailored bladder training schedule:
 - a. If **standardized** a fixed (or pre-determined) voiding schedule of half-hourly or hourly voids is implemented for an agreed time period. Once achieved, this schedule is increased by a pre-determined duration of 5, 10, 15 or 30 min at each progression point.
 - b. If **tailored**, individualised voiding intervals are implemented based on the person's average voiding interval calculated from their voiding diary. Progression time to prolong voiding intervals is negotiated on an individual basis, for example increase by 5, 10, 15, 30 min per week.
- The health care practitioner regularly reviews the bladder training program with the person to determine specific voiding interval progression in line with their goals. Voiding diary data and self-report inform this process.
- New continence skills are developed in the form of personalized urge suppression strategies.
- Urge suppression or deferment involves:
 - a. **relaxation**—the person is instructed to stop, sit down if possible, relax their whole body, in particular their abdomen and focus on slow, controlled breathing.
 - b. **pelvic floor muscle contraction**—the person completes 5-8 fast pelvic floor muscle contractions, without increasing their intra-abdominal pressure.
 - c. **distraction techniques**—mental activities that demand cognitive attention and concentration are used to distract the person from their sensation of urgency and desire to void.
 - d. The individual should decide what will work for them. Examples include counting backwards from 100 in 7's, identifying different girl's names through the alphabet, singing out loud, word searches/crossword puzzles, digital games, reading, making lists.
 - e. Use of **self-affirming statements** such as 'I can control my bladder' and 'I don't have to go now'
 - f. **applying perineal pressure**—sit on a hard surface, rolled towel or stimulate foot sensation using toe curls and heel pressure until the urgency subsides.
- Urgency sensation may subside within 1-2 min.
- When urgency is controlled, and if voiding is permitted according to the bladder training program, the person is encouraged to walk to the toilet at a normal pace.
- The healthcare practitioner positively reinforces the person's bladder control skills and improved and/or prolonged bladder control.
- Individuals are actively encouraged and supported to:
 - a. self-monitor their:
 - relaxation capability and capacity to control their response to urgency and fear of incontinence episodes
 - duration of urge suppression
 - intensity of urgency sensations
 - number of incontinence episodes
 - reduction in negative voiding habits such as 'just in case' or anticipatory voiding
 - progress toward achieving a normal bladder pattern
 - b. self-determine their:
 - progression time, for example increasing urge suppression/voiding delay time
 - decisions about when to increase their urge suppression/voiding delay time.
 - c. self-affirm their:
 - Use of personally meaningful self-coping statements such as 'I don't have to go now; I can wait'; 'I am in control of my bladder'

Evaluation

- Regular contact between the person and the healthcare practitioner is made during the bladder training program to review progress, assess adherence, provide positive reinforcement and adjust voiding program/intervals.
- At the end of the bladder training program a range of person-focused outcomes are assessed. These may include:
 - perceptions of bladder condition and improvement
 - influence of bladder on daily activities
 - satisfaction with bladder training
 - tolerability of bladder training and adherence
 - frequency and severity of urgency and incontinence episodes
 - improvements in lower urinary tract symptoms
 - voiding interval changes
 - lifestyle changes
 - changes in quality of life
 - change in body-worn absorbent product use

TABLE 2 Consensus statement on bowel training**Consensus statement on bowel training****Assessment**

- Healthcare practitioners conduct an assessment of the person's bowel symptoms to ensure the cause and type of bowel dysfunction is identified before recommending a bowel training program
- Current lifestyle and risk factors for bowel dysfunction (eg, aggravating foods, medication side effects) are assessed.
- Underlying physiological abnormalities are excluded before recommending a bowel training program
- The person's suitability to undertake bowel training is assessed including:
 - potential for benefit
 - functional ability to use the toilet/toilet aid
 - cognitive capacity
 - motivation to undertake and adhere to a personalized bowel training program
 - expectations of treatment
 - ability to voluntarily contract pelvic floor muscles

Planning

- The person's goals for bowel training are established with the healthcare practitioner, for example: a reduction in the frequency and severity of symptoms, the ability to go out and socialize, reduced carer burden such as laundering soiled clothing and linens, increased socialization and travel, decreased cost of absorbent products, etc.
- The practitioner develops or structures the person's bowel training program in collaboration with them, taking into account the following factors before commencing the program:
 - frequency of defaecation
 - duration of the full bowel training program in weeks/months
 - indicators of improvement
 - types of urgency suppression techniques the person will use (where appropriate)
 - methods to normalize and regulate stool consistency
 - method the person will use to self-monitor their progress, for example bowel diaries
 - lifestyle changes

Intervention

- The healthcare practitioner ensures the bowel training program is structured and supervised. The program duration will vary according to the person's progress and goals.
- The healthcare practitioner provides adults undertaking bowel training with verbal and written information and education on:
 - normal bowel function
 - how fecal incontinence occurs
 - factors affecting bowel functioning including diet and dietary fiber, fluids, smoking, exercise, psychological/emotional status and environment
 - medication and laxatives
 - purpose of bowel training and how it works
 - the need for active involvement, commitment and ongoing motivation by the person
 - psychological strategies to support success
 - use of containment products during bowel training
 - realistic expectations about the efforts required and the potential challenges
 - expected outcomes
- The person's bowel diary (minimum 5-7 d) is interpreted jointly by the person and the healthcare practitioner to identify individual bowel function and patterns and align with agreed goals.
- The healthcare practitioner offers the person a bowel training program that includes information about:
 - optimal time of day for defaecation
 - frequency of defaecation attempts, for example, daily, alternate days, three times per week
 - optimal type and amount of food intake
 - optimal type and amount of fluid intake
 - individual advice on smoking cessation
 - use of drugs, dietary fiber, or rectal irrigation for fecal incontinence; antidiarrheal drugs or stool bulking agents may be used to establish and maintain a normal stool consistency and frequency; laxatives, suppositories, enemas or transanal irrigation may be used to completely empty the rectum to avoid leakage

(Continues)

- An external anal sphincter (EAS) and pelvic floor muscle exercise program, tailored to the lifestyle and needs of the person is agreed with the healthcare practitioner. This will include specific exercises aimed at improving strength, speed and endurance of the external anal sphincter and pelvic floor muscle contraction and relaxation.
- Concerns/anxieties affecting the person's psychological/emotional state are actively screened for and managed.
- The healthcare practitioner ensures the person can use effective defaecation techniques:
 - correct positioning on the toilet—may involve use of footstools and leaning forward to increase hip flexion, straighten the anorectal angle, and ensure stability of sitting position.
 - allowing sufficient time to fully empty bowel
 - ensuring privacy and no interruptions
 - attention to privacy and comfort measures for example toilet temperature, noise and odor reduction
- The healthcare practitioner encourages the person to develop individualized urge suppression strategies:
- When the person feels the urge to defecate they are encouraged to suppress the urge using the techniques below until the sensation is reduced sufficiently to allow them to get to a toilet without rushing. Once they are in the toilet they are encouraged to wait for a minute or so before actually sitting on the toilet to open their bowels.
- They gradually increase the amount of time they wait before they use the toilet.
- Urge suppression or deferment involves:
 - a. **relaxation**—the person is advised to stop, relax their whole body, in particular their abdomen and focus on slow, controlled breathing.
 - b. **external anal sphincter and pelvic floor muscle contraction**—the person completes 5-8 fast contractions, without increasing their intra-abdominal pressure.
 - c. **distraction techniques**—mental activities that demand cognitive attention and concentration will distract the person from their sensation of urgency and desire to evacuate. The individual should decide what will work for them (different techniques may be used at different times). Examples include: counting backwards from 100 in 7's (or 5's for older adults), identifying girl's names through the alphabet, singing out loud, word searches/crossword puzzles, digital games, reading, making lists.
 - d. **applying perineal pressure**—sit on a hard surface, rolled towel
- Bowel urgency sensation may subside within 1-2 min. When urgency is controlled, encourage the person to walk to the toilet at a normal pace.
- The healthcare practitioner positively reinforces the person's continence skills and improved and/or prolonged bowel control.
- Individuals are actively encouraged and supported to:
 - a. self-monitor their:
 - perceived capability to relax—to stop what they are doing, take slow, deep breaths, relax their body especially their abdomen and not rush to the toilet until the urgency sensation has diminished
 - duration of urge suppression
 - intensity of urgency sensations
 - number of fecal incontinence episodes
 - reduction in negative defecation habits such as prolonged or frequent toilet use
 - progress toward achieving a normal bowel pattern
 - lifestyle changes
 - b. self-determine their:
 - progression time for example increased urge suppression/delay time
 - decisions about when to increase duration of their urge suppression/delay time.
 - c. self-affirm their:
 - use of personally meaningful self-coping statements such as 'I don't have to go now; I can wait'; 'I am in control of my bowel'

Evaluation

- Regular contact between the person and the healthcare practitioner is made during the bowel training program to review progress, assess adherence, provide positive reinforcement and adjust schedules.
- At the end of the bowel training program a range of person-focused outcomes are assessed. These may include:
 - a. perceptions of bowel condition and any improvements/changes
 - b. satisfaction with bowel training
 - c. tolerability of bowel training processes and adherence to recommended program
 - d. frequency and severity of bowel symptoms including urgency and incontinence episodes,
 - e. defecation intervals
 - f. lifestyle changes
 - g. quality of life
 - h. change in absorbent product use (eg, decrease in number)

Statement the following definition of bowel training was developed:

Bowel training is an intervention that actively enables a motivated person, without significant cognitive or physical impairment, with urgency fecal incontinence or defecation urgency to make lifestyle and behavioral changes to regain a controlled response to urgency and a satisfactory pattern of defecation through education, progressively increasing intervals between defecations, use of urgency suppression techniques, and positive reinforcement of effort and success.

7 | HOW BOWEL TRAINING WORKS

Similar to bladder training the mechanism of bowel training is poorly understood and robust evidence on approaches to bowel training and effectiveness of intervention is urgently needed.² There are physical and psychological elements in a bowel training program that aim to establish predictable, regular patterns of bowel elimination, using personalized education and support to adhere to routines.² The functional integrity of the external anal sphincter is a key focus because the external anal sphincter is a continuation of the striated puborectalis muscle and therefore it is voluntarily controlled and can be trained. Pelvic floor muscle exercises to strengthen the external anal sphincter, improve contraction speed, endurance and sphincter coordination are an important component of bowel training²⁷; however, there is no evidence on the most effective protocol to achieve improvements or sustain the effects.⁷

The psychological components of bowel training aim to reduce anxiety and panic associated with sudden onset bowel urgency, to enable the person to develop and maintain a sense of control, which will allow them to reach a toilet before any leakage occurring.²⁸ These include general anxiety reduction techniques (including stopping, focusing, deep breathing and positive self-talk). Establishing a routine for defaecation and ensuring the bowel is fully emptied are important parts of the program, as they will increase the predictability of bowel activity and therefore reduce associated anxiety.²⁷ As with bladder training, patients undertaking bowel training need to have the mental and physical capacity to (a) identify the urge to defecate; (b) understand how their bowel functions, (c) rapidly contract their pelvic floor muscles; and/or (d) apply relaxation and distraction

techniques to suppress the urge to defecate and (e) prolong intervals between defecations.² Thus, education and coaching are key components of the intervention. Individual motivation to participate, as well as the cognitive and physical ability to adhere to a progressive training schedule, are considered as essential to a positive outcome for bowel training as they are for bladder training.²⁰

The Consensus Statement on Bowel Training is presented in Table 2, however, the full document, which includes supporting evidence for each statement as well as suggestions on demonstrating its use in practice, is provided as Appendix B.

8 | POTENTIAL USE

The Consensus Statement on Bladder and Bowel Training can be used by nurses and other healthcare professionals in developing and implementing a plan of care for promoting continence with adults. The document offers expert consensus to fill a gap in current knowledge with the aim of supporting bladder and bowel continence nursing care and improving patient outcomes. The document highlights the sparse evidence base for bladder and bowel training, and it is hoped that it will stimulate research to provide further evidence to inform its content and improve its applicability and effectiveness.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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APPENDIX A: CONSENSUS STATEMENT ON BLADDER TRAINING

Consensus Statement on Bladder Training		
Statement	Supporting evidence	Demonstrating in practice
Assessment		
<p>➤ Adults with urinary incontinence or other lower urinary tract dysfunction are assessed by a healthcare practitioner for lifestyle, risk factors and quality of life to ensure the type of bladder dysfunction is identified:</p> <ul style="list-style-type: none"> ○ urinary incontinence (UI) – urgency UI, mixed UI ○ overactive bladder (OAB) or other storage lower urinary tract symptoms <p>and that the person:</p> <ul style="list-style-type: none"> ■ is suitable for bladder training and potentially will benefit. ■ has the functional ability to use the toilet either independently or with assistance ■ is cognitively able to participate ■ is motivated to undertake and adhere to a personalised bladder training programme ■ has realistic expectations of treatment ■ has ability to voluntarily contract pelvic floor muscles 	<ul style="list-style-type: none"> • Bladder training may be an effective first-line behavioural therapy for adults²⁹ (including older adults³⁰) with urgency UI/mixed UI: OAB symptoms resolved 12%-73%; OAB symptoms improved 57%-87%¹⁰ • Understanding of bladder function, the purpose of bladder training and the need to progressively increase the voiding interval are essential for bladder training to be effective³¹ • Active participation is essential to modify behaviour and develop central control over the bladder³² • Individual beliefs and expectations are fundamental to a person's behaviour and indicates their likely participation and adherence³³ 	<p>A complete assessment includes:</p> <ul style="list-style-type: none"> • Documented comprehensive individual assessment including lifestyle factors, (eg, obesity, smoking, fluid and caffeine intake, etc) • Voiding diary (minimum 72 h) including measured volumes • Diagnosed lower urinary tract disorder based on signs and symptoms or a urodynamic diagnosis • Individual expectations of bladder training and lifestyle changes are documented.
Planning		
<p>➤ The person's goals for bladder training are established with the healthcare practitioner. For example, a reduction in the frequency and severity of symptoms, the ability to sleep at night without going to the toilet; the ability to go out and socialise, reduced carer impact, etc.</p> <p>➤ The practitioner develops or structures the person's bladder training programme in collaboration with them, taking into account their personal goals and the following factors, before commencing the programme:</p> <ul style="list-style-type: none"> ■ the frequency of voiding and voiding intervals ■ duration of bladder training the person will practice before attempting to increase the voiding interval ■ whether the person prefers a standardised bladder training schedule or one that is individually tailored ■ how long the person will attempt to suppress the urge to void when urgency is experienced (eg, 5, 10, 15 or 30 min, or until urgency subsides) 	<ul style="list-style-type: none"> • It is important for healthcare practitioners to assist individuals to set specific goals that are personal, and realistic²¹. Personal goals for bladder training may be different to goals set within the programme for symptom improvement, but both are important for effective planning and are part of the evaluation³⁴ • Jointly agreeing on personal and programme goals supports engagement with the bladder training programme.¹⁴ Working towards a specific goal improves motivation and performance^{34,35} • Daytime voiding intervals of 2.5 to 4 h are recommended^{30,36} 	<ul style="list-style-type: none"> • Personal goals and specific progression criteria are documented in the bladder training plan. • Review dates and end of bladder training programme dates are specified

- the duration of the full bladder training programme in weeks
- the indicators of improvement and readiness to progress (eg, reduction in number of incontinence episodes, urge reduction, demonstrated commitment to the schedule)
- the types of urgency suppression techniques the person will use
- the method the person will use to self-monitor their progress for example bladder diaries, measured voided volumes

Intervention

- The health care practitioner ensures the bladder training programme is structured and supervised. The bladder training programme duration will vary according to the person's progress and goals but should be at least 6 wk.
 - Healthcare practitioners should review clients on a regular basis and adjust the mode and frequency of contact according to their professional judgement and the person's goals and preferences. The degree of reinforcement (coaching) patients require will vary.
 - Follow-up support to maintain effects of bladder training should be provided, in accordance with the person's goals and preferences.
 - The health care practitioner provides adults undertaking bladder training with verbal and written information and education on:
 - a. what constitutes a healthy bladder, including its function, anatomy and potential susceptibility to dysfunction
 - b. what happens to the bladder in overactive bladder syndrome/ urinary incontinence
 - c. their individual bladder function and patterns, including anticipatory/'just in case' voiding habits and incontinence episodes (based on bladder diary)
 - d. effects of current medication, diet and fluids on bladder function
 - e. how to self-monitor symptoms and interpret their bladder diary
 - f. purpose of bladder training
 - g. how bladder training works
 - h. the rise and de-escalation of the sensation of urgency, sometimes known as the 'urge wave'²⁶
 - i. the staged approach to bladder training
- Regular practice of skills to maintain continence is essential to maintain performance²⁶
 - Intensive supervision by a healthcare practitioner improves the likelihood of positive outcomes^{2,24}
 - Successful bladder training is structured and involves frequent patient contact^{22,24}
 - Clinical guidelines, based on limited evidence recommend a 6-wk minimum bladder training programme duration^{3,4}
 - Follow up is essential.¹ Effectiveness of bladder training may diminish after the programme has ceased.
 - Education is central to all behavioural therapy^{15,22} and forms the first phase of all bladder training programmes²²
 - Understanding the differences between their own bladder function and normal bladder function enables a person to identify where they can change their behaviour³⁷
 - Understanding the purpose and content of bladder training allows a person to actively engage^{22,38,39}
- A documented bladder training plan, including mode and frequency of contact between person and healthcare practitioner
 - Personal goals and specific progression documented in the bladder training plan.
 - Contact appointments are agreed
1. Details of verbal education and written information provided are recorded in bladder training plan, with time frames and methods for providing information.

(Continues)

- j. the need for active involvement, commitment and ongoing motivation
 - k. psychological strategies to support success
 - l. realistic expectations about the efforts required and the potential challenges
 - m. expected outcomes
- An initial bladder training programme and voiding intervals are agreed and implemented based on the person's baseline voiding diary information and individual goals.
 - Bladder training is usually implemented during waking hours only
 - Voiding intervals are set in accordance with the person's preference for a standardised bladder drill or individually tailored bladder training schedule:
 - a. If **standardised** a fixed (or pre-determined) voiding schedule of half-hourly or hourly voids is implemented for an agreed time period. Once achieved, this schedule is increased by a pre-determined duration of 5, 10, 15 or 30 min at each progression point.
 - b. If **tailored**, individualised voiding intervals are implemented based on the person's average voiding interval calculated from their voiding diary. Progression time to prolong voiding intervals is negotiated on an individual basis for example increase by 5, 10, 15, 30 min per week.
 - The health care practitioner regularly reviews the bladder training programme with the person to determine specific voiding interval progression in line with their goals. Voiding diary data and self-report inform this process.
 - New continence skills are developed in the form of personalised urge suppression strategies.
 - Urge suppression or deferment involves:
 - a. relaxation—the person is instructed to stop, sit down if possible, relax their whole body, in particular their abdomen and focus on slow, controlled breathing.
 - b. pelvic floor muscle contraction—the person completes 5-8 fast pelvic floor muscle contractions, without increasing their intra-abdominal pressure.
- Educating patients to resist urgency sensations and postpone voiding using a scheduled voiding programme is believed to result in an increased functional bladder capacity and reduced urgency, and ultimately reduces voiding frequency^{24,30}
 - At this point in time, evidence about bladder training is limited to daytime. In general, bladder training is not performed during sleeping hours as it may interrupt the quality and duration of a person's sleep.
 - No evidence is available on how to select the most effective voiding programme – individually tailored or standardised. Limited evidence suggests both approaches are effective^{9,40}
 - Successful and sustained increases in voiding intervals may build and embed new voiding habits but evidence is lacking on psychological and physiological effects
 - Positive reinforcement of progress towards goal attainment is a fundamental part of bladder training.¹⁵ Frequent patient contact is essential to achieve this.²⁴
- Bladder training uses techniques to enable urgency to be resisted, voiding postponed, voiding intervals to be prolonged, functional bladder capacity increased and frequency and urgency reduced as a result.¹⁹
 - Urgency may induce feelings of anxiety or panic, which affects ability to concentrate.^{21,32} Hyperventilation and contraction of abdominal muscles are associated with anxiety and panic and raise intra-abdominal pressure.²¹ The role of cognition and emotion in suppressing the urge to void is not well established, however deep
- Agreed voiding programme is documented in bladder training plan.
 - The person is provided with a copy of their bladder training plan
 - Documented assessment of progress towards attaining bladder training goals
 - Voiding diaries are completed during bladder training.
1. Education about urge suppression strategies and person's selected techniques is documented in bladder training plan

- c. distraction techniques— mental activities that demand cognitive attention and concentration are used to distract the person from their sensation of urgency and desire to void.
- d. The individual should decide what will work for them. Examples include: counting backwards from 100 in 7's, identifying different girl's names through the alphabet, singing out loud, word searches/crossword puzzles, digital games, reading, making lists.
- e. Use of self-affirming statements such as 'I can control my bladder' and 'I don't have to go now'
- f. apply perineal pressure—sit on a hard surface, rolled towel or stimulate foot sensation using toe curls and heel pressure until the urgency subsides.
- Urgency sensation may subside within 1-2 min.
- When urgency is controlled, and if voiding is permitted according to the bladder training programme, the person is encouraged to walk to the toilet at a normal pace.
- The health care practitioner positively reinforces the person's bladder control skills and improved and/or prolonged bladder control. Individuals are actively encouraged and supported to
- a. self-monitor their:
- relaxation capability and capacity to control their response to urgency and fear of incontinence episodes
 - duration of urge suppression
 - intensity of urgency sensations
 - number of incontinence episodes
 - reduction in negative voiding habits such as 'just in case' or anticipatory voiding
 - progress toward achieving a normal bladder pattern
- b. self-determine their:
- progression time for example increasing urge suppression/voiding delay time
 - decisions about when to increase their urge suppression/voiding delay time.
- breathing is hypothesised to induce subsidence of bladder urgency sensation and relaxation of detrusor²¹
- Rushing to the toilet raises intra-abdominal pressure and exposes the individual to visual cues that can trigger incontinence²¹
 - Rapid pelvic floor muscle contractions can inhibit detrusor contraction and diminish urgency²⁶
 - Attention is diverted away from the sensation of urgency when concentrating on competing mental activities, which allows the urgency to subside temporarily giving the person time to walk to the bathroom at a normal pace²¹
 - Learning to 'stop & squeeze'⁴¹ and experiencing success positively reinforces the chosen urge suppression technique.
 - Well-designed controlled trials of urge suppression have shown mean frequency of weekly urinary incontinence episode reductions of 50%-80% in women^{30,42,43}
 - The MOTIVE trial⁴⁴ showed urge suppression techniques were as effective as antimuscarinics in men without bladder outlet obstruction who continue to have OAB symptoms with alpha-blocker therapy.
1. Operant learning through experiencing positive effects of bladder training builds confidence in individual ability to control bladder⁴⁵
- Self-monitoring refers to monitoring of specific physiologic parameters or symptoms of a health condition⁴⁶
 - Two components of self-monitoring include:
 - *awareness* of bodily symptoms, sensation, daily activities, voiding habits and cognitive processes
 - *measurement* including reading and recording results eg using a bladder diary
 - Together these inform understanding and provide information for action by the individual, in consultation with health care practitioners³²
 - Supporting an individual's autonomy and competence development fosters motivation towards bladder training, ongoing engagement and adherence³⁵
 - Conscious awareness of automatic thoughts through examining them can enable them to be self-managed. Techniques can be learned to change incontinence-related cognitions,
- Record of progress is documented.
 - Use of written bladder training programme adherence records, agreed by person and health care practitioner.

(Continues)

c. self-affirm their:

- Use of personally meaningful self-coping statements such as 'I don't have to go now; I can wait'; 'I am in control of my bladder'

emotions and behaviours from negative to positive³²

- Use of positive self-coping statements (verbally out loud is better) can interrupt automatic thoughts and act as a counter directive for example 'I can wait 2-3 min to go to the bathroom or 'I can conquer this feeling, I do not have to go now' rather than 'I can't wait, I have to go now'³¹

Evaluation

Regular contact between the person and the healthcare practitioner is made during the bladder training programme to review progress, assess adherence, provide positive reinforcement and adjust voiding programme/intervals. At the end of the bladder training programme a range of person-focused outcomes are assessed. These may include:

1. perceptions of bladder condition and improvement
1. influence of bladder on daily activities
2. satisfaction with bladder training
3. tolerability of bladder training and adherence
4. frequency and severity of urgency and incontinence episodes
5. improvements in lower urinary tract symptoms
6. voiding interval changes
7. lifestyle changes
8. changes in quality of life
9. change in body-worn absorbent product use

- Frequent patient contact is a fundamental component of successful bladder training¹⁸ and the most intensive supervision by a healthcare practitioner as is possible is recommended.^{2,3}
- Feedback and reinforcement of overall changes from start of training programme confirms effectiveness and motivates continued adherence to maintain progress made^{23,24,40}

- Voiding diaries completed and repeated during the bladder training programme³⁰
- Use of validated, standardised symptom and quality of life tools, to ensure robust measurement and ability to compare outcomes in different populations, study settings etc.
- Measures are recorded before and after the bladder training programme.
- Goals are reviewed and level of achieving them is periodically evaluated

APPENDIX B: CONSENSUS STATEMENT ON BOWEL TRAINING

Consensus statement on bowel training		
Statement	Supporting evidence	Demonstrating in practice
Assessment		
<ul style="list-style-type: none"> ➤ Healthcare practitioners conduct an assessment of the person's bowel symptoms to ensure the cause and type of bowel dysfunction is identified prior to recommending a bowel training programme ➤ Current lifestyle and risk factors for bowel dysfunction (eg aggravating foods, medication side effects) are assessed. ➤ Underlying physiological abnormalities are excluded prior to recommending a bowel training programme ➤ The person's suitability to undertake bowel training is assessed including: <ul style="list-style-type: none"> • potential for benefit. • functional ability to use the toilet/toilet aid • cognitive capacity • motivation to undertake and adhere to a personalised bowel training programme • expectations of treatment • has ability to voluntarily contract pelvic floor muscles 	<ul style="list-style-type: none"> • Assessment is essential to establish the cause of the faecal incontinence/bowel dysfunction²⁸ • Bowel training is any programme that includes scheduled attempts to defecate⁴⁷ • Conservative management, including bowel training, is recommended when faecal incontinence is mild or moderate²⁸ • Active participation is essential to modify behaviour and develop central control over the bowel⁵² • Individual beliefs and expectations are fundamental to a person's behaviour and indicates their likely participation and adherence³³ 	<p>A complete assessment includes:</p> <ul style="list-style-type: none"> • Documented comprehensive individual assessment including lifestyle factors • Diagnosed functional bowel disorder. • Completed bowel diary (minimum 5-7 d) • Individual expectations of bowel training and planned lifestyle changes documented^{5,48}
Planning		
<ul style="list-style-type: none"> ➤ The person's goals for bowel training are established with the healthcare practitioner, for example, a reduction in the frequency and severity of symptoms; the ability to go out and socialise; reduced carer burden such as laundering soiled clothing and linens, decreased socialization and travel, cost of absorbent products etc. ➤ The practitioner develops or structures the person's bowel training programme in collaboration with them, taking into account the following factors before commencing the programme: <ul style="list-style-type: none"> • the frequency of evacuation • the duration of the full bowel training programme in weeks/months • the indicators of improvement • the types of urgency suppression techniques the person will use (where appropriate) • methods to normalise and regulate stool consistency 	<ul style="list-style-type: none"> • It is important for healthcare practitioners to assist individuals to set specific goals that are personal, and realistic²⁵ • Working towards a specific goal improves motivation and performance^{34,35} 	<ul style="list-style-type: none"> • Personal goals and indicators of success documented in bowel training plan. • Review dates and end of bowel training programme dates are specified

(Continues)

- the method the person will use to self-monitor their progress for example bowel diaries
- lifestyle changes are described

Intervention

- The healthcare practitioner ensures the bowel training programme is structured and supervised. The programme duration will vary according to the person's progress and goals.
- The healthcare practitioner provides adults undertaking bowel training with verbal and written information and education on:
 - normal bowel function
 - how faecal incontinence occurs
 - factors affecting bowel functioning including diet and dietary fibre, fluids, smoking, exercise, psychological/emotional status and environment
 - medication and laxatives.
 - purpose of bowel training and how it works
 - the need for active involvement, commitment and ongoing motivation by the person
 - psychological strategies to support success
 - use of containment products during bowel training
 - realistic expectations about the efforts required and the potential challenges
 - expected outcomes
- The person's bowel diary (minimum 5-7 d) is interpreted jointly by the person and the healthcare practitioner to identify individual bowel function and patterns and align with agreed goals.
- The healthcare practitioner offers the person a bowel training programme that includes information about:
 - optimal time of day for evacuation
 - frequency of evacuation attempts, for example, daily, alternate days, three times per week
 - optimal type and amount of food intake
 - optimal type and amount of fluid intake
 - individual advice on smoking cessation
 - use of drugs, dietary fibre, or rectal irrigation for faecal
- Regular practice of skills to maintain continence is essential to maintain performance^{5,39}
- Intensive supervision by a healthcare practitioner improves the likelihood of positive outcomes⁵
 1. Education is central to all behavioural therapy^{15,22}
 2. Understanding the differences between their own bowel function and normal bowel function enables a person to identify where they can change their behaviour²⁸
 3. Expert opinion suggests that understanding the purpose and content of bowel training allows a person to actively engage^{47,49}
 4. A single nurse-led education session improved post-stroke bowel function⁵⁰; 4-5 nurse-led education sessions reduced faecal incontinence by more than half in one randomised controlled trial⁵¹
- Documented bowel training programme including mode and frequency of contact between person and healthcare practitioner in bowel training plan.
- Contact appointments agreed
- Details of verbal education and written information provided are recorded in bowel training plan.
- Bowel habit training is undertaken to establish regular, effective and predictable bowel evacuation patterns and adherence to a bowel routine.
- Peristaltic colon contractions increase in frequency following awakening from sleep and meals (gastro-colic reflex). The period after breakfast is the best time for scheduled defaecation⁴⁷ or after evening meal.
- Many foods and fluids are known to influence stool consistency and bowel patterns²⁸
- Educating patients to resist bowel urgency sensations and postpone evacuation has not yet been subject to rigorous research^{4,5}
- Randomized controlled trials show that dietary fibre supplementation decreased faecal incontinence⁵¹⁻⁵³ Observed effects of dietary fibre were
- An agreed bowel routine is documented in the bowel training plan
- The person is provided with a copy of their bowel training plan
- Regular bowel diaries are recorded during training programme.
- Documented review of progress towards attaining bowel training goals

- incontinence; antidiarrheal drugs or stool bulking agents may be used to establish and maintain a normal stool consistency and frequency; laxatives, suppositories, enemas or transanal irrigation may be used to empty the rectum to avoid leakage.
- An external anal sphincter (EAS) and pelvic floor muscle exercise programme, tailored to the lifestyle and needs of the person is agreed with the healthcare practitioner. This will include specific exercises aimed at improving strength, speed and endurance of the external anal sphincter and pelvic floor muscle contraction and relaxation.
 - Concerns/anxieties affecting the person's psychological/emotional state are actively screened for and managed.
 - The healthcare practitioner ensures the person can use effective evacuation techniques:
 - Correct positioning on the toilet—may involve use of footstools and leaning forward to increase hip flexion, straighten the anorectal angle, and ensure stability of sitting position.
 - Allowing sufficient time to fully empty bowel
 - Ensuring privacy and no interruptions
 - Attention to privacy and comfort measures for example toilet temperature, noise and odour reduction
 - The healthcare practitioner encourages the person to develop individualised urge suppression strategies:
 - When the person feels the urge to defecate they are encouraged to suppress the urge using the techniques below until the sensation is reduced sufficiently to allow them to get to a toilet without rushing. Once they are in the toilet they are encouraged to wait for a minute or so before actually sitting on the toilet to open their bowels.
 - They gradually increase the amount of time they wait before they use the toilet.
- reduced faecal incontinence frequency and firming of stool consistency in some studies^{54–56}
- Observational studies show that dietary fibre supplementation decreased urgency faecal incontinence¹¹
 - Observational studies show transanal irrigation decreased fecal incontinence⁵
 - Reported exercise regimens for external anal sphincter and pelvic floor muscles vary widely in terms of the type, number and intensity of exercises taught: for example maximum contraction held for increasing duration up to 10 s (for strength); submaximal contraction held for several seconds (for endurance); fast, short contractions (for speed); how many exercises per day and in what pattern and duration over which the exercises should be performed⁷
 - Psychological and emotional concerns are both a cause and a consequence of faecal incontinence and should be actively screened for²⁸
 - Increased hip flexion in squatting straightens the anorectal angle and reduces strain associated with defecation⁵⁷
- Bowel training uses techniques to enable urgency to be resisted and evacuation to be postponed until a suitable time and place can be reached. However, teaching people to resist bowel urgency sensations and postpone evacuation has not yet been subject to rigorous research⁵
 - Bowel urgency may induce feelings of anxiety or panic, which affects ability to concentrate⁷². Hyperventilation and contraction of abdominal muscles are associated with anxiety and panic and raise intra-abdominal pressure, thus increasing the sense of urgency to evacuate.
 - Waiting in the toilet before sitting down to evacuate their bowel
 - Education about urge suppression strategies and person's selected techniques is documented in bowel training plan
 - Documented assessment of feelings (anxiety and panic) related to bowel training.

(Continues)

- Urge suppression or deferment involves:
 - a. relaxation—the person is advised to stop, relax their whole body, in particular their abdomen and focus on slow, controlled breathing.
 - b. external anal sphincter and pelvic floor muscle contraction—the person completes 5-8 fast contractions, without increasing their intra-abdominal pressure.
 - c. distraction techniques— mental activities that demand cognitive attention and concentration will distract the person from their sensation of urgency and desire to evacuate. The individual should decide what will work for them (different techniques may be used at different times).
Examples include: counting backwards from 100 in 7's (or 5's for older adults), identifying girl's names through the alphabet, singing out loud, word searches/ crossword puzzles, digital games, reading, making lists.
 - d. applying perineal pressure—sit on a hard surface, rolled towel. Bowel urgency sensation may subside within 1-2 min. When urgency is controlled, encourage person to walk to the toilet at a normal pace.
- The healthcare practitioner positively reinforces the person's continence skills and improved and/or prolonged bowel control.
- Individuals are actively encouraged and supported to:
 - a. self-monitor their:
 - perceived capability to relax—to stop what they are doing, take slow, deep breaths, relax their body especially their abdomen and not rush to the toilet until the urgency sensation has diminished
 - duration of urge suppression
 - intensity of urgency sensations
 - number of faecal incontinence episodes
 - reduction in negative evacuation habits such as prolonged or frequent toilet use
 - progress toward achieving a normal bowel pattern
 - lifestyle changes
- reinforces the person's ability to hold off and the success of urge suppression in a safe environment.
- A study of internal anal sphincter pressure wave patterns in 72 adults showed relaxation breathing promotes more regular pressure wave patterns and may aid in reducing fecal urgency and incontinence⁵⁴
- Learning to 'stop & squeeze'⁴¹ and experiencing success positively reinforces the chosen urge suppression technique and may lead to improved control of faecal urgency/incontinence
- Explanations for bladder training effects include diverting attention away from the urgency sensation using competing mentally demanding activities.²¹ This proposed mechanism may be equally applicable to bowel training
- Operant learning through experiencing positive effects of bowel training may build confidence in bowel control ability. Positive reinforcement of progress towards goal attainment is a fundamental part of bowel training⁵⁵
- Self-monitoring refers to monitoring of specific physiologic parameters or symptoms of a health condition.⁴⁶ Two components of self-monitoring include:
 - i) *awareness* of bodily symptoms, sensation, daily activities, voiding habits and cognitive processes and
 - ii) *measurement* including reading and recording results
- Together these inform understanding and provide information for action by the individual, in consultation with health care practitioners³²
- Supporting an individual's autonomy and competence development will
- Record of progress is documented.
- Use of written bowel training programme records, agreed by person and health care practitioner.
- Documented patient concerns/ anxieties that affect the patients psychological/emotional state and how they are being managed

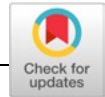
- b. self-determine their:
 - progression time for example increased urge suppression/delay time
 - decisions about when to increase duration of their urge suppression/delay time.
- c. self-affirm their:
 - use of personally meaningful self-coping statements such as 'I don't have to go now; I can wait'; 'I am in control of my bowel'

foster motivation towards bowel training, ongoing engagement and adherence³⁵

- Conscious awareness of automatic thoughts through examining them can enable them to be self-managed. Techniques can be learned to change incontinence-related cognitions, emotions and behaviours from negative to positive³²
- Use of positive self-coping statements (verbally out loud is better) can interrupt automatic thoughts and act as a counter directive for example 'I can wait 2-3 min to go to the bathroom or 'I can conquer this feeling, I do not have to go now' rather than 'I can't wait, I have to go now'¹¹

Evaluation

- Regular contact between the person and the healthcare practitioner is made during the bowel training programme to review progress, assess adherence, provide positive reinforcement and adjust schedules.
- At the end of the bowel training programme a range of person-focused outcomes are assessed. These may include:
 - a. perceptions of bowel condition and any improvements/changes
 - b. satisfaction with bowel training
 - c. tolerability of bowel training processes and adherence to recommended programme
 - d. frequency and severity of bowel symptoms including urgency and incontinence episodes
 - e. evacuation intervals
 - f. lifestyle changes
 - g. quality of life
 - h. change in body-worn absorbent product use (eg, decrease in number)
- Feedback and reinforcement of overall changes from start of training programme confirms effectiveness and motivates continued adherence to maintain progress made²⁶
- Positive reinforcement of progress towards goal attainment is a fundamental part of bowel training⁵⁵
- Bowel diaries completed during the training programme.
- Use of validated, standardised symptom and quality of life tools, to ensure robust measurement and ability to compare outcomes in different populations, study settings etc.
- Measures are recorded before and after the bowel training programme.
- Goals are reviewed and level of achieving them is periodically evaluated



Prevalence of female urinary incontinence in the developing world: A systematic review and meta-analysis— A Report from the Developing World Committee of the International Continence Society and Iranian Research Center for Evidence Based Medicine

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Abstract

Aims: The prevalence of urinary incontinence (UI) in the developing world varies widely. Factors influencing prevalence rates are a key area of interest, and knowledge of these would provide appropriate planning for preventive primary and secondary health care programs. The objective of this report was to synthesize the best available evidence to determine UI prevalence rates in adult women in a population setting.

Methods: A comprehensive search strategy was employed to find published and unpublished studies. Databases searched included PubMed, Embase, Scopus, Web of Science, and Google Scholar. We used the standardized Joanna Briggs Institute Meta-Analysis of Statistics, Assessment, and Review Instrument to appraise the included studies.

Results: In total, 54 studies with 138,722 women aged 10 to 90 years were included in this meta-analysis. Prevalence of UI ranged from 2.8% in Nigeria to 57.7% in Iran. The total prevalence of UI was 25.7% (95% CI: 22.3-29.5) and the prevalence rates for stress, urgency, and mixed UI were 12.6% (95% CI: 10.3-15.4), 5.3% (95% CI: 3.4-8.3), and 9.1% (95% CI: 7.0-11.8), respectively. When we excluded the elderly population, UI prevalence only slightly changed (26.2%; 95% CI: 22.6-30.2). Prevalence rates varied considerably during different recall periods, ranging from 15.6% for UI during the last 12 months to 41.2% for UI during the last 3 months. However, the study quality and use of validated vs nonvalidated questionnaires only had a minor impact on the prevalence rates.

Conclusions: The prevalence, methodology, and definition of UI vary widely. A large-scale multinational study with a homogeneous methodology is

necessary to correctly calculate and compare the prevalence rates to improve health policies in the developing world.

KEYWORDS

developing countries, prevalence, urinary incontinence

1 | INTRODUCTION

Urinary incontinence (UI) is a global medical problem observed in all age groups in different countries, cultures, and ethnicities.¹⁻³ The International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction defined UI as a “complaint of loss of urine.”⁴ UI is a clinical condition⁵ and not a disease itself.⁶ UI is often underestimated and underdiagnosed in both the developed and developing world.⁷ UI is more common in older women² and can affect up to 58% to 84% of the elderly population.⁵ However, its general prevalence is reported to be approximately 34% in elderly women and 22% in elderly men.⁸ A British survey showed that the prevalence of female UI may only be approximately 14%.⁹ The prevalence rates vary in different countries because of the utilization of various definitions of UI, target populations, study characteristics, assessment tools, response rates, age groups, gender, availability of health care, and other factors.^{10,11}

There are many definitions and assessment tools for the diagnosis of UI. This variety limits the establishment of UI prevalence rates and definition of the problem. Many women consider UI as an inevitable part of their life which can delay or even prevent the diagnosis.¹² Milsom et al¹³ stated that (a) most of the people with UI do not seek help, (b) only a small portion of this population receive medication or surgery, and (c) the worldwide estimation of UI is limited due to the lack of epidemiological data from the underrepresented research populations. These statements apply especially for women living in developing countries. Parameters with an influence on the (change of) symptomatology are a key area of interest, and knowledge of these factors can be useful for primary prevention or prevention of deterioration of the condition. The association of UI with other diseases, socioeconomic status, ethnicity, and lifestyle has only been examined in a few studies.^{6,14}

UI is associated with a number of psychological issues such as anxiety, embarrassment, fear, loss of self-esteem, worry, vulnerability, shame, depression, paranoia, and uncleanliness.¹⁵ UI has been declared as a global medical problem with a considerable impact on health care systems.^{15,16} Several studies have been conducted to determine the effect of UI on quality of life.^{17,18}

Recent studies demonstrated that UI is also a predictor of death.¹⁹⁻²² When compared to continent patients, UI is associated with increased mortality with a pooled nonadjusted hazard ratio of 2.22 (95% CI: 1.77-2.78). The mortality risk increases with UI severity: 1.24 (95% CI: 0.79-1.97) for light, 1.71 (95%CI: 1.26-2.31) for moderate, and 2.72 (95% CI: 1.90-3.87) for severe UI.²³ Therefore, health systems should be able to predict the burden and mortality of the condition in different populations to improve continence programs.

1.1 | Aim of the review

Based on our initial literature search, no systematic review or meta-analysis on UI in the developing world has been published so far. Our review aims to identify studies on UI in the developing world, calculate the total prevalence, the prevalence rates of SUI, UUI, and MUI, and define parameters that could influence UI prevalence rates (eg, study quality, recall periods, different questionnaires, and geographical regions).

2 | MATERIAL AND METHODS

The title of our analysis has been registered in http://joannabriggs.org/research/registered_titles.aspx

2.1 | Review questions

Primary outcome measure was the UI prevalence rate in adult women living in developing countries, as published in population-based studies. The definition of developing countries followed the recommendations of the World Bank for low- or middle-income countries.²⁴ Secondary outcome measures were the establishment of prevalence rates of UI subtypes and determination of their associated risk factors.

2.2 | Inclusion criteria

- Participants: the quantitative component of this review only considered studies that included adult women

who live in developing countries. Only population-based studies were included.

- **Outcomes:** this review considered all related studies that included the following outcome measures: pooled prevalence and prevalence rates for different types of UI (including SUI, UUI, and MUI).
- **Types of studies:** the quantitative component of the review considered epidemiological study designs including prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies. The quantitative component of the review also considered descriptive epidemiological study designs, including descriptive cross-sectional studies.

2.3 | Search strategy

The search strategy aimed to identify both published and unpublished studies. A three-step search strategy was utilized in this review. Initially, a limited search of the PubMed/Medline and CINAHL databases was undertaken, followed by the analysis of the text identifying words used in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms was then undertaken across all included databases (see list below). Afterwards, the reference list of all identified reports and articles was searched for additional studies. Studies published in any language were considered suitable for this systematic review.

2.4 | Databases

- Stage 1: PubMed/Medline, CINAHL, Virginia Henderson Library.
- Stage 2: Medline, CINAHL, Academic Search Premiere, Web of Science, DARE, PsyINFO, and ERIC.
- Grey Literature: Virginia Henderson Library, MEDNAR (which includes Google Scholar), New York Academy of Medicine Grey Literature Report, scirus.com, and Proquest Dissertations. Others resources were professional organizations relevant to the review objective to search for reports, guidelines, or unpublished research.

Initial keywords were “urinary incontinence” and “prevalence” (Supporting Information **Appendix 1**).

2.5 | Assessment of methodological quality

Publications with quantitative data were selected by two independent reviewers (HM and SH) for assessment of

the methodological validity before inclusion in the review using the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI)²⁵ (Supporting Information **Appendix 2**). Disagreements between the reviewers were resolved by discussion or a third reviewer (HSP). Selected studies were categorized into three quality groups based on the score of each study. A total score of greater than 80% was defined as high quality, a score between 60% and 80% as medium quality and a score less than 60% as low quality.

2.6 | Data collection

Quantitative data extracted from papers used the standardized data extraction tool from JBI-MAStARI (Supporting Information **Appendix 3**). Extracted data included specific details about the study populations, methods, and outcomes of interest for the review question and other specific objectives.

2.7 | Data synthesis

Quantitative papers, whenever possible, were pooled in the statistical meta-analysis by using the JBI-MAStARI and Comprehensive Meta-Analysis (CMA) software (version 2.2; Biostat, Englewood, NJ). All results were subject to double data entry. Weighted mean differences (for continuous data) and their 95% confidence intervals (95% CI) were calculated for the analyses. Heterogeneity was assessed statistically by using the standard χ^2 test and also explored by using subgroup analysis based on the different quantitative study designs included in this review. Where statistical pooling was not possible, findings were presented in a narrative form, including tables and figures.

2.8 | Assessment of heterogeneity

Both fixed method and random effects models were used. Statistical heterogeneity was assessed by using the I^2 value and the result of the χ^2 test. Results of the appropriate model are presented as forest plots.

3 | RESULTS

3.1 | Selection of studies

We initially identified a total of 3225 studies. We then removed duplicate articles ($n = 38$) and screened the title as well as abstract of the remaining studies ($n = 3187$). Articles

unrelated to UI were excluded, for example fecal incontinence. Studies related to other urinary problems, for example overactive bladder, urinary tract infections or male incontinence, and studies in developed countries were also excluded. Of the initially selected titles and abstracts, 2982 had to be excluded and, finally, 205 articles were retrieved for the detailed full-text review. Of these, 151 articles were excluded because they did not meet the inclusion criteria, for example prevalence studies in pregnant women. Finally, a total of 54 studies were included in the systematic review.^{2,6,8,9,23,26-71} All studies underwent methodological quality assessment. The summary of search results and study selection is shown in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram (Figure 1). Although all studies were included in the meta-analysis, five studies only reported about the prevalence rates for UI subtypes but not about the total prevalence rate.^{8,54,63,66,67} Therefore, not all of the 54 selected studies appeared in the forest plots for all subgroup analyses.

3.2 | Assessment of the methodological quality

All articles were selected for quality synthesis (Table 1). The JBI checklist for critical appraisal of systematic reviews was used for this purpose.²⁵ No article had to be excluded because of the acceptable overall quality of the included studies. The numbers of high-, medium-, and low-quality articles were 23 (42.6%), 25 (46.3%), and 6 (11.1%), respectively (Figure 2).

3.3 | Assessment of heterogeneity

To evaluate the level of heterogeneity, I^2 statistic was calculated in the whole study and the subgroups. The I^2 across all studies and considering the random effect model was 48.84. In the subgroups based of the quality of the studies, I^2 was "0", 45.17, and 55.42 for low-, medium- and high-quality studies, respectively. In the

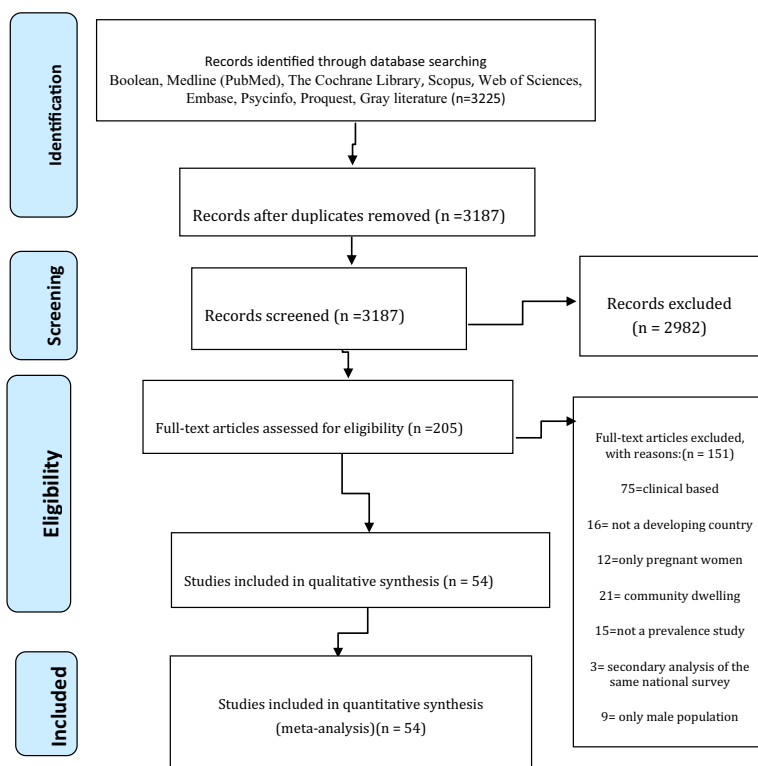


FIGURE 1 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) chart to demonstrate the selection of studies for analysis of the prevalence of urinary incontinence in the developing world

TABLE 1 Characteristics of the included studies and probability of urinary incontinence (UI) and incontinence types, listed in alphabetical order by first author

Reference	Study method	country	Prevalence of UI (%)	Age (y)	Sample size (n)	Definition of incontinence	Questionnaire
Ahmadi ²	cross-sectional	Iran	38.4	>40	800/800	not ICS	
Amaro ⁶		Brazil	27	>20	685/685	not ICS	
Bodhare ⁹	cross-sectional/ descriptive	India	10	>35	552	ICS	self-administered
Brieger ⁸		Hong Kong		10- 90	819/3248	not ICS	Kings College Urodynamics (Chinese version)
Castro ³³		Colombia	48		40-59	609/609	not ICS
Cayan ²⁸		Turkey	14.6	>18	1217		ICIQ-sf
Chen ²⁹		Taiwan	53.7	>20	1584	ICS	Bristol(Chinese version)
Choi ³⁰	cross-sectional/ telephone survey	Korea	23.8	>30	500/500	ICS	
Choo ¹²	telephone survey	Korea	40.8	30-79	1303/1500	ICS	
El-Azab ³¹	cross-sectional	Egypt	54.8	>20	1652/1652	ICS	UDI-6(Arabic version)
Eshkoor ³⁶		Malaysia	3.8	>60	2322/2322	not ICS	
Garcia-Perez ³³	population-based cross-sectional	Mexico	18.4	25-54	1307/1307	not ICS	self-administered
Ge ⁷²		China	22.1	>20	3100	ICS	ICIQ-FLUT
Hajbrahim ²⁷	cross-sectional	Iran	23.6	15-53	400	not ICS	
Hemachandra ⁵⁴		Sri Lanka		15-49	1800	ICS	
Hornge ³²	national health interview system	Taiwan	22	35-64	4661	ICS	self-administered
Hsieh ⁴²	national survey	Taiwan	29.8	>60	2410	not ICS	
Islam ³³		Bangladesh	23.7	30-59	1590/1590	not ICS	QUID
Javadifar ³⁴	cross-sectional	Iran	57.7	15-49	2000/2000	not ICS	ICIQ-sf
Jiang ⁶⁸		China	27.7	>18	2750	not ICS	ICIQ-SF
Jokhio ¹⁵	cross-sectional	Pakistan	11.5	>15	5064/5284	not ICS	self-administered

(Continues)

TABLE 1 (Continued)

Reference	Study method	country	Prevalence of UI (%)	Age (y)	Sample size (n)	Definition of incontinence	Questionnaire
Juliato ⁵⁶	cross-sectional	Brazil	23.6	45–60	749	ICS	ICIQ-SF (Portuguese version)
Lee ³⁶		Korea	24.4	>19	13,484/13,484	ICS	questionnaire used in 4 European studies
Li ⁶⁹	cross-sectional	China	30.9	>20	19024	ICS	ICIQ-FLUT
Liu ⁵⁸		China	23.3	>20	5433/5467	ICS	adapted from ICIQ-FLUT
Kim ⁷³	cross-sectional	Korea	7.5	19–65	5,928	not ICS	
Kwon ⁵⁷	national survey	Korea	7.9	>20	9873	not ICS	
Ma ⁵⁵		Hong Kong	34	>18	1018	not ICS	not defined
Manonai ³⁷	cross-sectional	Thailand	36.5	15–95	1126/1500	ICS	
Marques ³⁸	cross-sectional	Brazil	29.4	>60	1700/1705	ICS	
Megabiaw ³⁹	cross-sectional	Ethiopia	7.8	16–80	395/395	ICS	adapted from EPINCONT
Menezes ⁵⁵	population-based/ cross-sectional/ epidemiological	Brazil	10.7	>40	657	ICS	
Mikou ⁴⁰		Morocco	27.1	>18	1000	ICS	
Mohd Sidik ⁴³	cross-sectional	Malaysia	9.9	>60	223/223	not ICS	Malay version of the Barthel's Index (BI)
Mourad ⁷¹	cross-sectional survey (EPIC)	Egypt	27	≥18	3600	ICS	
Nobrega ⁶⁰	observational cross-sectional analytical	Brazil	17.5	19–59	194	ICS	self-administered
Ojengbade ⁶¹	prospective cohort	Nigeria	2.8	>18	5001/5001	not ICS	
Ozerdogan ⁴⁴	cross-sectional	Turkey	25.8	>20	625/625	ICS	Thomas et al.
Onur ⁶²	cross-sectional	Turkey	46.3	17–80	2275/2275	ICS	UDI-6
Pang ⁶³	telephone survey	Hong Kong		10–90	749	not ICS	UDI-6
Pathiraja ⁶⁴	cross-sectional	Sri Lanka	55.5	>18	2354	not ICS	

TABLE 1 (Continued)

Reference	Study method	country	Prevalence of UI (%)	Age (y)	Sample size (n)	Definition of incontinence	Questionnaire
Prabhu Shruti ⁴⁵	cross-sectional/descriptive	India	25.5	>20	353	ICS	
Santos ⁴¹	cross-sectional/epidemiological	Brazil	20.1	>18	519	ICS	reference to other article
Stones ⁴⁵		China	6.2	15–34	3150/3150	not ICS	
Tamanini ⁴⁶	cohort	Brazil	28.2	>60	1413	not ICS	not defined
Tseng ⁴⁸		Taiwan	21.6	>65	504/504	not ICS	
Tozun ⁴⁷		Turkey	49.5	>20	1585/1585	ICS	ICIQ-sf
Velazquez Magna ⁴⁹	observational transverse and descriptive	Mexico	46.5	20–80	80/80	ICS	ICIQ-UI-sf
Wong ⁶⁶	telephone survey	China		17–77	540/540	not ICS	UDI-6
Wu ⁵⁰		China	35.2	>20	2448/2500	ICS	ICIQ-FLUT
Yu ⁷⁰	cross-sectional	China	33.4	>60	743/743	not ICS	ICIQ-FLUT
Zhang ⁶⁷		China		>20	6066	not ICS	Bristol
Lei Zhang ⁵¹	cross-sectional	China	31.9	>20	20,000	ICS	Bristol + ICIQ-FLUTS
Zhu ⁵²	cross-sectional	China	38.5	>20	5300	ICS	ICIQ-FLUT
Reference	Time of UI diagnosis	Validation status	country/region	year	Sex	Incontinence type (%)	
Ahmadi ²	daily leak/activity/using pads	no	region	2007	F	SUI	UUI
Amaro ⁵	any involuntary loss of urine	no	region	2009	F		
Bodhare ⁹	any involuntary loss of urine	yes	region	2010	F	5.7	2.3
Brieger ⁸	unacceptable involuntary loss of urine	yes	telephone survey	1996	F	7	15
Castro ⁵³	any involuntary loss of urine	no	region (Amazon tribes)	2010	F		
Cayan ³⁸	UI in the past 4 weeks	yes	country	2016	F	4.7	1.8

(Continues)

TABLE 1 (Continued)

Reference	Time of UI diagnosis	Validation status	country/region	year	Sex	Incontinence type (%)		
						SUI	UII	MUI
Chen ²⁹	UI in the past 4 weeks	yes	region	2003	F	18	18.6 (overflow)	17.1
Choi ³⁰	involuntary loss in the last 6 months	no	Country(3 cities)	2012	F			
Choo ¹²	UI in the past 4 weeks	yes	telephone survey	2003	F	22.9	3.1	14.9
El-Azab ³¹	any involuntary loss of urine	yes	region	2007	F	14.8	15	25
Eshkoot ²⁶		no	country		M/F			
Garcia-Perez ³³	involuntary loss in the last year	yes	region (northern Mexico)	2005	F	10.4	1.8	57.2
Ge ⁷²	UI in the past 4 weeks	yes	region	2009	F	12.9	1.7	7.5
Hajebrahimi ²⁷	any involuntary loss of urine	no	region	1998–1999	F			
Hema-chandra ⁵⁴		no	country	2006–2007	F	9.8		
Horange ³²	Involuntary loss in the last year	no	national survey	2005	F			
Hsieh ^{4,2}	any involuntary loss of urine	no	country	1999	F			
Islam ³³	UI in the past 4 weeks	yes	country	2013–2014	F			
Javadifar ³⁴	UI in the past 4 weeks	yes	region	2018	F			
Jiang ⁶⁸	UI in the past 4 weeks	yes	region	2016	F	23.1	1.6	3.0
Jokhio ³⁵		no	region	2012	F	4.7	3.2	2.8
Juliato ⁵⁶	any involuntary loss of urine	yes	region	2012–2013	F	6.4	7.8	9.5
Lee ³⁶	any involuntary loss of urine	no	national survey	2005	F	11.9	1.9	10.2
Li ⁶⁹	UI in the past 4 weeks	yes	country	2006	F		2.6	9.4
Liu ⁵⁸	UI in the past 4 weeks	yes	region	2010–2012	F	14	3	6.3

TABLE 1 (Continued)

Reference	Time of UI diagnosis	Validation status	country/region	year	Sex	Incontinence type (%)		
						SUI	UUI	MUI
Kim ⁷³	any involuntary loss of urine	no	4 th Korean National Health & Nutrition Examination Survey	2008–2009	F	OR (95%CI) for working women with a daytime work schedule was 2.14 (1.18–3.87) evening work schedules, it was 1.35 (1.05–1.74)		
Kwon ⁶⁷	do you have UI?	no	national survey	2007–2009	F			
Ma ⁵⁵	any involuntary loss of urine	yes	region	1994	F			
Manonal ³⁷	UI in the past 4 weeks	yes	region	2003–2004	F	33.6		
Marques ³⁸	any involuntary loss of urine	yes	region	2009–2010	M/F			
Megabiau ³⁹	involuntary loss in the last year	no	region	2012	F	1.2		
Menezes ³⁵	any involuntary loss of urine	no	region	2003	M/F			
Mikou ⁴⁰	UI in the past 4 weeks	no	region	1998	F			
Mohd Sidik ⁴³	any involuntary loss of urine	yes	region	2002	M/F			
Mourad ⁷¹	any involuntary loss of urine	no	country	2018	F	6	6	12
Nobrega ⁶⁰	any involuntary loss of urine	no	region	2013	F			
Ojengbade ⁶¹	any involuntary loss of urine	no	country	2009	F	2.3	1	0.6
Ozerdogan ⁴⁴	UI in the past 4 weeks	no	region	2003	F	11.1	7.04	7.7
Onur ⁶²	any involuntary loss of urine	yes	region	2009	F	46	43	
Pang ⁶³	any involuntary loss of urine	yes	telephone survey	2001–2002	F	13	15.5	30.9
Pathiraja ⁶⁴	UI in the past 3 months	no	country	2015–2016	F	10	15.6	29.9

(Continues)

TABLE 1 (Continued)

Reference	Time of UI diagnosis	Validation status	country/region	year	Sex	Incontinence type (%)		
						SUI	UII	MUI
Prabhu Shrutfi ⁶⁵	definition of ICS was used	yes	region	2010–2011	F	14.3	8.2	3
Santos ⁴¹		no	region	2007–2008	M/F			
Stones ⁴⁵	not defined	no	country(3 regions)	2003	F			
Tamanini ⁴⁶	UI in the past 3 months	yes	region	2010	F			
Tseng ⁴⁸	any involuntary loss of urine	no	region	1997	M/F	10.9	6.6	6.3
Tozun ⁴⁷	UI in the past 4 weeks	yes	region	2007	F	16.1	8.5	24.9
Velazquez Magna ⁴⁹	UI in the past 4 weeks	yes	region	2006	F			
Wong ⁶⁶	UI in the past 3 months	yes	country	2005	F	40.8	20.4	15.9
Wu ⁵⁰	UI in the past 4 weeks	yes	region	2009	F	26.4	1.9	6.9
Yu ⁷⁰	UI in the past 4 weeks	yes	region	2007	F			
Zhang ⁶⁷	UI in the past 4 weeks	yes	region	2005	F	16.6	10	
Lei Zhang ⁷¹	UI in the past 4 weeks	yes	country	2006	F	18.9	2.6	9.4
Zhu ⁷²	UI in the past 4 weeks	yes	region	2005	F	22.9	2.8	12.4

Blank cells indicate missing data.

Abbreviations: F, females; M, males; MUI, mixed urinary incontinence; SUI, stress urinary incontinence; UII, urgency urinary incontinence.

No	Authors	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
1	Ahmadi [2]	😊	😊	😊	😊	😊	😞	😊	😊	😊
2	Amaro [6]	😊	😊	😊	😊	😊	😊	😊	😊	😊
3	Bodhare [9]	😊	😊	😊	😊	😊	😊	😊	😊	😊
4	Brieger [8]	😊	😊	😊	😊	😊	😊	😊	😊	😊
5	Castro [53]	😊	😊	😊	😊	😊	😞	😊	😊	😊
6	Cayan [28]	😊	😊	😊	😊	😊	😊	😊	😊	😊
7	Chen [29]	😊	😊	😊	😊	😊	😊	😊	😊	😊
8	Choi [30]	😊	😊	😊	😊	😊	😞	😊	😞	😊
9	Choo [12]	😊	😊	😊	😞	😊	😊	😊	😊	😊
10	El-Azab [31]	😊	😊	😊	😊	😊	😊	😊	😊	😊
11	Eshkooor [26]	😊	😊	😊	😊	😊	😞	😊	😊	😊
12	Garcia-Perez [33]	😊	😊	😊	😊	😊	😊	😊	😊	😊
13	Ge [72]	😊	😊	😊	😊	😊	😊	😊	😊	😊
14	Hajebrahimi [27]	😊	😊	😊	😊	😊	😞	😊	😊	😊
15	Hemachandra [54]	😊	😊	😊	😊	😊	😊	😊	😊	😊
16	Hornge [32]	😊	😊	😊	😊	😊	😊	😊	😊	😊
17	Hsieh [42]	😞	😊	😊	😊	😊	😊	😊	😊	😊
18	Islam [33]	😊	😊	😊	😊	😊	😊	😊	😊	😊
19	Javadifar [34]	😊	😊	😞	😞	😊	😊	😊	😊	😊
20	Jiang [68]	😊	😊	😊	😊	😊	😊	😊	😊	😊
21	Jokhio [35]	😊	😊	😊	😊	😊	😞	😊	😊	😊
22	Juliato [56]	😊	😊	😊	😊	😊	😊	😊	😊	😊
23	Lee [36]	😊	😊	😊	😊	😊	😞	😊	😊	😊
24	Li [69]	😊	😊	😊	😊	😊	😊	😊	😊	😊
25	Liu [58]	😊	😊	😊	😊	😊	😊	😊	😊	😊
26	Kim [73]	😊	😊	😊	😊	😊	😞	😊	😊	😊
27	Kwon [57]	😊	😊	😊	😊	😊	😊	😞	😊	😊
28	Ma [55]	😊	😊	😞	😊	😊	😊	😊	😊	😊
29	Manonai [37]	😊	😊	😊	😊	😊	😞	😊	😊	😊

FIGURE 2 Quality scoring results with the JBI Critical Appraisal Checklist for Studies Reporting Prevalence Data consisting of nine questions (Q1-Q9, see Supporting Information Appendix 2). The questions with answer “yes” are shown as 😊, with answers “no” as 😞, and answer “unclear” as 😐. A total score of greater than 80% was defined as high quality, a score between 60% and 80% as medium quality and a score less than 60% as low quality

30	Marques [38]	😊	😊	😊	😊	😊	😊	😊	😊	😊
31	Megabiaw [39]	😊	😊	😊	😊	😊	😞	😊	😊	😊
32	Menezes [55]	😊	😊	😊	😊	😊	😞	😞	😞	😞
33	Mikou [40]	😞	😊	😞	😊	😞	😞	😞	😊	😞
34	Mohd Sidik [43]	😞	😊	😊	😊	😊	😊	😊	😊	😞
35	Mourad [71]	😞	😞	😊	😞	😊	😞	😊	😊	😊
36	Nobrega [60]	😊	😞	😞	😊	😊	😞	😞	😊	😞
37	Ojengbede [61]	😊	😊	😊	😊	😊	😞	😊	😊	😞
38	Ozerdogan [44]	😊	😊	😊	😊	😊	😞	😊	😊	😞
39	Onur [62]	😊	😊	😊	😊	😊	😊	😊	😊	😊
40	Pang [63]	😊	😊	😊	😞	😊	😊	😊	😊	😊
41	Pathiraja [64]	😊	😊	😊	😊	😊	😊	😊	😊	😞
42	Prabhu Shruti [65]	😊	😊	😊	😊	😊	😊	😊	😊	😊
43	Santos [41]	😊	😊	😊	😊	😊	😞	😞	😊	😞
44	Stones [45]	😊	😊	😊	😊	😊	😞	😊	😊	😞
45	Tamanini [46]	😞	😊	😊	😊	😊	😊	😊	😊	😊
46	Tseng [48]	😞	😊	😊	😊	😊	😞	😊	😊	😊
47	Tozun [47]	😊	😊	😊	😊	😊	😊	😊	😊	😞
48	Velazquez Magna [49]	😊	😊	😊	😊	😊	😊	😊	😊	😊
49	Wong [66]	😊	😊	😊	😊	😊	😊	😊	😊	😊
50	Wu [50]	😊	😊	😊	😊	😊	😊	😊	😊	😊
51	Yu [70]	😊	😊	😊	😊	😊	😊	😊	😊	😊
52	Zhang [67]	😊	😞	😊	😊	😊	😊	😊	😊	😊
53	Lei Zhang [51]	😊	😊	😊	😊	😊	😊	😊	😊	😊
54	Zhu [52]	😊	😊	😊	😊	😊	😊	😊	😊	😊
Total		87.0%	94.4%	90.7%	92.6%	98.1%	55.6%	87.0%	94.4%	62.7%

FIGURE 2 Continued

subgroups based on the definition of UI, I^2 was 17.26, 47.91, 4.44, 0, 65.28, and 46.90 for UI defined as “any involuntary loss of urine”, “involuntary loss of urine in the last 4 weeks”, “involuntary loss of urine in the last 3 months”, “involuntary loss of urine in the last 6 months”, “involuntary loss of urine in the last year”, and “not identified”, respectively. The I^2 was 60.55 in the studies that used a validated questionnaire and 19.48 for the studies that used nonvalidated questionnaires. Finally,

the I^2 was calculated 64.70 in the “country” subgroup and 26.87 in “region” subgroup.

3.4 | Publication bias

To assess the publication bias of the selected studies, a funnel plot was drawn. It seems that the sample size of the included studies is appropriate for the purpose of

FIGURE 3 Funnel plot analysis of 54 studies. Only one study on the left side (*) below is totally out of distribution⁵⁰

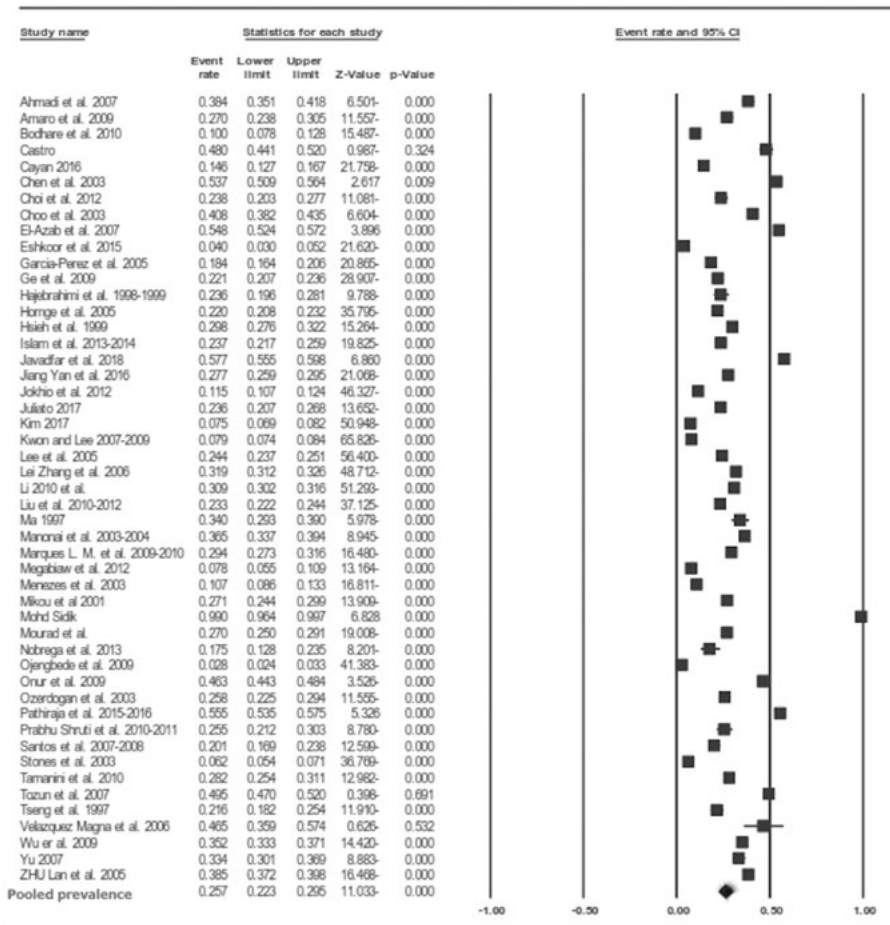
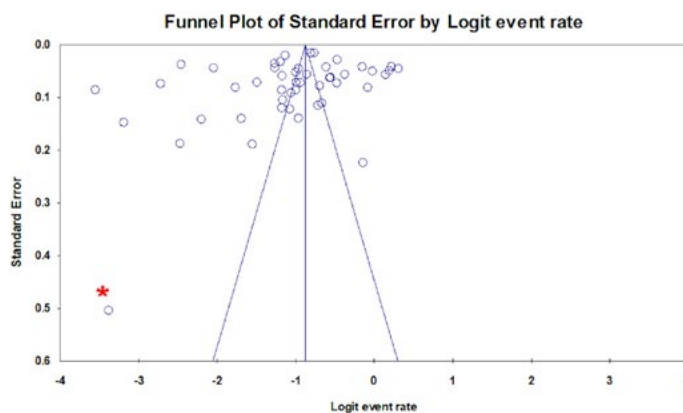


FIGURE 4 Prevalence of urinary incontinence in the individual studies of the selected literature resulting in a pooled prevalence rate of 25.7% (95% confidence interval: 22.3-29.5) using random-effects analysis

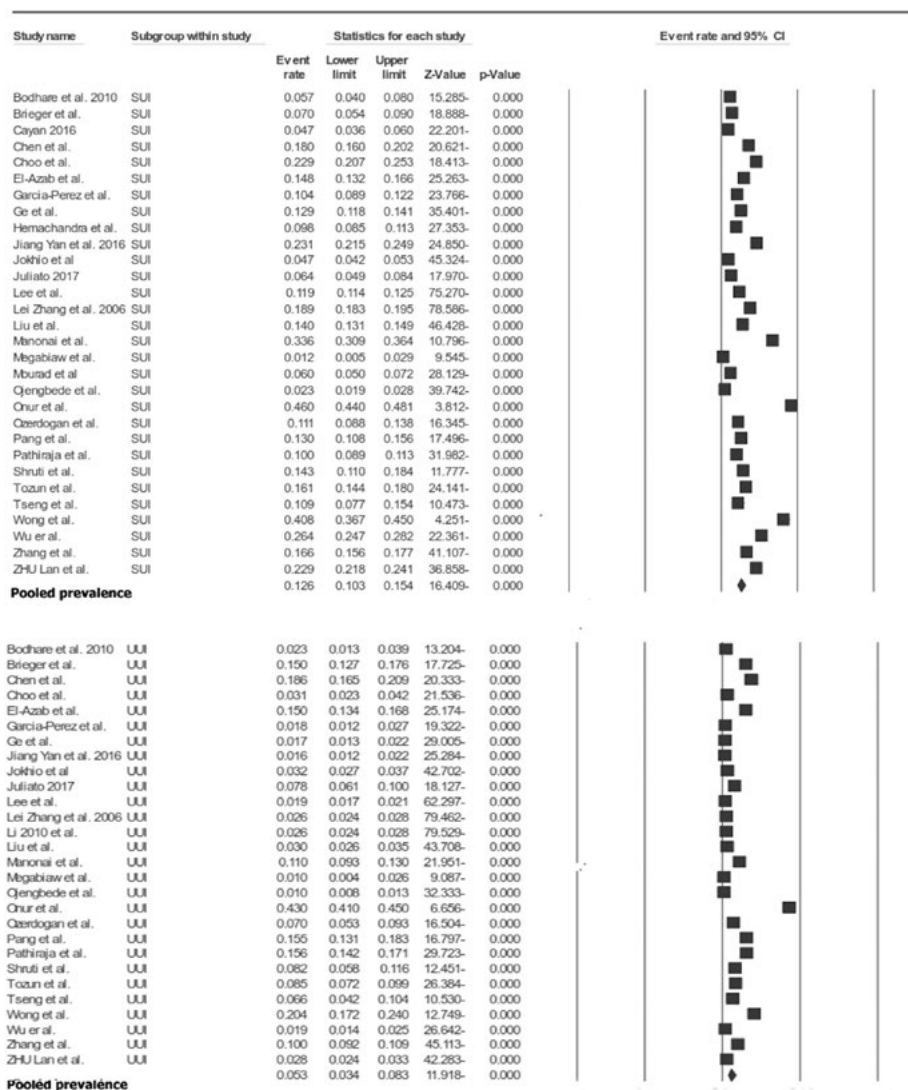


FIGURE 5 Prevalence rates for subtypes of urinary incontinence using random-effects analysis: stress urinary incontinence (SUI) 12.6% (95% confidence interval 10.3-15.4), urgency urinary incontinence (UII) 5.3% (95% confidence interval 3.4-8.3) and mixed urinary incontinence (MUI) 9.1% (95% confidence interval 7.0-11.8)

our analysis but the pattern of distribution is not completely symmetric. This could have been caused by a publication bias or methodological flaw. We did not exclude any of these studies and performed subgroup analyses because only one study⁴³ was totally out of distribution (Figure 3).

3.5 | Prevalence of UI

The prevalence rates of the individual studies and the total prevalence of UI is shown in Figure 4. In the fixed method analysis, prevalence of UI was 29.4% (95% CI: 29.1-29.6) but I^2 was more than 50% which demonstrates

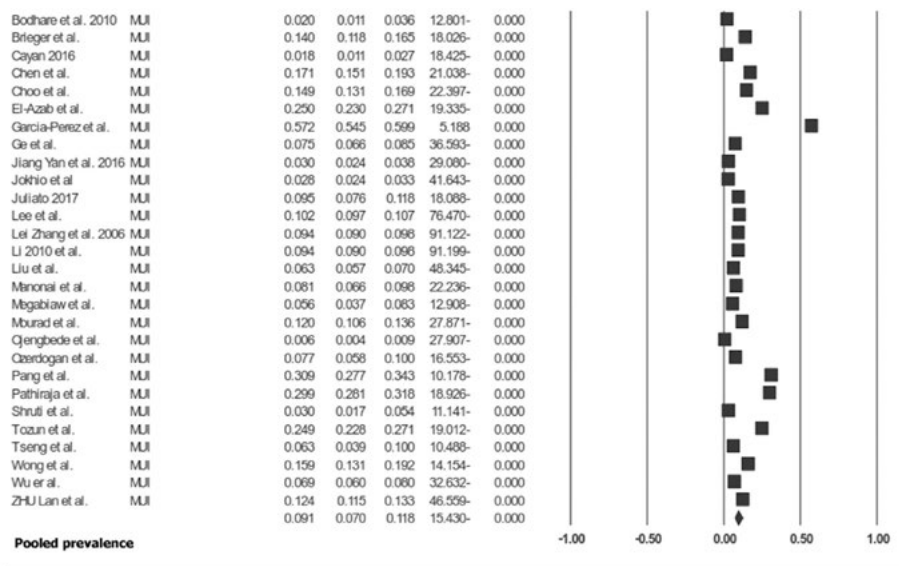


FIGURE 5 Continued

high heterogeneity of the studies. We therefore used the random effect model here and for all additional analyses that showed an overall UI prevalence of 25.7% (95% CI: 22.3-29.5). The prevalence of different UI types was 12.6% (95% CI: 10.3-15.4), 5.3% (95% CI: 3.4-8.3), and 9.1% (95% CI: 7.0-11.8) for SUI, UUI, and MUI, respectively (Figure 5).

3.6 | Prevalence of UI without elderly women

The prevalence of UI significantly increases with age.² However, we could not perform the age-based analysis for our patient groups because this data was unavailable in the literature. For this reason, we performed a subgroup analysis after excluding studies focussing on the elderly population in the title or text ($n = 6$). This analysis showed that the total UI prevalence only changed slightly to 26.2% (95%CI: 22.6-30.2; Figure 6).

3.7 | Prevalence of UI based on the definition of incontinence

There are several definitions for UI that may influence the prevalence. The prevalence of UI for any involuntary loss of urine independent on the time period was 25.5% (95% CI:

18.5-34.2; Figure 7). When UI was defined as involuntary loss of urine in the last 4 weeks, the prevalence rate was 33.4% (95% CI: 29.5-37.5). However, when UI was defined as involuntary loss of urine during the last 3 months, the prevalence rate was 41.2% (95% CI: 18.4-68.5), whereas the prevalence rate of any involuntary loss of urine during the last year was 15.6% (95% CI: 10.9-21.8).

3.8 | Prevalence of UI according to the study quality

To demonstrate the effects of the study quality on data pooling, we divided the retrieved studies according to their methodological quality. The UI prevalence was 28.2% (95% CI: 24.0-32.9), 19.4% (95% CI: 15.0-24.8), and 21.8% (95% CI: 11.1-38.3) for studies with high, medium, and low quality, respectively (Figure 8).

3.9 | Prevalence of UI according to the use of validated vs nonvalidated questionnaires

The methods to assess the prevalence of UI varied widely. Only approximately half of the studies (55.5%) utilized validated questionnaires ($n = 30$). For this reason, we analyzed the prevalence of UI according to the use of validated or

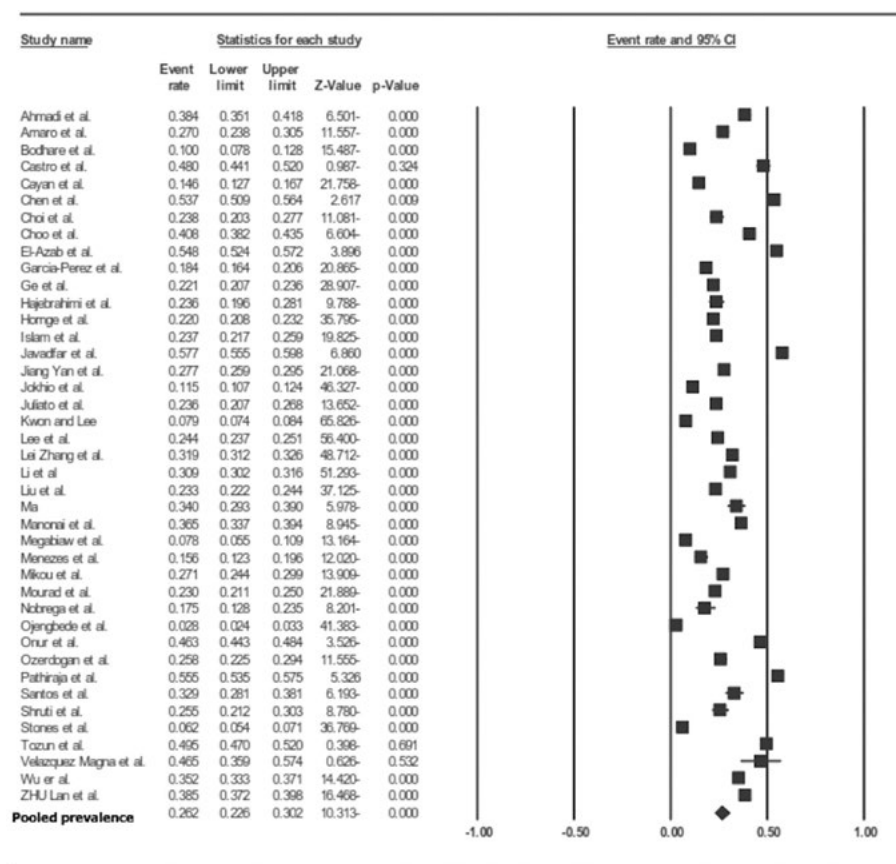


FIGURE 6 Prevalence of urinary incontinence excluding elderly women using random-effects analysis

nonvalidated questionnaires. In the studies with validated questionnaires, the prevalence rate of UI 23.5% (95% CI: 19.4–28.1). In contrast, the prevalence rate was 27.7% (95% CI: 22.6–33.4) in studies that used nonvalidated questionnaires.

3.10 | Prevalence of UI according to geographical region

Included studies were also analyzed according to their geographical origin (Figure 9):

- Eastern Asian and Pacific region: 25.6% (95% CI: 21.4–30.2)
- South Asia: 14.2% (95% CI: 6.1–29.8)
- Europe and Central Asia: 32.2% (95% CI: 18.9–49.15)
- Middle East and North Africa: 37.3% (95% CI: 25.8–50.5)
- Sub-Saharan region: 4.6% (95% CI: 1.7–12.3)
- Latin America: 28.8% (95% CI: 22.2–36.4).

In large population studies in individual regions or countries, the prevalence rate of UI was 18.9% (95% CI: 14.4–24.3). In contrast, the prevalence of UI was 28.8% (95% CI: 24.4–33.5) when only a small population sample was investigated. The results of all subgroup analyses are summarized in Table 2.

4 | DISCUSSION

Our systematic review and meta-analysis is the first comprehensive report of UI prevalence rates in the developing world. Our analysis demonstrates that approximately 26% of the adult female population in developing countries has UI. However, more accurate prevalence data is difficult to retrieve from the epidemiologic literature since striking differences exist among the studies in terms of methodology, definitions of UI and

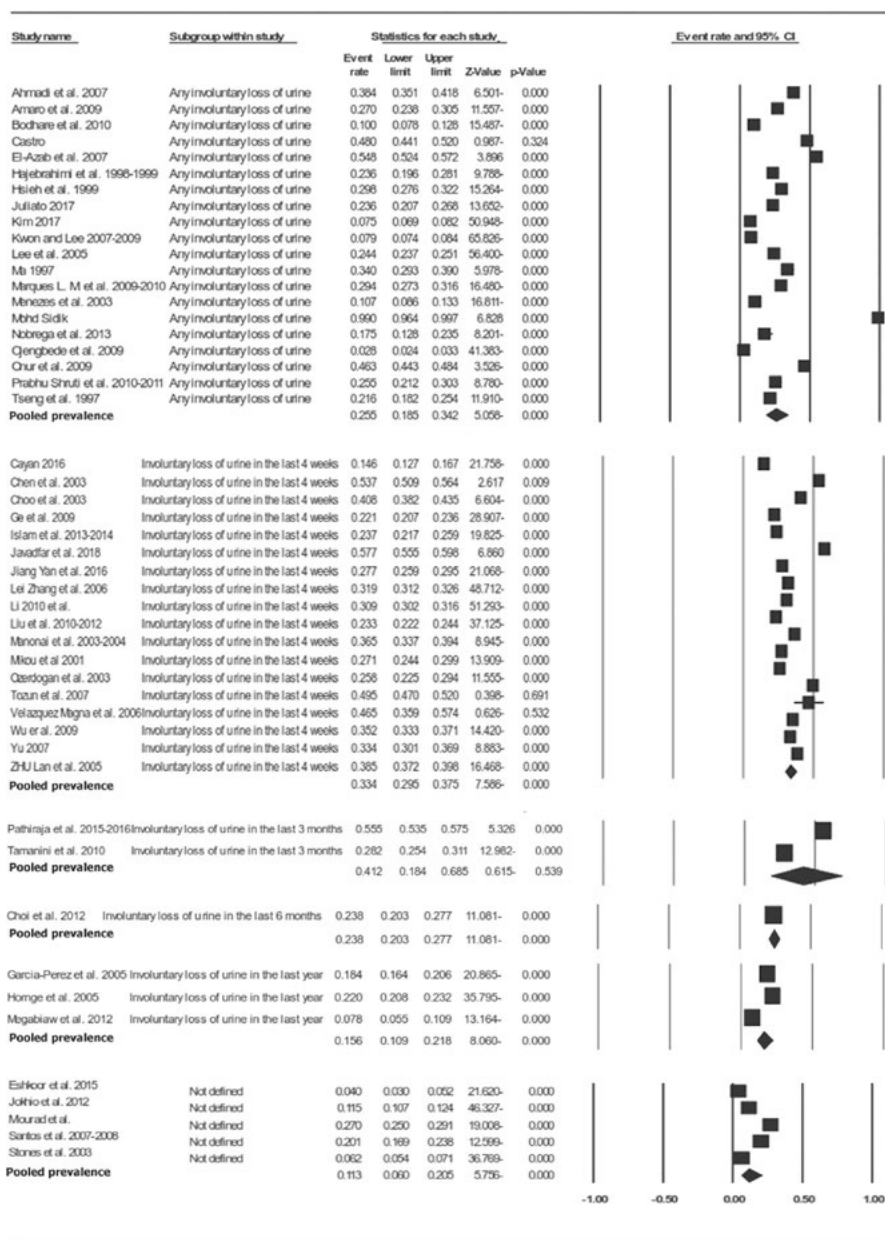


FIGURE 7 Prevalence of urinary incontinence (UI) based on its definition using random-effects analysis. Some studies defined UI as any involuntary loss of urine, whereas other studies defined incontinence as involuntary loss of urine during the last 4 weeks, 3 months, or 12 months. However, some studies did not define the recall period for UI

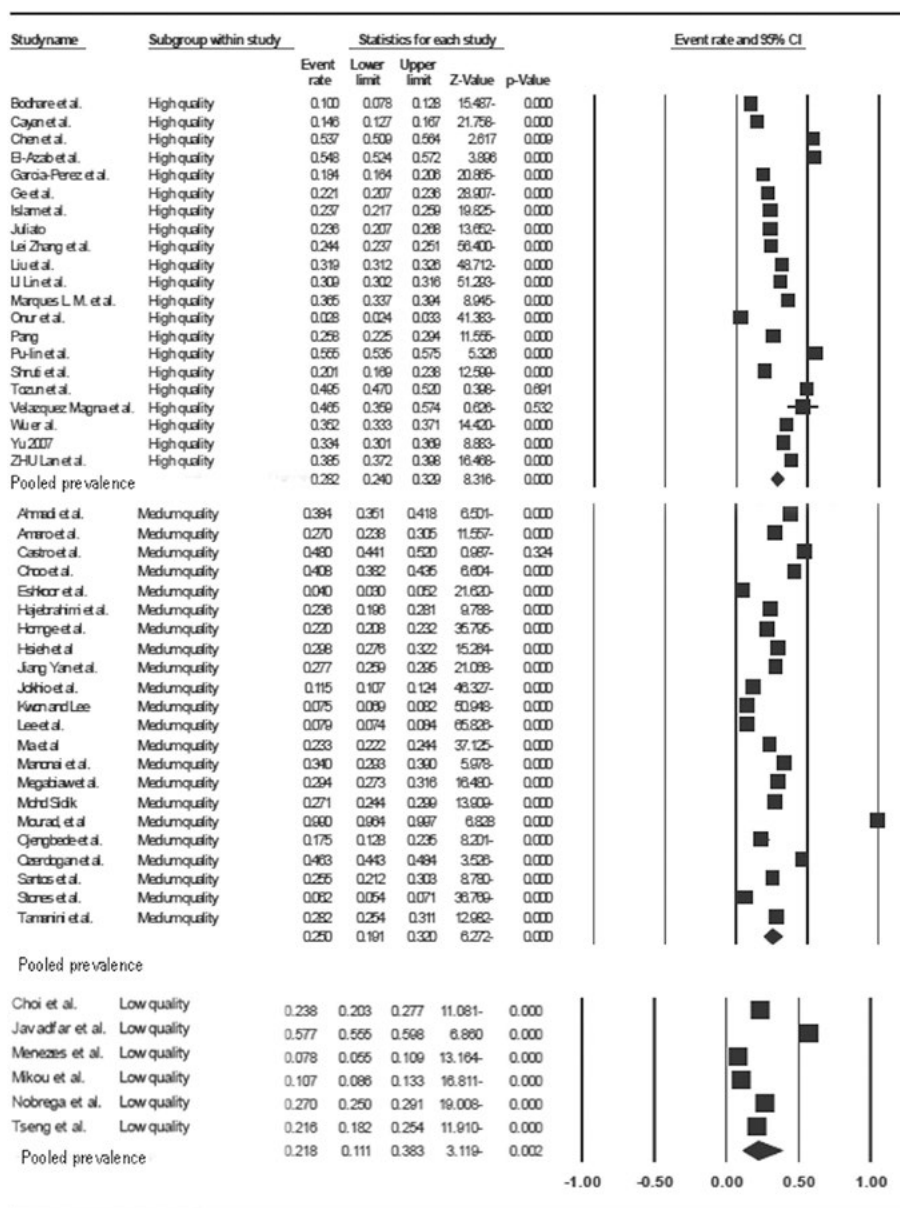


FIGURE 8 Prevalence of incontinence according to the study quality using random-effects analysis. Publications with quantitative data were selected for assessment of the methodological validity before inclusion in the review by using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MASARI) (Supporting Information Appendix 2). Selected studies were categorized into three groups based on the score of each study. A total score of less than 80% was defined as high quality, a score between 60% and 80% as medium quality and a score less than 60% as low quality

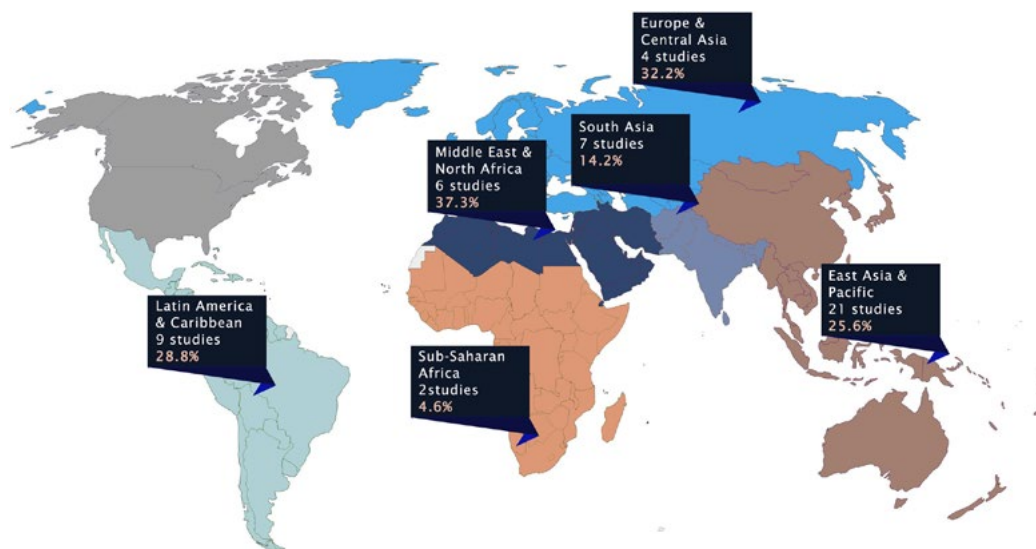


FIGURE 9 Urinary incontinence prevalence rates based on studies in different geographical locations

populations that together limit the calculation of more accurate estimates. The heterogeneity between the studies prevented additional calculations but our results still provide some important insights into the parameters that influence the UI prevalence in the developing world.

The prevalence rate of SUI (12.6%) was higher than the prevalence rates of MUI (9.1%) or UUI (5.3%). Most strikingly, the prevalence of MUI in the developing world is almost two-fold higher than for UUI. Contradictory data appeared when comparing the prevalence rates for the recall periods of 3 months (41.2%) and 12 months (15.6%). Patients may have overestimated the frequency of UI during the shorter recall period or forgotten urinary leakage episodes during a longer recall period, especially in women with infrequent or less severe UI. In the present analysis, we did not have any time restriction of the published literature. Therefore, it is also possible that more recently published studies demonstrate a higher prevalence of UI due to greater awareness and reporting.

In our meta-analysis of 54 studies, heterogeneity in the fixed method model was high. Nevertheless, the heterogeneity in a meta-analysis of clinical trials should be small because all included studies estimate the same condition for a similar population in one region.⁷⁴ However, this heterogeneity is still possible due to differences in study populations, measurement methods, and possible cultural differences, especially when effects are measured by applying patient-reported outcomes.⁷⁵ Because of the high heterogeneity of the studies, we

performed random-effect analyses for the main results and subgroups. It is arguable whether random-effect analyses are more suitable because different studies may measure different items in epidemiological studies.⁷⁶ The situation is different when results are pooled from several epidemiological studies. Here different studies definitely measure different things. There is no way of controlling for all possible confounders and, therefore, substantial heterogeneity can be expected.⁷⁴

In the current meta-analysis, the funnel plot was not symmetric for the selected studies and, therefore, some kind of publication bias or methodological effect is likely. Inadequate response rate can also cause an asymmetric funnel plot. In other words, we cannot see a uniform methodology and assessment tool for screening and diagnosing UI across the studies.

The difficult task in the interpretation of the meta-analysis results, despite its purely statistical tool nature, is to draw general conclusions for the real world based on analyses in the theoretical world in which all models are correct and all prerequisites are fulfilled.²³ The majority of the included studies were conducted in Eastern Asia and the Pacific region and only a few studies were carried out in Sub-Saharan Africa. The high number of studies in a highly populated country like China^{45,50-52,58,66-70,72} is plausible but the high number of studies in less populated countries like Turkey^{28,44,47,62} may influence the overall outcome of the meta-analysis. This appears to be important because ethnicity can influence the prevalence

TABLE 2 Summary of subgroup analyses for urinary incontinence in the developing countries

Variables	Event rate	
	Random-effect analysis % (95% CI)	Fixed method model % (95% CI)
Total UI prevalence	25.7% (22.3-29.5)	29.4% (29.1-29.6)
SUI	12.6% (10.3-15.4)	17.3% (17.0-17.6)
UUI	5.3% (3.4-8.3)	7.6% (7.4-7.8)
MUI	9.1% (7.0-11.8)	12.1% (11.8-12.3)
UI prevalence without elderly women	26.2% (22.6-30.2)	29.3% (29.1-29.6)
UI prevalence based on its definition		
Any involuntary loss of urine	25.5% (18.5-34.2)	23.4% (22.9-23.8)
Involuntary loss of urine in the last 4 wk	33.4% (29.5-37.5)	32.5% (32.2-32.9)
Involuntary loss of urine in the last 3 mo	41.2% (18.4-68.5)	48.3% (46.6-50.1)
Involuntary loss of urine in the last year	15.6% (10.9-21.8)	20.7% (19.7-21.7)
UI prevalence based on study quality		
High quality	28.2% (24.0-32.9)	31.5% (31.1-31.8)
Medium quality	25.0% (19.1-32.0)	21.6% (21.2-22.0)
Low quality	21.8% (11.1-38.3)	36.3% (34.9-37.7)
UI prevalence based on questionnaire type		
Validated	23.5% (19.4-28.1)	27.7% (27.4-28.0)
Nonvalidated	27.7% (22.6-33.4)	34.0% (33.5-34.6)
UI prevalence based on geographical location		
East Asia and Pacific	25.6% (21.4-30.2)	27.5% (27.3-27.8)
South Asia	14.2% (6.1-29.8)	26.3% (25.3-27.2)
Europe and Central Asia	32.2% (18.9-49.1)	40.3% (38.9-41.6)

TABLE 2 (Continued)

Variables	Event rate	
	Random-effect analysis % (95% CI)	Fixed method model % (95% CI)
Middle East and North Africa	37.3% (25.8-50.5)	42.8% (41.6-43.9)
Sub-Sahara	4.6% (1.7-12.3)	3.4% (2.9-3.9)
Latin America	28.8% (22.2-36.4)	29.8% (28.5-31.0)

Results of both the random-effect analysis, which were used throughout the articles, and the fixed method model are provided.

Abbreviations: MUI, mixed urinary incontinence; SUI, stress urinary incontinence; UI, urinary incontinence; UUI, urgency urinary incontinence; 95% CI, 95% confidence interval.

and type of UI.^{34,52} The highest prevalence of UI, with more than 37% of population affected, was seen in Middle East and North Africa as well as in Europe and Central Asia, whereas the lowest prevalence rate was seen in Sub-Saharan countries. These variations in the prevalence rates of UI confirm that the region with different cultures and races influences results.^{1-3,77} Other explanation for the geographical differences is its impact on social activities and responsibilities in different cultures and regions. Embarrassment, shame, lack of trust to the health system as well as the lack of knowledge and understanding of incontinence as a disease decrease the help seeking behavior in the patients. Thus, some patients rather hide their condition and others might consider it a natural process of aging.⁷⁸ Different definitions of UI complicate the calculations and produce heterogeneous data.^{79,80} For example, the UI prevalence rate of UI ranged from 12% to 53% with a mean of 35.1% in the study of Diokno et al. In this study, the authors defined UI as urinary leakage at 6 or more days during the last 12 months.⁸¹ When UI was defined as any uncontrolled loss of urine with frequency of at least twice per month, the prevalence rate ranged from 4.5% to 37%, with a mean of 18%.⁸² These findings show that the accurate and reproducible prevalence of UI cannot be measured without using standardized definitions and validated questionnaires in well-designed high-quality studies.⁷⁹

Several studies reported about the prevalence of different UI types, including SUI, UUI, and MUI. The most prevalent type of UI in the individual studies and in our meta-analysis was SUI. The prevalence ranged between 13% and 50% in younger and between 6.4% and 42.2% in older women. The number of participants included in the group with younger women ranged from 405 to 27 936 and the number of

participants included in the group with older women from 227 to 142 651.^{40,55,62,64,68} It seems that the lower and upper limits of prevalence rates are different in first world countries where study participants were mainly evaluated by population-based or cross-sectional surveys. In contrast, data in the developing world was frequently collected by non-validated questionnaires for self-completion, postal surveys or face-to-face interviews.^{29,31,33,34,41,43,47,49,50,56,58,62,63,66,69,70}

This was the reason why we performed a subgroup analysis to distinguish the UI prevalence rates with validated or nonvalidated questionnaires. Our subanalysis showed that UI prevalence rates with nonvalidated questionnaires are almost identical to those obtained by validated questionnaires. Therefore, we are confident that the use of non-validated questionnaires in 45% of the studies did not have a relevant impact on the overall result.

4.1 | Recommendations for future research

There are still limited numbers of studies assessing the UI prevalence in developing countries. More studies are needed to draw a more accurate, valid, and homogenous picture of the problem. Furthermore, there is a need to use one internationally accepted method for assessing the prevalence of UI which includes, next to others, the same sampling strategy, definition of UI, questionnaires, and age groups. Since there is a high prevalence rate of UI in different regions of the world, additional studies can help estimating the true and accurate prevalence rates worldwide.

5 | CONCLUSIONS

Despite differences in the definition of UI, assessment tools, geographical regions, and ethnicities, we were able to calculate the overall prevalence of female UI in the developing world, which is approximately 26%. However, UI prevalence rates vary widely throughout the world and, therefore, prevalence rates of 2.8% or 57.7% can both be meaningful. Surprisingly, the prevalence of UI varied widely in smaller regions. We were unable to perform an age-based analysis of UI because of the lack of data in the included studies. A multinational study in the developing world with inclusion of different age groups and regions/ethnicities as well as use of identical validated questionnaires and study methodology are necessary for future research and health care policies. Our analysis may stimulate researchers and stakeholders in designing appropriate studies for determination of the exact prevalence of UI.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Artificial Urinary Sphincter: Executive Summary of the 2015 Consensus Conference

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INTRODUCTION

The AMS800™ device, by far the most frequently implanted artificial urinary sphincter (AUS) worldwide, is considered to be the “gold-standard” when male incontinence surgical treatment is contemplated. Despite 40 years of experience, it is still a specialized procedure with a number of challenges. Here, we present the recommendations issued from the 2015 ICS AUS Consensus Group, regarding indications, management, and follow-up AMS800™ implantation or revision.

MATERIALS AND METHODS

Under ICS auspices, an expert panel met on July 10, 2015 in Chicago, IL, in an attempt to reach a consensus on diverse issues related to the AMS800™ device. Participants have been selected on the basis of their practice in a University hospital and their number of implanted AUSs according to AMS (American Medical System Holdings Inc., Minnetonka, MN) records and/or major published articles. Listed topics were selected by a pre-meeting email brainstorming by all

participants. The co-chairs distributed topics randomly (except for one) to all participants. Each participant had to propose a statement on their topic(s) for approval by the conference after a short evidence-based presentation, when possible.

RESULTS

A total of 25 urologists were invited to participate, 19 able to attend the conference. The present recommendations, based on the most recent and relevant data available in the literature as well as expert opinions, successively address multiple specific and problematic issues associated with the AMS800™ through a eight-chapter structure: pre-operative assessment, pre-operative challenges, implantation technique, post-operative care, trouble-shooting, outcomes, special populations, and the future of AUSs.

Preoperative Assessment

The AUS should be offered to individuals with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD),

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having failed conservative management. It should be considered no earlier than 6 months after prostatectomy in patients presenting with sufficient dexterity and cognitive function to operate the device.

SUI should be evaluated and verified by careful history and physical examination. UDS should be carried out at the discretion of clinicians in cases where it will help with diagnosis or counseling and follow-up, while pre-operative endoscopic evaluation of the lower urinary tract is highly recommended prior to AUS placement.

Pre-operative teaching must deliver a full explanation of device function. Furthermore, patients must be fully informed about expected rates of mechanical failure, erosion, and infection.

Preoperative Challenge

Clinicians must manage bladder neck or vesico-urethral anastomotic stricture prior to AUS placement. Surgeon must treat clinically relevant bladder neck or vesico-urethral anastomotic stricture either prior to or during AUS implantation.

Radiated patients should be informed that they constitute a high-risk population with increased adverse outcomes and associated complications, including cuff erosion as well as reoperation. When AUS implantation is considered in males presenting with post-prostatectomy incontinence, the potential indication for adjuvant radiation therapy should be taken into account, and risks and benefits of cancer control versus urinary outcome need to be weighed.

Detrusor overactivity should be treated before surgery, but does not constitute a contraindication for AUS implantation.

Implantation Technique

Surgery for AUS implantation may be performed either in lithotomy or supine position. Surgeons should be permitted their choice of razors or clippers for pre-operative preparation of the male genitalia. A 5-min pre-operative topical antimicrobial scrub is recommended and Chlorexidine-alcohol skin preparation should be performed.

Pre-operative prophylactic antibiotics should be administered for all AUS procedures within 60 min of the incision and all efforts should be made to ensure low bacterial counts at the time of AUS placement.

The perineal approach should be preferred for AUS cuff placement while trans-scrotal approach may represent a useful alternative in some select instances. The peri-urethral cuff placement should be favored while the trans-corporal implantation may be considered under certain circumstances.

Prosthesis may be filled with either sterile saline or contrast filling solution, at the surgeon's discretion. A 61–70 cmH₂O pressure-regulating balloon should be used for most patients implanted with bulbular urethral cuff and filling volume range with empty cuff should be 22–27 cc, depending on cuff size and number of cuffs. It must be placed under the abdominal wall fascia and may be inserted into the retro-pubic space or into a space created between the abdominal musculature and the transversalis fascia. The pump should be placed in the dependent portion of the scrotum, anterior to the testicle, to ensure that patients can access it post-operatively.

At the end of the procedure, urethral injury should systematically be ruled out and proper functioning should be confirmed by device cycling. Closure should finally be done multi-layered with absorbable sutures after copious irrigation.

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Post-Operative Care

A14 French urethral catheter should be left in place and removed after a brief period (usually overnight). Post-operative prescriptions should consist of oral analgesia and stool softener, if indicated by patient history, while no evidence currently supports the standard administration of post-operative antibiotics. Patients should be advised to limit physical activity during the 6-week post-operative period.

Although a virgin AUS should be activated at 4–6 weeks post-implantation, activation times after device replacement or revision may be adjusted on the basis of clinical situation and patient comfort.

Patients must be informed to forewarn healthcare professionals in the event of catheterization. They should avoid perineal pressure and be instructed to wear a *MedicAlert* type of bracelet.

Physical long-term follow-up should be ensured between 3 and 6 months post-operatively. Subsequently, yearly follow-up may be undertaken in person or by mailed questionnaire.

Trouble Shooting

Patients who complain of leakage problems after AUS placement may have technical issues with the device, another urodynamic factor or a combination of the two. Therefore, assessment of men with unsatisfactory outcomes after AUS requires a systematic evaluation to determine if AUS malfunction, urodynamic changes, or other influences occur.

Sub-cuff urethral atrophy is defined as progressive loss of initial continence after AUS implantation in the absence of erosion, mechanical malfunction or leak, and/or bladder-related causes of worsening urinary continence. In AUS patients presenting with recurrent or gradual worsening of incontinence, sub-cuff urethral atrophy should be considered as diagnosis of exclusion, after dismissing erosion on cysto-urethroscopy and mechanical failure by other modalities. Treatment should first take the most conservative revision approach, followed by procedures for cuff revision requiring complex surgery or additional hardware.

If AUS infection is suspected, cysto-urethroscopy should be undertaken to evaluate the urethra for cuff erosion. In gross or persistent infections, the entire device should be explanted as soon as it is clinically safe, and reimplantation should be delayed.

In case of urethral cuff exposure or erosion, the decision to remove the cuff exclusively or the device entirely will mainly depend on time since AUS implantation. The decision to perform concomitant urethroplasty should be based on the extent of urethral loss at the time of cuff explantation. Eroded cuffs should be replaced at different urethral locations or even through a trans-corporal approach, depending on local conditions.

Definitive diagnosis of mechanical AUS failure is demonstrated by decreased fluid in the system, either by intra-operative aspiration or pre-operative radiologic evidence of diminished fluid in the pressure-regulating balloon. In case of mechanical failure, whole system replacement is generally preferred at the time of AUS revision.

Special Populations

Inflated penile prosthesis placement after trans-corporal AUS cuff insertion should be considered a high risk and the procedure should be done in specialized, high-volume centers.

It should be noted that trans-corporal AUS could have a potentially negative impact on erectile dysfunction.

AUSs can successfully manage urinary incontinence in neurogenic bladder patients. However, it is associated with a higher numerical complication rate versus post-prostatectomy patients. Erosion is frequent in this specific population and all effort should be made to prevent its occurrence. Furthermore, long-term follow-up with bladder and upper urinary tract monitoring is essential.

Placement of indwelling urethral catheters in patients with AUSs is the most common cause of erosion and should be avoided at all costs. When catheters are absolutely required the device must be inactivated in the open position, and the smallest size urethral catheter should be used for the shortest time period (less than 48 hr). When fluid monitoring in obtunded patients is required, the device should be deactivated and an externally secured collection method, such as a condom catheter, should be attempted. In cases that require prolonged drainage (>48 hr), a supra-pubic tube should be considered, with imaging guidance.

In females, AUSs are indicated in cases of pure SUI or mixed UI in female patients if ISD is present and is the main reason for SUI. They have never been compared in this population with any technique, especially slings, and they should, therefore, be

considered as a salvage technique in bothered patients after mid-urethral sling failure in the absence of urethral mobility. AUSs in women should be contra-indicated after pelvic radiotherapy.

The retro-pubic approach is recommended over the vaginal approach because of a lower infection rate.





Future of AUS

The "ideal" AUS should be easily manipulated and inactivated, modify cuff pressure after implantation, be able to adapt occlusive cuff pressure in a real-time manner, have a simple and robust design, be safely implanted via a minimally invasive procedure, and be as cost effective as possible.

CONCLUSION

The present guidelines are issued from brainstorming by 19 urological surgeons, all considered expert in the use of the AMS800™. The most recent and relevant data available in the literature as well as expert opinions were taken into account to reach a consensus on each of the presented statements. These recommendations will undoubtedly help urologists in their daily practice with the AMS800™.

International Continence Society consensus on the diagnosis and treatment of nocturia

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Abstract

Introduction: Patients with nocturia have to face many hurdles before being diagnosed and treated properly. The aim of this paper is to: summarize the nocturia patient pathway, explore how nocturia is diagnosed and treated in the real world and use the Delphi method to develop a practical algorithm with a focus on what steps need to be taken before prescribing desmopressin.

Methods: Evidence comes from existing guidelines (Google, PubMed), International Consultation on Incontinence-Research Society (ICI-RS) 2017, prescribing information and a Delphi panel (3 rounds). The International Continence Society initiated this study, the authors represent the ICI-RS, European Association of Urology, and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU).

Results: Diagnostic packages: there is a consensus on history taking for all causalities, intake diary (fluid, food) and bladder diary, not for its duration. Pelvic (women) or rectal (men) examination, prostate-specific antigen, serum sodium check (SSC), renal function, endocrine screening: when judged necessary. Timing or empty stomach when SSC is not important. Therapeutic packages: the safe candidates for desmopressin can be phenotyped as no polydipsia, heart/kidney failure, severe leg edema or obstructive sleep apnea syndrome. Lifestyle interventions may be useful. Initiating desmopressin: risk management consensus on three clinical pictures.

Follow-up of desmopressin therapy: there was consensus on SSC day 3 to 7, and at 1 month. Stop therapy if SSC is <130 mmol/L regardless of symptoms. Stop if SSC is 130 to 135 mmol/L with symptoms of hyponatremia.

Conclusion: A summary of the nocturia patient pathway across different medical specialists is useful in the visualization and phenotyping of patients for diagnosis and therapy. By summarizing basic knowledge of desmopressin, we aim to ease its initiation and shorten the patient journey for nocturia.

Karel Everaert and Francois Hervé contributed equally to this study.

Editorial assistance was provided by Caroline Loat, PhD.

KEYWORDS

Delphi technique, desmopressin, expert opinion, guideline, interdisciplinary research, nocturia, nocturnal polyuria

1 | INTRODUCTION

Nocturia was defined in 2002 as a complaint that the individual has to wake at night one or more times to void.*¹ It affects a high proportion of adults.² Nevertheless, for a long time, the symptom received very little specific research attention as it was considered just one of a number of lower urinary tract symptoms (LUTS) indicating overactive bladder (OAB) or benign prostatic obstruction (BPO). In recent years, however, there has been growing recognition that it is a specific symptom in its own right, with wide-ranging pathophysiology (including blood pressure changes, cardiac dysfunction, fluid shift into the lower limbs, polyuria, sleep apnea, insomnia, pharmacotherapy, and polypharmacy). Furthermore, it is associated with significant negative outcomes in terms of patient health, sleep, and quality of life. Yet there is no consensus on how to identify and manage nocturia patients for the best possible outcomes.

During the 2017 meeting of the International Consultation on Incontinence-Research Society (ICI-RS) in Bristol, a nocturia think-tank discussed how to study the gaps in our knowledge to develop a practical patient-oriented diagnostic and therapeutic algorithm for nocturia.³ It was obvious that the many and varied causes of the condition are underdiagnosed and that many clinicians of different disciplines see patients with nocturia without paying specific attention to diagnosing and treating their excessive nocturnal voiding.

Nocturia guidelines are mainly hidden within broader LUTS guidelines because nocturia has historically been linked primarily to OAB and BPO, even though its main cause is nocturnal polyuria (NP).⁵ A one-year delay between onset of LUTS symptoms and consultation of a medical professional has been reported.⁶ Patients with nocturia are treated by healthcare providers from numerous different disciplines because nocturia is prevalent in many other conditions, such as cardiovascular disease, diabetes, and OAB. However, the specific condition of nocturia is ignored by most specialities, and only rarely does it improve with treatment of other underlying conditions. Different medical disciplines diagnose and treat nocturia or its underlying diseases

using their own guidelines and recommendations based on levels of evidence available from prior research and literature. Diagnostic and therapeutic “packages” from each discipline are helpful to visualize the approach to nocturia that is taken in clinical practice.

No single treatment can effectively treat nocturia in all contexts. However, desmopressin is the only evidence-based pharmaceutical therapy for nocturia.⁷ Despite this, the breadth of its use in clinical practice is limited.^{6,8} Patients with nocturia have to face many hurdles before being diagnosed properly and treated with desmopressin, instead of OAB/BPO medication.⁶ Potential reasons for this, besides side effects, are the limited knowledge of clinicians regarding the drug and how to use it, and anxiety about safety, regardless of the evidence that with the available low-dose formulations, hyponatremia is extremely rare, even in older patients.^{9,10} There is a clear need for a summary of the available information and a simple algorithm on how desmopressin should be used in adults with nocturia.

The aim of this paper, based on the International Continence Society’s (ICS) 2002 document,¹ is to:

- 1) Summarize the nocturia patient pathway.
- 2) Explore how nocturia is diagnosed and treated in the real world.
- 3) Use the Delphi method to develop a practical algorithm based on the ICS’s 2002 standardization of terminology in nocturia,¹ with a focus on what steps need to be taken before prescribing desmopressin.

2 | METHODS

An initial consultation between 12 urologists was held during the ICS 2017 meeting in Florence, with participants representing the ICS, ICI-RS, European Association of Urology (EAU), and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU). Following the meeting, a nonsystematic keyword-based literature search was performed using Google (search on “guidelines 2010-2017” + symptom/sign/disease terms [edema, hypertension, heart failure, diet, menopause, male LUTS, OAB, prolapse, renal failure, diabetes insipidus, and diabetes mellitus]). All expert panel members were also invited to add any additional important guidelines from the different

*The nocturia definition was recently updated by the International Continence Society (see the article by Hashim et al¹) as: The number of times urine is passed during the main sleep period. Having woken to pass urine for the first time, each urination must be followed by sleep or the intention to sleep. This should be quantified using a bladder diary.

medical disciplines relevant to the diagnosis and treatment of nocturia and its underlying causes. Some of these guidelines specifically target nocturia, and others aspire to target the underlying cause.

In areas where there was an absence of evidence and consistency between guidelines, the Delphi method was used to obtain an expert consensus—see Figure 1 for details. After the ICS 2017 meeting, a survey to gain views regarding the format, content, and additional panel members needed for the consensus report was distributed among nine of the urologists who agreed to participate as authors of the report, using the www.surveymonkey.com platform (round 1); 75% agreement was needed to reach a consensus. As part of this round, it was decided that a broader range of experts should be included in the panel for round 2 to provide a multidisciplinary perspective. The initial Delphi panel for round 2 comprised of 20 clinicians, but 1 invitee did not respond to any of the rounds, and so the consensus was reached based on the views of the remaining 19 who participated. These 19 included 11 urologists (9 from the original group), 1 gynecologist, 1 epidemiologist/physiotherapist, 1 sleep specialist, 1 nephrologist, 1 geriatrician, 1 general practitioner, 1 neurologist, and 1 pharmacist. The Delphi panel members were asked to indicate whether they agree or disagree with statements about the diagnosis and treatment of nocturia patients. Again, 75% of the panel had to agree to achieve a consensus. If there was a criticism of the statement/question, it was reformulated for an additional subround, of which there were 2 in round 2 (Figure 1). In round 3, a different set of statements were presented to the multidisciplinary Delphi panel, and the same level of agreement was needed (ie, $\geq 75\%$) for a consensus, but panel members were also asked to rate appropriateness of the statement on a scale of 1 to 9 (1-3 inappropriate; 4-6 uncertain; 7-9 appropriate). From the panel responses, a median appropriateness score was derived. As in round 2, if there was a criticism of the statement/question proposed, it was reformulated for an additional subround.

This consensus report on the diagnosis and treatment of nocturia is therefore based on real-life clinical practice, guideline/literature reviews, and where needed, an expert consensus obtained using the Delphi method.

3 | RESULTS

The real-life diagnostic and therapeutic pathways for nocturia patients, based on the underlying causes of nocturia,⁶ are summarized in Figure 2. There was a consensus that we should treat bothersome nocturia but there was no consensus on whether this should be

confined to two or more voids per night, or include any level of nocturia. There was a consensus that nonbothersome nocturia, or convenient voids, should not be treated with desmopressin.

3.1 | Diagnostic packages

The diagnostic packages in each subdiscipline dealing with nocturia patients are summarized below with reference to guidelines, prescribing information and the Delphi consensus—see Table 1 for an overview. History-taking, physical examination, and clinical assessment including disease-specific questionnaires (DSQ) are recommended diagnostic tools. The EAU 2018 guidelines suggest the severity and bother of individual LUTS (nocturia) should be identified with a symptom score, supplemented by directed questioning if needed. Examples of nocturia-specific questionnaires are the international consultation on incontinence questionnaire—nocturia; nocturia quality of life questionnaire, and the nocturia impact diary. In line with the diagnostic considerations from each of the relevant therapeutic areas, a questionnaire has recently been developed to help to unify approaches to nocturia diagnosis.¹¹ The TANGO questionnaire is a short patient-administered screening metric designed to help the clinician assess nocturia and diagnose these different contributory mechanisms. Although some further validation is needed, the tool is available for clinical use in English and Dutch, and validation in French and Spanish is ongoing.

3.1.1 | The lower urinary tract package

History-taking with or without the use of validated questionnaires is structured based on symptoms of the filling phase and the emptying phase of the bladder.^{4,12} Physical examination focusses mainly on assessment of the prostate, vaginal examination for pelvic organ prolapse, and any urethral pathology, according to the relevant guidelines.

The 2018 EAU male LUTS guidelines⁴ recommend to add urine analysis, serum prostate-specific antigen (PSA) test (if a diagnosis of prostate cancer will change the management), and to measure postvoid residual urine volumes.

Three-day bladder diaries, including sleep and wake up time, as well as the next morning's first void, have been recommended as giving the optimal balance between compliance and reliability.¹³ The Delphi panel agreed (15/19) that it is necessary to demonstrate the presence of NP using a bladder diary before prescribing desmopressin. There was no consensus on the duration of

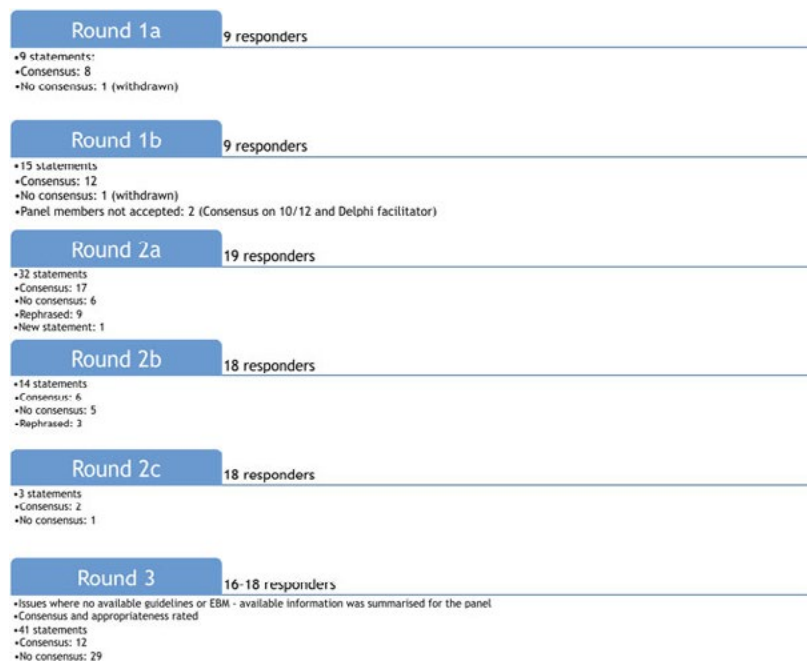


FIGURE 1 Summary of the Delphi process [Color figure can be viewed at wileyonlinelibrary.com]

bladder diary required, including on whether patients with cognitive impairment or impaired executive function warrant the use of a shorter duration of bladder diary. Approximately half of the panel (9/17) believe that all patients need to complete a 3-day diary; while the remainder (8/17) believe that the diary period can be shortened if the patient had his/her symptoms during the observation day. In the latter case, it would be necessary to include a question in the bladder diary regarding whether this was a typical night for LUTS, or if it was better or worse than usual, for example, to give an indication of whether the case night was indicative of the patient's condition. Even if there was an accurate questionnaire (>95% accuracy) that could predict NP, 13/18 (no consensus, 72%) would still ask patients to complete a bladder diary. This perseverance with the use of a bladder diary may reflect an underlying lack of conviction amongst the panel that such a questionnaire could feasibly be developed.

The maximum voided volume, void frequency, and the ratio of nocturnal to 24-hour urine production are the most used diary parameters to study and assess nocturia.¹⁴ A maximum voided volume of 350 mL is generally considered as reduced without real evidence to support this criterion. When the nocturnal urine production exceeds the maximum voided volume, then

nocturia is predictable, with some safety margin (nocturia index of >1.3 is generally accepted as a reliable cut-off).¹⁵ The frequent causes of reduced voided volumes include an OAB and residual urine (secondary to obstruction or detrusor underactivity). A residual urine measurement is, therefore, part of the initial assessment of nocturia.⁴ When reduced voided volumes are seen, imaging, urodynamics, and occasionally cystoscopy are performed, as appropriate.

Excessive nocturnal or 24-hour urine output is diagnosed using a bladder diary. According to the ICS definition, NP is diagnosed if more than one-third (>33%) of the 24-hour urine volume is produced during the night in patients over 65 years, and after excluding patients with 24-hour polyuria (>40 mL/kg/d). In the United States, the FDA's regulatory decision-making regarding desmopressin use has been based on these definitions. In younger people (21-35 years) the cut-off for NP is >20% of 24-hour urine.¹ No definition of NP between these age categories has been established. The "one-third" definition in older people is the most widely used definition and has a high sensitivity but low specificity. Other definitions are available,¹⁶ but the most appropriate definition of NP is still the subject of much discussion.^{17,18} However, the definition of NP is not the scope of this document.



FIGURE 2 Summary of the nocturia patient diagnosis and treatment pathways. Note that obesity can be indicative of excess caloric intake but is also associated with metabolic syndrome and is therefore also relevant to the cardiovascular pathway. Clinical specialties that deal with specific conditions may vary by country—for example, OSAS patients may be treated by a variety of specialists (including sleep, ear nose, and throat). BOO, bladder outlet obstruction; OAB, overactive bladder; OSAS, obstructive sleep apnea syndrome; RLS, restless legs syndrome [Color figure can be viewed at wileyonlinelibrary.com]

The Delphi panel considered that, in women, a pelvic examination is necessary before starting desmopressin either in all cases (7/19) or in those women with daytime symptoms (8/19)—an overall consensus of 15/19 in favor of pelvic examination.

There was a consensus from the panel that a PSA check need not be standard in all older men before starting desmopressin (0/18); 7/18 answered that there is no need to check PSA and 11/18 agreed that PSA measurement is only appropriate when considered necessary for other reasons. LUTS have no relation to PSA except in advanced prostate cancer (owing to the associated bladder outlet obstruction), and NP specifically is not associated with prostate cancer.

There was a consensus that older men with nocturia should complete a DSQ (13/17, median 7.4), post-void residual (14/17, median 7.4), bladder diary is mandatory (14/17, median 8.7), and there was no consensus on the need for a digital rectal examination (10/17, median 7).

3.1.2 | Nephrological causes of nocturia and their diagnosis

Renal causes of polyuria include renal diseases such as nephrogenic diabetes insipidus and loss of different circadian rhythms of the kidney, for example through aging of the kidney.^{19,20} Nephrogenic diabetes insipidus can also be caused by some medications, including lithium. Renal failure can also lead to leg edema with NP as a consequence.

When (nocturnal) polyuria is found, it is possible to diagnose the cause of the excess in urine output using renal function profiles.¹⁹ These renal function profiles help in distinguishing whether the excess in urine production is due to an increase in free water clearance (vasopressin-related), osmotic diuresis (mainly salt, but can be urea [protein], glucose [diabetes], calcium [hypercalciuria], or lithium), or a combination. However, renal function profiles are only advised after the failure of desmopressin therapy, and for research purposes. In clinical practice, elevated free water clearance is the most

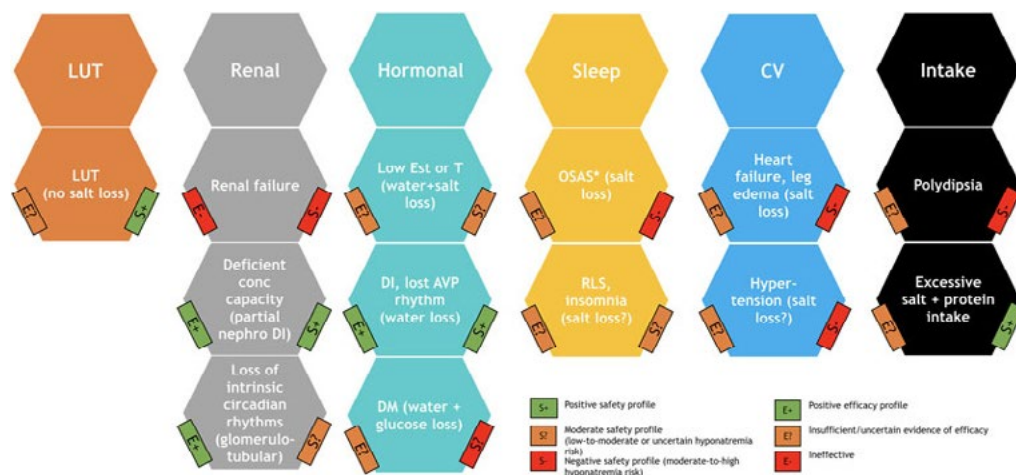


FIGURE 3 Phenotyping nocturia for uncontrolled causalities when prescribing desmopressin, based on guidelines, prescribing information or Delphi panel. *Based on evidence and guidelines to use CPAP for sleep apnea and the high levels of ANP and nocturnal salt loss. Conc, concentration; CV, cardiovascular; DI, diabetes insipidus; DM, diabetes mellitus; Est, estrogen; E, efficacy; LUT, lower urinary tract; OSAS, obstructive sleep apnea syndrome; RLS, restless legs; S, safety; T, testosterone [Color figure can be viewed at wileyonlinelibrary.com]

frequent cause of NP throughout the lifespan and increases with age. The second most frequent etiology is an increased sodium clearance (eg, due to excess intake, leg edema, heart failure, hypertension, obstructive sleep apnea syndrome [OSAS], and medication), and this also increases with age. In summary, at first assessment, phenotyping (Figures 2 and 3) based on history taking, concomitant medication and a general physical examination help the clinician to implement lifestyle interventions and therapies such as desmopressin (assuming minimum glomerular filtration rate [GFR] of 50 mL/kg/min).

3.1.3 | Hormones and nocturia

Vasopressin is the main water-regulating hormone in our body. Vasopressin deficiency and vasopressin resistance of nephrogenic (receptor) origin are the main mechanisms leading to a lack of antidiuretic response within the body. The result is 24-hour polyuria and polydipsia, known as diabetes insipidus, which is a rare condition diagnosed via a bladder diary and a low morning (fasting) serum and urine osmolality. An abnormal circadian rhythm of vasopressin is the main mechanism for NP.^{21,22} Asplund described a lack of circadian rhythm in patients with NP and nocturia in both men and women,²³ but plasma levels in adults without nocturia peak at around 8 pg/mL in men and 4 pg/mL in women—both with a circadian rhythm.²⁴ These levels fall and a gender difference becomes more obvious in adults, as described

by Graugaard et al,²⁴ and levels are even lower in the elderly, as described by Asplund. There is further evidence of an effect of the menstrual cycle in women,²⁵ which may also increase female sensitivity to desmopressin. If doses are given in identical strengths in men and women (not measuring the dynamic endpoint of NP), we would expect more safety concerns in women, especially elderly women. Vasopressin itself is difficult to measure as a routine test; copeptin is a by-product of vasopressin and is being explored as a biomarker of vasopressin levels.

The sex hormones are also involved in regulation of diuresis.²⁶ Deficiency in sex hormones (estrogen, testosterone) is diagnosed based on history taking and physical examination and can be confirmed with blood analysis. Some validated questionnaires are available for diagnosing menopause. Nocturia is not discussed in these guidelines.²⁷

3.1.4 | Sleep and the central nervous system (CNS) as a cause of nocturia

Sleep pathology, insomnia, and sleep disruption are well-known causes of NP and nocturia,^{28,29} and as such, they need to be diagnosed, especially as they are associated with morbidity and mortality.^{30–32} In epidemiological studies, nocturia is associated with restless legs syndrome.³³ History taking and physical examination can be complemented with questionnaires including the Pittsburgh Sleep Quality Index,³⁴ which screens for both

TABLE 1 Summary of diagnostic and therapeutic packages

Diagnostic		Therapeutic		
Diagnostic test	Guidelines (see the Supporting Information Materials for refs.)	Prescribing information for dDAVP	Delphi panel	Pharmacological
Lower urinary tract				
History and physical examination, DSQ	Nocturia within other guidelines (OAB, LUTS)	Nocturia, nocturia due to nocturnal polyuria	Consensus	OAB/BOO medication
Pelvic—digital rectal examination	+	—	Consensus	Bladder training (level 2 evidence) Pelvic floor training (level 2 evidence)
PSA	+	—	If judged necessary	Consider combination therapy for refractory nocturia (Delphi consensus)
PVR	+	—	If judged necessary	Botulinum toxin, sacral neuromodulation
	+	—	Consensus	Prostatic and urethral surgery, prolapse correction
Kidney				
History and physical examination, DSQ	Nocturia within other urological guidelines	Nocturia, nocturia due to nocturnal polyuria	Consensus	No dDAVP if eGFR <50 (Delphi consensus)
Need/use for/off questionnaire for screening NP	+	—	No consensus	Consider dDAVP in low/moderate renal failure
Bladder diary	+ 3 d	+	1. Consensus on the use of a diary, no consensus on duration (50/50) 2. No consensus on the definition, NPI33 is widely used and practical but too sensitive. Use the right definition for the right population	Antihypertensive medication

(Continues)

TABLE 1 (Continued)

Diagnostic		Guidelines (see the Supporting Information Materials for refs.)		Prescribing information for dDAVP	Delphi panel	Lifestyle	Pharmacological
Diagnostic test							
Baseline GFR estimation	+	+		+	<ol style="list-style-type: none"> No consensus, as by PI Consensus no desmopressin below 50 mL/kg/min 		Kidney transplantation
Baseline serum sodium	+	+		+	<ol style="list-style-type: none"> Age cutoff as by PI, consensus, but not stringent Consensus <130 mmol/L is contraindication for desmopressin; majority (66%) prefers >135 Timing and having an empty stomach or not are of no importance to the timing of test, consensus 		Nephrectomy
History and physical examination, DSQ	+	Nocturia not mentioned		-		Sleep hygiene	Menopause-related nocturia should be treated with lifestyle interventions and HRT (Delphi consensus)
Serum LH, FSH, testosterone, estrogen	+	Nocturia not mentioned		-		Limit drinking	dDAVP for patients with blunted AVP secretion at night
History and physical examination, DSQ	+	Nocturia not mentioned		-		Bladder/pelvic floor training	CPAP in patients with OSAS (level 1a evidence)
Polysomnography	+	Nocturia not mentioned		-	RLS: no consensus to refer/diagnose	Weight loss	Sleep clinic/dDAVP in patients with insomnia, nocturia, and NP (consensus)
Cardiovascular and edema		Nocturia not mentioned		-		Physical activity	Prampexol, sleep aids
						Physical activity, weight loss	Antihypertensive medication, timed diuretics

(Continues)

TABLE 1 (Continued)

Diagnostic		Therapeutic			
Diagnosis	Guidelines (see the Supporting Information Materials for refs.)	Prescribing information for dDAVP	Delphi panel	Lifestyle	Pharmacological
History and physical examination and assess leg edema, DSQ	+	-		Salt restriction	dDAVP with caution only in those with Class I mild congestive heart failure and no severe leg edema
BNP	+ (excludes heart failure if suspected)	-		Postural drainage stockings	Varicose vein surgery
Intake	Nocturia not mentioned	+		Fluid restriction	Consider dDAVP
History and physical examination, DSQ, Intake diary	+	+ (limited to fluid intake)	Consensus useful (fluid, food, and calories)	Salt, protein, and calorie restriction – balanced diet	Bariatric surgery

Abbreviations: AVP, arginine vasopressin; BNP, brain natriuretic peptide; BOO, bladder outlet obstruction; CPAP, continuous positive airway pressure; dDAVP, desmopressin; DSQ, disease-specific questionnaire; FSH, follicle stimulating hormone; GFR, glomerular filtration rate; HRT, hormone replacement therapy; LH, luteinising hormone; LUTS, lower urinary tract symptoms; NP, nocturnal polyuria; NP133, nocturnal polyuria index >33%; OAB, overactive bladder syndrome; OSAS, obstructive sleep apnea syndrome; PI, prescribing information; PSA, prostate-specific antigen; PVR, post-void residual urine; RLS, restless legs syndrome.

nocturnal and diurnal symptoms related to sleep disorders. The Berlin questionnaire³⁵ and the STOP questionnaire³⁶ are screening tools for OSAS. Polysomnography is performed when a diagnosis of sleep disorders is suspected.

Parkinson's disease and restless legs syndrome are conditions characterized by a dopamine deficiency.^{37,38} Sleep disruption and deprivation are associated with low dopamine levels in the central nervous system.³⁹ Both Parkinson's disease and restless legs syndrome are associated with NP and a reduced bladder capacity due to OAB and sphincter dysfunction.⁴⁰⁻⁴² However, a recent study suggested that the prevalence of NP in Parkinson's disease is no higher when compared with a control population, indicating some uncertainty in this regard.⁴³ The diagnosis of a brain- or sleep-related cause of nocturia is made clinically, and when suspected, patients need to be referred to neurologists or sleep specialists.

Evidence-based medicine⁶ supports the need to refer and diagnose nocturia patients with suspected obstructive sleep apnea. Among the Delphi panel, there was no consensus whether suspected restless legs syndrome required a referral (9/17 [6 would treat NP simultaneously with referral]) or simply initiation of treatment for NP (8/17).

3.1.5 | Cardiovascular causes of nocturia

Hypertension is associated with nocturia and NP.²² Nondipping hypertensive patients are a subgroup who do not exhibit a nocturnal reduction in blood pressure. There is an association between nondipping hypertension and nocturia,⁴⁴ and a specific association has been reported between NP and nondipping hypertension.⁴⁵ Children with enuresis have also been found to have higher nocturnal blood pressure than controls.⁴⁶ Nondipping hypertension is associated with increased morbidity.⁴⁷ In addition, postural hypotension with low blood pressures when standing results in higher blood pressures when supine. Diagnosis is simply made by measuring the blood pressure as part of the general clinical examination. Available guidelines in this area do not discuss nocturia.⁴⁸⁻⁵³

The metabolic syndrome is strongly associated with nocturia and many conditions predisposing to NP,^{54,55} and it is an important burden for healthcare systems worldwide. The condition needs to be diagnosed when clinically suspected in patients with nocturia. Again, available guidelines in this area do not mention nocturia.^{56,57}

Heart failure often coincides with renal failure (30%-40%) and correlates with increased mortality. This cardio-renal syndrome presents as elevated brain natriuretic peptide (BNP) with hypovolemia (normal serum

sodium) or as overfilling (hyponatremia). Both conditions coincide with an elevated creatinine, a bad estimator of GFR in these patients, and demand referral before initiation of desmopressin or timed diuretic therapy.⁵⁸

Right-sided heart failure, in particular, is characterized by fluid retention and swelling of the abdomen, legs, and feet (<https://www.mayoclinic.org/diseases-conditions/heart-failure/symptoms-causes/syc-20373142>). Edema, and especially leg edema, causes NP and nocturia through resorption of fluid when supine,^{59,60} resulting in an immediate excess in urine output and a delayed increase in ANP-related salt diuresis. Leg edema is seen with liver, heart or kidney disease or following varices of the legs, lack of physical activity or muscle paralysis. Concomitant medications that can cause edema are listed in the section below on concomitant medication. Diagnosis of edema is based on expert opinion rather than empirical evidence, and the available guideline documents for edema do not mention nocturia.^{48,49}

As mentioned above, there was a consensus that older men with edema and nocturia should complete a DSQ (13/17), have a postvoid residual measurement (14/17), and a clinical evaluation of cardiovascular and leg edema (13/17); a bladder diary is mandatory (17/17). There was no consensus on a digital rectal examination (10/17). There was a consensus that older people with nocturia should have their blood pressure measured (13/17, median appropriateness 8). Older people with leg edema and nocturia were considered likely candidates for cardiovascular aetiological factors (13/17, median appropriateness 7), and it was agreed that clinical examination should focus on this pathophysiology (13/17, median 7).

3.1.6 | Fluid and food intake as a cause of nocturia

High intake of water, salt, or protein results in an increased excretion by the kidney and can result in NP and nocturia. An excess intake of osmoles leads to thirst, and increased fluid intake—a second reason for NP. An excess intake of calories results in obesity which may, even without the presence of the metabolic syndrome, result in NP due to the higher intra-abdominal pressure, mainly when supine, as a result of obstruction of the respiratory tract.⁶¹ History taking, physical examination, recording of fluid and food intake on a bladder diary, and hypothetically renal function profiles can diagnose the excess of intake of sodium (salt) and ureum (protein).^{62,63}

Dietary guidelines discuss the treatment of obesity^{56,64} but nocturia-related recommendations are not available. The consensus panel agreed that it is appropriate (13/17, median appropriateness 7) to investigate caloric intake and physical activity through history taking and/or diaries.

3.1.7 | Concomitant medication leading to nocturia

Concomitant medication is often difficult to interrupt or change but might have an important impact on nocturia through increasing or decreasing diuresis, changing bladder function, or through interfering with sleep. Other factors that will influence the impact of concomitant medication are the timing of administration, mode of administration, formulation (long- vs short-acting), and so on. Most of these factors have not been well studied.^{3,14}

For many medications, the net result on diuresis (water and osmotic diuresis) is unknown and insufficiently studied, and many medications have contradictory effects on water and osmotic diuresis. Even desmopressin, known to solely impact on free water excretion, can cause water retention resulting in renin-angiotensin-aldosterone system suppression, ANP, release and osmotic diuresis.

Another example of the contradictory effects of concomitant medication is calcium channel blockers—these increase salt excretion⁶⁵ to lower blood pressure, but side effects include leg edema, which can potentially worsen nocturia when the edema fluid is resorbed during the night.

Medications that typically increase diuresis are diuretics, all antihypertensive medication, progesterone, melatonin, lithium, and SECT-2-inhibitors (antidiabetic patients).⁶ Other medications decrease diuresis, such as the older antidiabetic patients, antidepressants, antiepileptics, estrogens, testosterone, corticoids, and nonsteroidal anti-inflammatory drugs (NSAIDs).

Medications that typically cause leg edema are antidepressants (monoamine oxidase inhibitors, trazodone), antihypertensives (beta-blockers, clonidine, hydralazine, methyldopa, minoxidil and so on), antivirals (acyclovir), hormones (sex hormones), NSAIDs (celecoxib, ibuprofen), and some chemotherapeutics and cytokines.⁶

There is a consensus that the following conditions are a contraindication for desmopressin: congestive heart failure (16/19), polydipsia (15/19), and concomitant medication with a high risk of hyponatremia (16/19).⁶⁶ There was no consensus for peripheral edema (12/19), uncontrolled hypertension (13/19), uncontrolled diabetes (11/19), and oral steroids (6/19). For nasal/inhalation steroids there was a reversed consensus (0/19).

Diagnostic packages:

- Consensus on history taking or questionnaires for all causalities.
- Pelvic (women) or rectal (men) examination when judged necessary.
- Blood pressure and edema check is necessary.

- Consensus for bladder diary, but not for its duration (3 days suggested).
- Consensus for diaries on sleep, intake (fluid and food), and physical activity.
- Consensus for postvoid residual measurements.
- PSA, serum sodium check (SSC), renal/heart function, and endocrine screening when judged necessary.
- Timing or empty stomach when SSC performed is not important.

3.2 | Therapeutic packages

Lifestyle interventions targeted towards the aetiology of nocturia may be useful in some patients (Figure 4).

3.2.1 | Lower urinary tract therapy

There is level two evidence that treating dysfunctions of the bladder and the prostate (eg, OAB and BPO) with lifestyle interventions such as bladder training and pelvic floor training, or evening exercise (eg, walking the dog), as well as medication or surgery, improve nocturia.⁶

There was a consensus from the panel that combination therapy should be considered for nocturia that is refractory to initial treatment (18/19).

3.2.2 | Nephrological causes of nocturia and their therapy

Lifestyle interventions aim to prevent rather than treat renal disorders, for example by avoiding obesity, hypertension, and diabetes. Salt, protein, and caloric restriction are advised in patients with renal failure but there is no evidence of its effect on nocturia. Desmopressin can have some effect in partial nephrogenic diabetes insipidus but is not the primary choice in patients with severe renal failure as the risk of hyponatremia is much higher (Table 3). For those undergoing an investigation of renal function, there was a consensus that desmopressin should not be prescribed if eGFR is <50, and that higher limits are dependent on local prescribing information. In patients with low to moderate renal failure, as is seen in most of the older population, a loss of circadian rhythms in diuresis is found and these patients are potentially good candidates for desmopressin therapy.

3.2.3 | Hormones and nocturia therapy

In the 2002 standardization document,¹ low estrogen and menopause are recognized as a cause of nocturia, and androgen deprivation is also associated with LUTS and nocturia. There is no evidence-based medicine to demonstrate that hormonal substitution in



FIGURE 4 Lifestyle interventions in nocturia according to pathophysiology. DM, diabetes mellitus [Color figure can be viewed at wileyonlinelibrary.com]

postmenopausal women is an effective treatment of nocturia (ICI-RS 2017).²⁶ The 2015 NICE guidelines (<https://www.nice.org.uk/guidance/ng23>) state that there is a good evidence that hormonal substitution is helpful for vasomotor symptoms (hot flushes) and for vaginal atrophy and its consequences, but do not mention nocturia.

There was a consensus that menopause-related nocturia and hot flushes should be treated with lifestyle interventions and hormone replacement therapy (17/18). These approaches were not considered useful when

menopause is asymptomatic, except for nocturia (5/18). Desmopressin should not be given during the first treatment consultation in the presence of menopausal symptoms (1/18 if menopausal symptoms), but when there is nocturia without menopausal symptoms, there was nearly a consensus that desmopressin can be given (13/18 [74%]).

Patients with NP due to a blunted increase in AVP secretion at night, leading to an increase in free water clearance, are good candidates for desmopressin therapy.⁶⁷ Patients with 24-hour polyuria due to central diabetes insipidus (in which production of AVP is compromised) are also effectively treated with desmopressin,⁶⁸ which is in these cases a type of hormone replacement therapy.

3.2.4 | Sleep and the CNS in nocturia therapy

There is level 1a evidence for the use of CPAP in patients with OSAS. There is only low level 2 or lower level evidence that sleep aids, treatment of low dopamine and treatment of restless legs syndrome have an impact on nocturia (ICI-RS 2015).⁴²

There was a lack of consensus from the panel regarding the treatment of patients with insomnia, nocturia, NP, and a diagnosis of RLS. There was no consensus (10/17) whether patients with insomnia and NP should be treated for insomnia and with desmopressin at the same time (median appropriateness was 7). There was no consensus on treating RLS, insomnia,

TABLE 2 Prescribing information for different desmopressin formulations indicated for nocturia, which is likely to influence clinician judgments

	Desmopressin 0.2 mg, tablets	Nasal spray 0.83-1.66 µg/0.1 mL (Noctiva)	Sublingual wafers 25-50 µg, (Nocturna)
Age for baseline sodium checks and follow up	65	65	65
Fluid restriction	Restrict	Moderation advised (do not drink large amounts close to bedtime)	Restrict 1 h before to 8 h after administration
GFR (lower limit for prescribing)	50 or 60 ^a	50	50-60 ^a
Sodium checks after baseline (≥65 y)	3 d + after uptitration	Within 7 d + after uptitration	4-8 d + 1 mo or 4-8 d, 1 mo, every 3 to 6 months, depending on clinical need
Cardiovascular contraindication	Cardiac insufficiency or conditions requiring diuretics	NYHA class II or higher CHF Diuretic use	Heart failure, edema
Frail elderly	Not mentioned	Not mentioned	Contraindicated

CHF, congestive heart failure; GFR, glomerular filtration rate; NYHA, New York Heart Association

^aModerate to severe renal failure or <50-60 mL/min depending on the formula used and cut-off used.

TABLE 3 Consensus summary of risk management for hyponatremia when considering desmopressin administration

Risk management	Standard vigilance to hyponatremia symptoms	Standard vigilance to hyponatremia symptoms + serum sodium check (SSC)	Contraindication
	< 65 y	65 y or older	Frail older people
	Baseline sodium > 135	Baseline sodium 130-135	Baseline sodium below 130
	eGFR > 50-60	eGFR 50-60	eGFR <50
	No concomitant medication that can cause hyponatremia	Concomitant medication weakly or moderately related to hyponatremia	Concomitant medication strongly related to hyponatremia
	No leg edema	Low to moderate leg edema	Important leg oedema
	No heart failure	Heart failure (NYHA class I)	Heart failure (NYHA class II or higher)
	No diabetes mellitus or hypertension	Controlled diabetes mellitus or hypertension	Uncontrolled diabetes mellitus or hypertension
		Need for a higher dose, up-titration	Psychogenic polydipsia (>3 L/d)
		Higher risk in women	Higher risk in women
Formulation	Any desmopressin formulation	Low dose desmopressin	Treat condition if possible and wait with desmopressin
SSC	No consensus on SSC	Consensus on SSC	-

insomnia with RLS, or NP with RLS and insomnia in any combination.

In patients with insomnia, nocturia, and NP without a diagnosis of RLS, there was a consensus to treat NP (14/17) but this was split across treatment of NP per se (8/17), referral to a sleep clinic (3/17), or both (6/17). Reasons for this lack of agreement across the panel on the appropriate steps may relate to a lack of evidence on which to base treatment of insomnia with nocturia/NP, or perhaps to the range of specialisms in the group with inconsistent views on the role of other disciplines, e.g., for example, sleep medicine.

3.2.5 | Cardiovascular causes of nocturia and their therapy

There is ample evidence that treating heart conditions, increasing physical activity, salt restriction, losing weight, and preventing edema treats nocturia.⁶

Desmopressin for nocturia is contraindicated in patients with mild (class II) to severe (class IV) congestive heart failure (New York Heart Association Class II to IV) or uncontrolled hypertension, and should be used with caution (eg, monitoring of volume status) in patients with New York Heart Association Class I mild congestive heart failure because of the risk of fluid overload and electrolyte abnormalities. Patients with heart failure may also be at increased risk for low sodium concentrations.⁶⁹

In people with moderate cardiac failure, there was a consensus that this condition should be treated before any attempt to address nocturia specifically (16/17, median 9). Use of desmopressin in such cases is completely inappropriate (16/17, median 2). There was no consensus concerning the use of daytime furosemide (4/17, median appropriateness 5).

In older people with NP, nocturia, and hypertension, there was no consensus as to whether hypertension should be treated first (11/18, median appropriateness 7). Treatment of NP first was considered inappropriate by 8/17 (median 4). The treatment of hypertension and NP simultaneously also had no consensus (5/17 inappropriate, 6/17 uncertain, and 6/17 appropriate; median appropriateness 5). The Delphi panel did not consider it useful to change antihypertensive drugs or their timing (other than diuretics) (8/17, median 6) to address nocturia.

In patients with varicose veins but no cardiac failure, there was no consensus on treating veins first (9/18, median 6) nor on using desmopressin first (10/17 inappropriate, 3/17 uncertain, and 4/17 appropriate; median 4).

3.2.6 | Intake as a target of nocturia therapy

Limiting excess fluid intake and changing the type of fluid is advised in most LUTS guidelines.⁷⁰ Less is known about the effect of diet and weight loss.⁶ Weight loss will decrease hyperfiltration and diuresis. Low protein intake

will decrease salt and ureum output and osmotic diuresis. Salt restriction might decrease osmotic diuresis. Low carbohydrate intake will not change diuresis directly. Low fat intake will not directly affect diuresis. During most diets, an increase in water intake is advised, increasing water diuresis. In conclusion, from a theoretical, nonevidence-based viewpoint, a protein-rich and fat/carbohydrate-restricted diet might increase urine output as well as reduce it in the longer-term via weight loss. A well-balanced calorie-restricted diet seems the most logical approach to avoid high excretion of ureum and salt in patients with nocturia. In general, guidelines suggest caloric restriction and summarize that a high protein intake results in more efficient weight loss.^{56,57}

There was no consensus from the Delphi panel on appropriate therapeutic options for patients with high BMI and nocturia (including losing weight [no consensus 9/18, median appropriateness 6]; weight loss with desmopressin [5/18, median 5]; desmopressin alone [6/18, median 5]; and adapting diet when there is a high osmotic load [6/18, median 5]).

Therapeutic packages:

- There is only good evidence for desmopressin and for CPAP.
- For all other therapies, the evidence is moderate (furosemide, OAB-BPH medication) or weak for most causalities.
- The safe candidates for desmopressin can be phenotyped as no polydipsia, heart/kidney failure, severe leg edema, or OSAS.

3.3 | Initiating desmopressin treatment

NP due to reduced nocturnal vasopressin is the primary target for desmopressin. Salt-related NP is associated with other causes such as sleep apnea (the primary target for CPAP), edema, obesity, hypertension, heart failure, and high salt intake. There is level 1a evidence that desmopressin and CPAP treat nocturia.^{4,7} A summary of the prescribing information for available desmopressin formulations for nocturia from the United States, Australia, and Europe is given in Table 2.

The panel agreed that bothersome nocturia should be treated (17/19); however, there was no consensus regarding what level of severity warrants treatment (≥ 2 voids/night [5/19], or any nocturia [12/19]). It was agreed that nonbothersome nocturia or convenience voids (ie, secondary to waking for a different reason) should not be treated with desmopressin (1 and 0/19).

There was no consensus among the Delphi panel as to an appropriate age limit above which serum sodium

should be checked before desmopressin treatment. This was also true for renal function (eGFR). This lack of consensus is likely affected by differences in prescribing information and recommendations between countries. However, there was a consensus that any age limit should not be treated too stringently, and patients who are near the limit may also be checked before treatment (17/19).

The Delphi consensus was that patients with a baseline serum sodium of ≤ 130 mmol/L should not be prescribed desmopressin (18/19), with the panel split between a cut-off of >130 mmol/L (6/19) and >135 mmol/L (12/19) for treatment. Again, the panel's views on this issue might be influenced by regional regulatory rules and prescribing information.

Dilutional hyponatremia takes several days of positive water balance to build up. To decrease by 5 mmol/L a positive water balance of 2 L is needed. There was a consensus (15/17) that SSCs can be performed at any time of day and are not affected by whether or not the stomach is empty (although note that polydipsia is a contraindication of the drug). There is sufficient literature to support that a sodium check can be done at any time of the day.⁷¹

The following conditions are agreed to be contraindications for desmopressin use: congestive heart failure (16/19), polydipsia (15/19), and concomitant medication with a high risk of hyponatremia (16/19). Concomitant medication with low risk for hyponatremia (5/19), peripheral edema (12/19), uncontrolled hypertension (13/19) or diabetes (11/19), oral steroids (6/19), and nasal steroids (0/16) did not reach consensus.

The panel agreed that women are more prone to hyponatremia and that this should have implications for desmopressin therapy and its follow-up (16/19). There is a consensus that some form of fluid restriction is needed by patients prescribed desmopressin (18/19)—either following thirst (14/19) or strict fluid restriction (4/19).

With earlier formulations of desmopressin (0.2 mg tablets), hyponatremia was seen mainly in older populations, leading to a restriction in use to those below 65 years of age. Lowering the dose to provide an antidiuretic effect of 6 to 8 hours was the logical way to treat the older (especially female) population. Low dose therapy is not a well-defined term but is today the best way to describe the newer formulations in the market, which have both been tested in an older population. Low dose therapy is advisable in older (but not frail) patients and serum sodium monitoring is needed; such monitoring can be individualized depending on patient-specific factors (eg, age, concomitant medication) and comorbidities (16/19). Frail older patients with bothersome nocturia and comorbidities or other risk factors should first be treated for other issues and comorbidities and then, if still required, desmopressin should be initiated with careful monitoring (15/18).

Young healthy patients can be treated with any licensed desmopressin formulation (15/18).

Initiating desmopressin:

- Risk management consensus on classification into three clinical pictures: (1) standard vigilance to symptoms of hyponatremia, (2) SSC, and (3) contraindications.
- Decision-based on age, renal function, heart failure, frailness, edema, baseline serum sodium, drinking habits, and medication.
- Low-dose formulations preferred in patients needing SSC.

3.4 | Follow-up of desmopressin therapy

Critical to the appropriate use of desmopressin and its analogs is an established schema for monitoring of sodium homeostasis in the acute and chronic phase of therapy. Contingent on stable dosing and otherwise unchanging comorbidities is the realization that shifts in fluid ingestion may potentiate the risk of hyponatremia in an otherwise stable patient. Therefore, an informed and the engaged patient is critical to desmopressin safety. In addition, acute alterations in concomitant comorbidities should be assessed for their potential to impact sodium levels.

There are various approaches to sodium monitoring in the literature. Before starting therapy, baseline sodium levels must be obtained in patients at risk for hyponatremia. Bioavailability and formulation delivery appear to have an impact on desmopressin half-life and the area under the curve (indicative of drug exposure), both of which impact the risk of hyponatremia.¹⁷ There is some evidence from analysis of a merged database¹⁷ that a sodium monitoring plan should begin with a baseline sodium ≥ 135 mmol/L with additional SSC at week 1 and month 1 after initiation of desmopressin in patients who are at increased risk (eg, due to older age, or concomitant medications). This conclusion is based on the fact that most clinically significant cases of hyponatremia were seen within 2 to 3 weeks of treatment initiation. A noteworthy observation is that time to return to normal after cessation of treatment was a median of 17 days (range 8-28).

As the optimal monitoring schedule is often debated, the Delphi panel was consulted. When baseline serum sodium levels were judged necessary, there was a consensus that serum sodium should be checked on a fixed schedule, beginning within 7 days of desmopressin initiation, but with no consensus

regarding exactly when in the first week this should occur (Day 3 [7/19] or Day 5-7 [9/19]). Weekly blood samples were not deemed necessary (1/18); 4/18 preferred 2-weekly and 13/18 (or 72%; no consensus) agreed that samples should be taken at the discretion of the physician. There was a consensus to perform an SSC as judged by the clinician at 1 month (17/18). Beyond 1 year, there is no consensus on follow up required—10/18 agree that monitoring should be performed when the patient's medical condition (eg, hospitalization, fever) or concomitant medication changes; 8/18 agreed with annual checks.

In young healthy patients, there was no consensus on SSC needed—the majority believed no checks were necessary (11/18), assuming no underlying medical conditions.

There was a consensus that some form of fluid restriction should be advised for all patients (only 1/18 found it unnecessary)—the consensus was split between advising patients to follow their own thirst (14/18) and strict fluid restriction (4/18).

If the response to desmopressin is insufficient at a low dose, there was a consensus that dose should be up-titrated (18/19), depending upon the frailty of the patient (11/19). An SSC should be carried out before up-titration, depending on the patient (17/19). If the dose is up-titrated and further sodium checks are appropriate (15/19), these should be carried out within 7 days.

If hyponatremia is found after initiating desmopressin therapy, there is a consensus (15/19) that treatment should be discontinued when an SSC is below 130 regardless of the presence of symptoms. If sodium check is between 130 and 135 and the patient is asymptomatic, treatment need not be discontinued (only 1/19 would stop the therapy), but further checks (8/19) or drug-free intervals (3/19) or lowering the dose (7/19) should be performed. See Figure 5 for a summary.

Follow-up of desmopressin therapy:

- If SSCs are necessary, follow-up on day 3 to 7 and 1 month.
- Further checks at clinician discretion.
- Stop therapy if serum sodium is < 130 mmol/L regardless of hyponatremia symptoms, and if serum sodium is 130 to 135 mmol/L with symptoms.

3.5 | Patient-oriented nocturia care path

Based on existing guidelines, evidenced-based medicine, and the Delphi panel, we developed a patient-oriented

multidisciplinary diagnostic and therapeutic algorithm for bothersome nocturia, aiming for a more holistic approach to nocturia from a multidisciplinary angle (Figure 6). The aim of this algorithm is to ease the work of clinicians and shorten the time to treatment.

4 | DISCUSSION

Diagnostic and treatment packages (Figure 2) are helpful in the visualization of the pathway of nocturia patients. We believe they could be a useful educational tool for training of healthcare professionals to improve patient care for nocturia, to limit the hurdles a patient has to get over to receive appropriate care and decrease the time to treatment.

The lifestyle interventions that are recommended in all LUTS guidelines are a good case in point. There is a growing interest globally in lifestyle interventions as a possible treatment for LUTS and, therefore, also for nocturia. The International Consultation on Incontinence summarized the need for research on conservative management of incontinence,⁷² and the possible lifestyle interventions that can be relevant in nocturia are weight loss, diet change, fluid intake modification, and exercise. Of these, weight loss and fluid management have a fair amount of scientific data to support their impact. Weight loss (Level 1 evidence) is mentioned as a first-line treatment to reduce the prevalence of urinary incontinence with a Grade A recommendation. Restricted

fluid intake, which could decrease the voiding frequency, urgency, and volume is mentioned with a Grade B recommendation. For nocturia specifically, no such high levels of evidence exist, with the exception of fluid restriction (Level 1b). In contrast, expert opinion supports weight loss, diet, foods, salt restriction, and protein restriction in the therapy of nocturia.⁶ This shows an important scientific knowledge gap in our understanding of approaches to the reduction of LUTS and nocturia.

There are a number of strategies to manage the risk associated with desmopressin therapy (namely hyponatremia risk). In young healthy people with nocturia, it is advised that any desmopressin formulation can be used, and dose can be up- or down-titrated when needed. In older people, the factors summarized in Table 3 should be checked, and a low dose formulation should be used or the patient should be excluded from desmopressin therapy. It is safer to start with a lower dose and to lower the threshold to perform SSC in women compared with men as women have a higher sensitivity to desmopressin and are more prone to hyponatremia. This gender difference in antidiuretic response has been found in animal studies⁷³ and in clinical studies.^{74,75} In female rats, it was shown that this gender difference is explained by a significantly higher expression of the V2 receptor in females.⁷³ It was suggested that this was caused by escape from X-chromosome inactivation by the X-linked V2R gene, causing increased V2R dosage in females.⁷⁶



FIGURE 5 Follow-up after desmopressin prescription when serum sodium checks wanted or needed. Symptoms of hyponatremia include: nausea and vomiting, headache, confusion, loss of energy, drowsiness, and fatigue, restlessness and irritability, muscle weakness, spasms or cramps, seizures, and coma. FU, follow up; SSC, serum sodium check [Color figure can be viewed at wileyonlinelibrary.com]

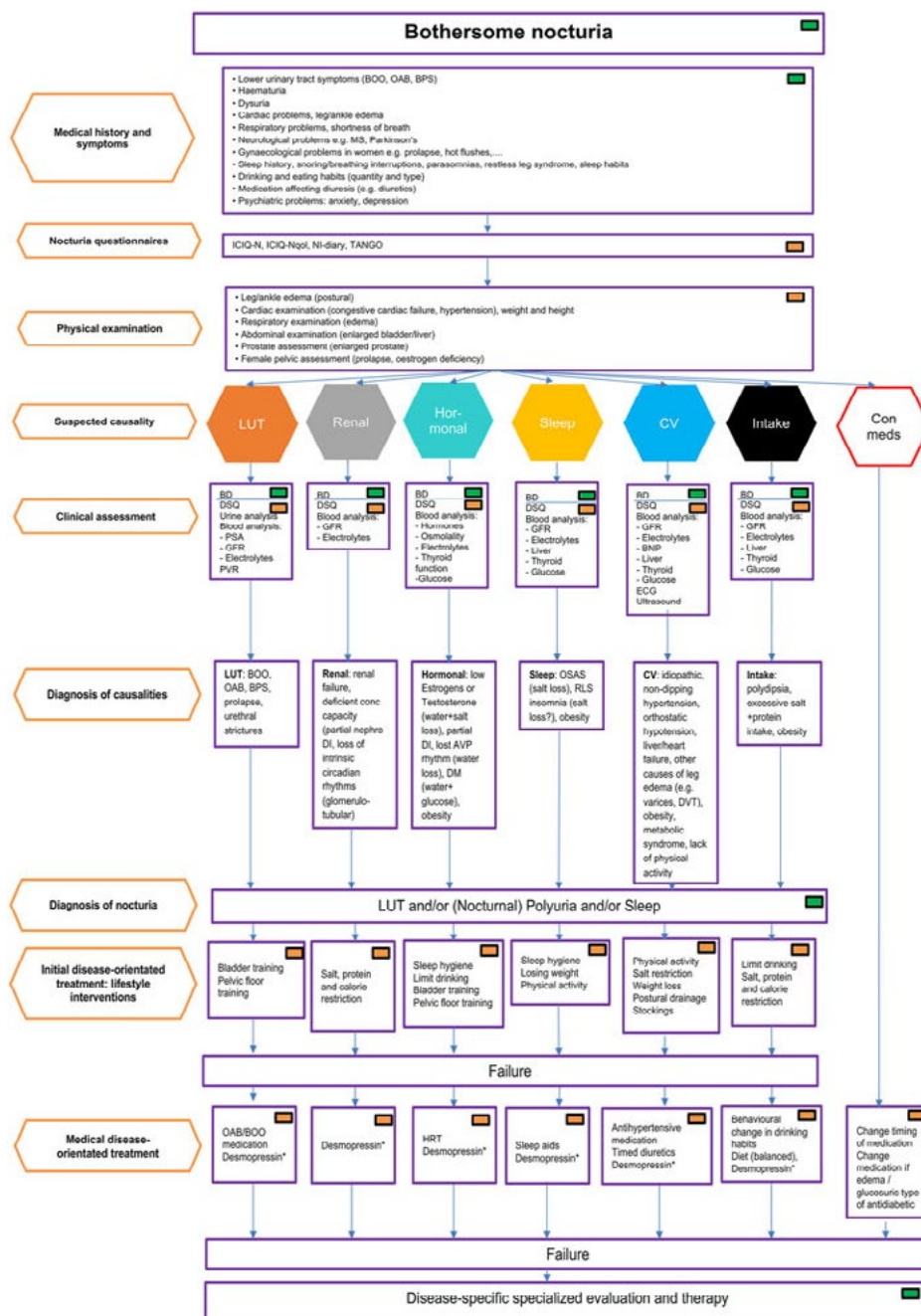


FIGURE 6 Continued.

High-risk medications for hyponatremia are thiazide diuretics, lithium, valproate, and carbamazepine⁶⁶ and use of these should be considered as a contraindication for desmopressin therapy. Low-to-moderate risk medications for hyponatremia are loop diuretics, antidepressants, ACE-inhibitors, and angiotensin-II-receptor blockers. These can be used concomitantly with desmopressin after consideration of the other factors from Table 3; concomitant use necessitates follow-up and sodium monitoring. Based on studies with loop diuretics,⁶ it is wise not to start both medications at the same time, but to allow an interval of 2 to 3 weeks between their initiation to help the kidney in resetting its salt gradient before administering the second drug.

Since it is important to consider the frail elderly as distinct from other older persons for the purpose of desmopressin therapy, a definition of what is meant by frailty would be helpful. Perhaps the combination of a clinical frailty scale and a Timed Up and Go test (to assess a person's mobility using static and dynamic balance) would capture enough about frailty for most clinicians. The modified frailty index is an 11 item frailty index described for noncancer gynecological patients which captures enough information to detect adverse outcomes and this might be useful.⁷⁷ There is also the G8 survey, which captures "frailty."⁷⁸ Regarding comorbid conditions, a Charleston comorbidity index would be of use, although it is somewhat limited in older people by a lack of variability.

In the consideration of heart failure and its diagnosis in nocturia patients, heart failure should be suspected when there is a history of heart disease, when edema and/or weight gain with rapid onset is found and/or a patient complains of exertional dyspnea or orthopnea. A normal serum BNP concentration rules out uncontrolled heart failure. It is clear that when this condition is suspected, even in mild form, clinicians should be careful with prescribing desmopressin and it is better to refer the patient to a cardiologist and await instructions.

The monitoring of serum sodium in nocturia patients treated with desmopressin lacks sufficient evidence to produce good guidelines. As hyponatremia is rare in well-selected patients with the currently available low-dose formulations, producing strong evidence for a safety

protocol will be difficult. It is likely that complex statistical studies on merged databases may be a promising strategy for the future and could help to produce a personalized medicine algorithm for serum sodium monitoring after desmopressin initiation. In the meantime, clinicians should err on the side of caution, even if it means more SSC.

From a clinical scientific perspective, when looking at Table 2, it would be interesting to demonstrate the actual plasma levels of desmopressin following the use of the three different formulations, as this explains better the rationale for the dose differentiation. We would suggest focussing on pharmacodynamic studies combined with pharmacokinetic studies to evaluate the strength and duration of the antidiuretic effect, and the effect on serum sodium levels. These studies would ideally be performed in nocturia patients during an overnight evaluation, as performed by Goessaert et al.⁷⁹

It is clear from this Delphi panel experience that items which suffer from a lack of evidence in the literature are difficult to form a consensus on with a multidisciplinary panel. This demonstrates the need for more studies on some of the smallest steps in the care path of nocturia patients. However, the performance of studies that are crucial to our understanding, but do not attract funding from the pharmaceutical industry (eg, effects of lifestyle interventions), will be challenging, as will be the study of low-frequency events and patient risk factors. There is also a difficulty in reaching consensus in relation to diagnostic tests such as serum PSA or clinical prolapse evaluation as the guidelines in these areas originated from urological or gynecological organizations (and indirectly from studies on urological and gynecological patients), whereas the Delphi panel is multidisciplinary and clearly votes from this broader perspective. Our algorithm needs more research mainly in relation to the causalities of the cardiovascular system and intake-related aetiologies. Even in urogynecology, many questions remain unanswered such as the efficacy of medication in nocturia patients with a reduced bladder capacity. For sleep disorders, little research has been done on restless legs syndrome and insomnia as a cause of nocturia. Finally, there is a need to study nocturia based on this multicausal origin, as well as from a diagnostic and a therapeutic angle. Development of a

FIGURE 6 A patient-oriented multidisciplinary diagnostic and therapeutic algorithm for nocturia. *If desmopressin, consider Figure 3 and Table 3 before initiating, and consider Figure 5 for follow-up. BD, bladder diary; BNP, brain-derived natriuretic peptide; BOO, bladder outlet obstruction; BPS, bladder pain syndrome; Con Med, concomitant medication; CPAP, continuous positive airway pressure; CV, cardiovascular; DI, diabetes insipidus; DM, diabetes mellitus; DSQ, disease-specific questionnaires; DVT, deep venous thrombosis; ECG, electrocardiogram; GFR, glomerular filtration rate; HRT, hormone replacement therapy; LUT(S), lower urinary tract (symptoms); MS, multiple sclerosis; OAB, overactive bladder; OSAS, obstructive sleep apnoea syndrome; PSA, prostate-specific antigen; PSG, polysomnography; PVR, post void residual; RLS, restless legs syndrome. ■ consensus, ■ consensus "when judged necessary by the clinician," ■ "combinations possible" [Color figure can be viewed at wileyonlinelibrary.com]

standalone evidence-based nocturia guideline will probably originate from a multidisciplinary organization, and in the future, we envisage that the nocturia care path will move away from the disciplines of urology and gynecology towards less narrowly focused specialisms such as internal medicine, geriatrics, and general practice.

5 | CONCLUSION

A summary of the nocturia patient pathway across different medical specialisms is useful in the visualization and phenotyping of patients for diagnosis and therapy. It also highlights that nocturia is in general not a urological symptom, but predominantly a symptom of a wide variety of causalities, many of which are easy to screen for with history taking, questionnaires, and physical examination. By providing some basic knowledge of desmopressin, its contraindications, safety concerns and follow-up here, we aim to ease its initiation for clinicians and to shorten the patient journey for nocturia.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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International continence society white paper regarding female genital mutilation/cutting

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Female genital mutilation/cutting (FGM/C)—also known as Female Genital Cutting or Mutilation—is defined as the partial or total removal of the female external genitalia for non-therapeutic reasons. This White Paper, prepared under the auspices of the International Continence Society (ICS), is intended by the ICS as a statement promoting the abandonment of this practice. The ICS also supports the respectful and evidence-based care or treatment of women and girls already affected by FGM/C, in keeping with the World Health Organization (WHO) Guidelines on the Management of Health Complications from Female Genital Mutilation.¹ Our members specialize in pelvic floor disorders from perspectives within a range of specialties; we encounter and treat women living with FGM/C and its consequences—particularly incontinence, infections, voiding dysfunction, sexual dysfunction, chronic pelvic pain, and obstetric trauma. Understanding the ethical, sociocultural, medical and surgical factors surrounding FGM/C is central to caring for women and girls with a history of FGM/C. The ICS voices herein state strong opposition to FGM/C. We encourage members to apply their skills to improve prevention strategies and the management of those affected.

KEYWORDS

circumcision, complications, cutting, defibulation, female genital mutilation, public health

1 | INTRODUCTION

Female Genital Mutilation (FGM/C), in its official World Health Organization Definition, “comprises all procedures that involve the partial or total removal of external genitalia or other injury to the female genital organs for non-medical

reasons.”¹ FGM/C is distinguished from female genital cosmetic surgery by consensual and other factors, as discussed below. This paper specifically addresses non-consensual procedures, which are for the most part performed on minors. There are no health benefits to FGM/C. FGM/C violates basic human rights. In addition there are significant immediate and long-term risks associated with FGM/C including obstetric, neonatal, urologic, gynecologic, infectious, sexual, and psychological health consequences as outlined below. FGM/C is a deeply ingrained sociocultural practice in many countries. The practice is seen within a range

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of cultures and ethnicities, and within Muslim, Animist, and Christian societies. However, it predates the Islamic and Christian religions and mention is absent from both the Koran and the Bible. Explanations for the practice may include safeguarding virginity, aesthetics, prevention of rape, ensuring fidelity—and therefore social acceptance, family honor and marriageability—and establishing ethnic identity.¹

The ICS position is that:

1. FGM/C should be prevented and progressively eradicated.
2. Healthcare professionals should not perform FGM/C, as medicalization¹ of the practice does not prevent many of the complications. Healthcare professionals should be trusted promoters of prevention/abandonment of the practice and care of already affected women and girls.
3. FGM/C complications should be screened, recognized, treated, and recorded appropriately and ultimately prevented.

1.1 | Status of FGM/C

FGM/C is in fact illegal in many countries (Figure 1). However, FGM/C is still practiced in approximately 30 countries around the world,² including many where outlawed.³ An estimated 200 million women have undergone FGM/C to date.³ A 2013 UNICEF report estimated another 30 million girls are at risk in the coming decade.³ The vast majority of FGM/C occurs in children prior to the age of 15.³ Cultural factors continuing the practice of FGM/C are not simple to change and will be explored below.

The WHO classification distinguishes four basic types of FGM/C with subclassifications (See Figure 2). These

comprise a wide range of practices from the excision of the labia with or without the external part of the clitoris, with or without covering/narrowing the introitus, to performing genital piercing, pricking or stretching. Research shows that women can accurately answer whether they have undergone FGM/C; therefore, simple surveys can provide reasonable estimates of prevalence.^{4,5} For the most part, women who have undergone FGM/C cannot correctly identify specifically what was done to them; this is not at all surprising as in many countries the majority of girls are cut before age five. Accurate classification requires examination by a trained observer (a visual reference and learning tool describing the WHO classification, including a video, has been published⁶). Proper classification, recording, and coding may have value clinically to individuals living with FGM/C as well as in research efforts to understand risks associated with the condition, optimal treatments, and in communication for academic and clinical endeavors. Classification is important for epidemiological and statistical purposes, for example, to study changing trends of the practice and the quality of care provided to patients. For example, following campaigns aimed at abandoning FGM/C, there is evidence that FGM/C may be performed at an earlier age and/or in a milder form.^{3,7}

1.2 | FGM/C should be prevented and ultimately eradicated

It is the position of the ICS that FGM/C should be prevented and thereby eradicated. There are no studies showing any medical benefit to any form of FGM/C. FGM/C causes

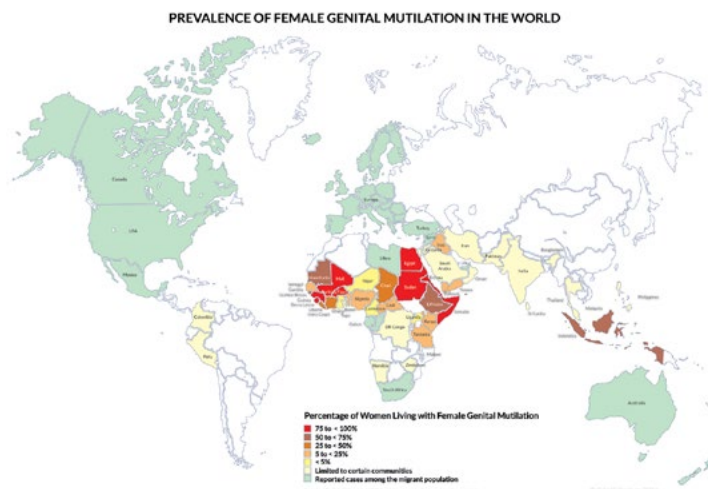


FIGURE 1 Prevalence of Female Genital Mutilation in the world. Courtesy of GAMS, based on DHS, MICS March 2016 and other nationally representative surveys, ©GAMS Belgium <http://gams.be>

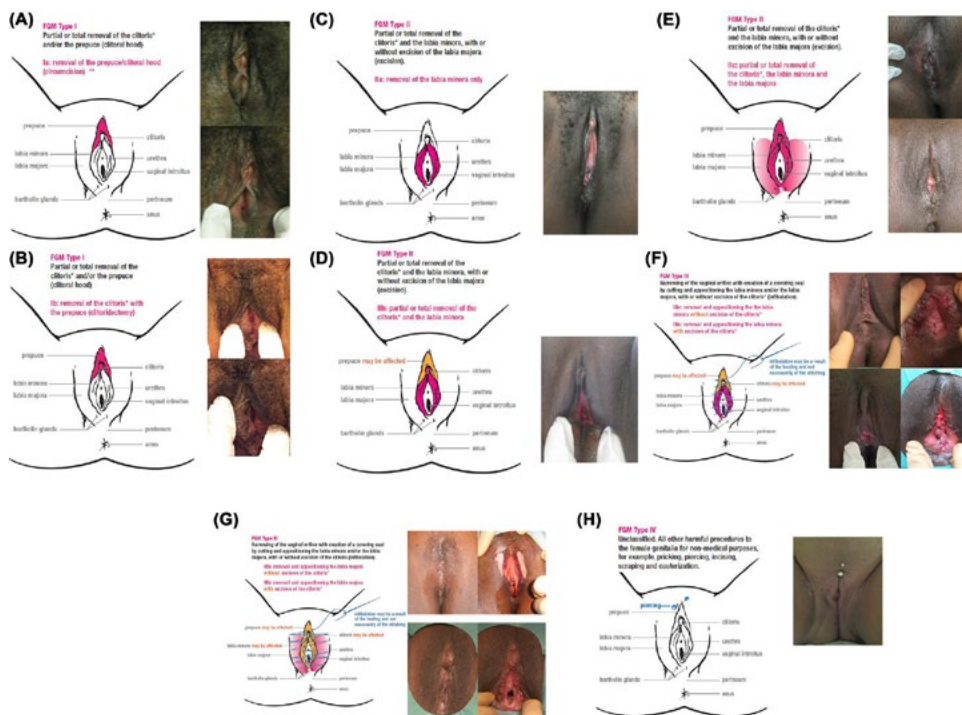


FIGURE 2 Classification of FGM/C. Photos courtesy Jasmine Abdulcadir. Drawings reprinted from World Health Organization. WHO guidelines on the management of health complications from female genital mutilation. <https://www.who.int/reproductivehealth/topics/fgm/management-health-complications-fgm/en/> Geneva (Switzerland); World Health Organization; 2016. Box 1.1 pages 2, 3, 4 (drawings of FGM types). (A) FGM Type Ia. (B) FGM Type Ib. (C) FGM Type IIa. (D) FGM Type IIb. (E) FGM Type IIc. (F) FGM Type IIIa. (G) FGM Type IIIb. (H) FGM Type IV.

significant immediate and long term complications. Most importantly, FGM/C is a violation of basic human rights.

1.2.1 | FGM/C violates human rights

As the WHO Guidelines state, “FGM/C violates a series of well-established human rights principles, including the principles of equality and non-discrimination on the basis of sex, the right to life when the procedure results in death, and the right to freedom from torture or cruel, inhuman or degrading treatment or punishment, as well as the rights of the child.” Many other international human rights organizations have called for an end to the practice, including the United Nations Populations Fund (UNFPA)/United Nations International Children’s Emergency Fund (UNICEF),⁸ the United Nations Convention on the Elimination of all Forms of Discrimination Against Women (CEDAW), the United Nations Convention on the Rights of the Child (CRC), and the Protocol on the Rights of Women in Africa (“the Maputo Protocol”), and the Pan African Parliament (PAP)⁹ among others.¹⁰

1.2.2 | Immediate morbidity and mortality of FGM/C

There are no reliable estimates of the morbidity and mortality attributable to FGM/C. Only a portion of the most serious complications ever reach medical attention. Nevertheless, given that the procedures are performed forcibly on young girls who are generally unaware of what will happen, and (the vast majority of the time) without the benefit of anesthesia, it is reasonable to assume that nearly all suffer pain and psychological trauma and that all are at risk of serious adverse events. Most subjects will experience bleeding. In many this will be physically and/or emotionally significant; hemorrhage and death can occur.¹¹ In a large majority of countries traditional practitioners without medical training do the cutting, typically using crude instruments (Figure 3). The lack of sterile environment and proper antiseptics leads to a risk of tissue infection, sepsis, and even death from infection. Tetanus is a particular risk given the circumstances and the lack of uniform national vaccination programs. Urinary tract infections also occur. There can be inadvertent injury to the urethra or even the



FIGURE 3 Representative instruments used for typical FGM/C. Courtesy Charlemagne Ouedraogo

rectum. Swelling and pain can produce acute urinary retention. Although unquantified, these risks are potentially serious and substantial. They are not offset by any type of benefit.

1.2.3 | Long-term consequences of FGM/C

Damage caused by FGM/C can have a domino effect leading to many long-term consequences as presented in Figure 4. In 2005, a systematic review regarding the health consequences of FGM/C was published, noting difficulty in study design and capturing the data.¹² Observation itself is complex in limited health delivery systems; reporting may not be accurate (observers or subjects may not identify the FGM/C type correctly); sampling bias is present on multiple levels (incidence of complications, time of data collection, difficulty in finding comparison groups); and confounders abound (FGM/C effect vs poor medical care). Regardless, ICS specialists should be familiar with the spectrum of possible complications following FGM/C, and be prepared to screen, diagnose, record, code and manage them. The WHO has

published a detailed handbook “Care of Girls and Women Living with Female Genital Mutilation” (<http://www.who.int/reproductivehealth/publications/health-care-girls-women-living-with-FGM/en/>) which covers each of these topics as well as the general approach to these patients.

1. Obstetric and Neonatal complications: FGM/C, particularly type III, includes an increased rate of adverse obstetric¹³ and neonatal¹⁴ outcomes including hemorrhage, obstructed labor, perineal tears and stillbirth.¹⁵ FGM/C may contribute to the obstetric factors leading to fistula. A 2006 multicenter study by the WHO showed increased relative risks for: cesarean delivery (RR 1.31), postpartum hemorrhage (RR 1.69), extended maternal hospital stay (RR 1.98), infant resuscitation (RR 1.66), and stillbirth or early neonatal death (RR1.55).¹⁶ A secondary analysis of such data showed that women with FGM/C had an increased risk of C-section performed for unclear indications, probably due to a lack of training of providers in performing defibulation or in managing FGM/C.¹⁷ A large systematic review and meta-analysis written in the USA and Europe in 2014¹⁴ as well as a prior review from 2005¹² corroborated these findings. Several studies performed on obstetric outcome after FGM/C in high income countries show that with trained and appropriate management, such risks can be significantly reduced and controlled.^{18–20} Educational material on deinfibulation has been published and is available online.²¹ A great concern in managing a pregnant woman with FGM/C, particularly Type II and III, is perineal tearing. More recent studies and secondary analysis of the 2006 WHO paper showed that the high rate of C-section in FGM/C seems related to inappropriate indications for the C-section. This probably relates to unfamiliarity of providers concerning defibulation during/outside pregnancy or in labor and a low threshold for Cesarean for women with FGM/C. One study showed that there was no

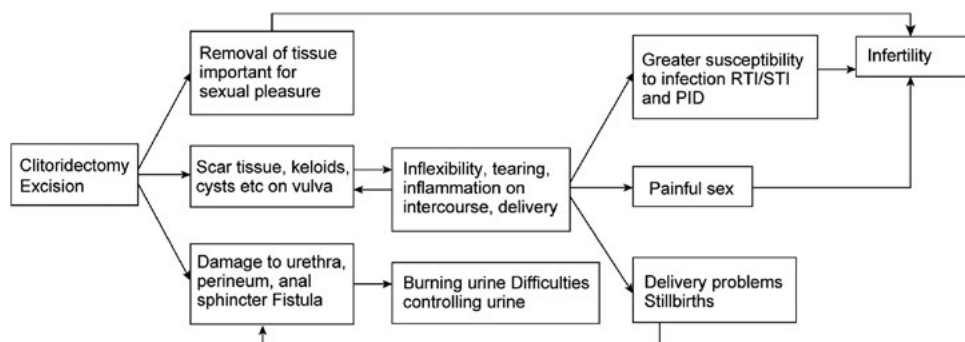


FIGURE 4 Conceptual framework for long term consequences of FGM/C. Reproduced from Morison L, Scherf C, Ekpo G, Paine K, West B, Coleman R, Walraven G. The long-term reproductive health consequences of female genital cutting in rural Gambia: a community-based survey. *Tropical Medicine and International Health* 2001 6(8) 643–653

difference in the incidence of strong medical indications for C-section between women with and without FGM/C. However, C-sections were performed more often on women with FGM/C lacking a clear medical indication in relation to various maternal factors or arrest disorders.¹⁶ Another study found that episiotomies were protective against anal sphincter tears and post-partum hemorrhage after Type III FGM/C, however in this study it is unclear if an associated defibulation was also performed.²² Routine episiotomy is not currently recommended for women with FGM/C in the 2016 WHO guidelines,ⁱ however a lower threshold for episiotomy is recommended in this group.²³

2. Urinary tract complications: Lower urinary tract complications are of special concern to ICS members and are prevalent following FGM/C.²⁴ Damage to the urethra at the time of FGM/C is common due to its intimate relation to the clitoris and labia²⁵ (Figures 5 and 6)—the cephalad apex of the clitoral hood is only 12 mm from the urethral orifice at age 0-3 and 17 mm at age 4-8.²⁶ Urethral injuries result in scarring/stricture/stenosis and subsequent lower urinary tract dysfunction. Unfortunately, good data on urinary complications is lacking. ICS membership could contribute in research initiatives. A 2005 systematic review reported significant prevalence of dysuria (58-64%), urinary retention (12-70%), urinary tract infection including recurrent UTI (2-38%), incontinence (6%) and unspecified urinary symptoms (15-25%).¹² Another group recruited 251 patients specifically to investigate lower urinary tract symptoms (LUTS). They found at least one LUT symptom was present in 38.8% of women. Nocturia was reported in 38.6%, intermittency in

23.5%, and incomplete voiding in 22.7%, with all three reported in 11.6% of the women. Women with a history of Type II and Type III FGM/C had a significantly higher risk of reporting all 3 LUTS than those with Type I.²⁷

3. Infections: Infection is common in the short term after FGM/C.²⁸ A Tetanus is a serious potential risk and can even cause death after FGM/C in regions where no vaccination/immunoglobulins are available. In the long term, as noted above, girls and women may be at increased risk of urinary tract infections after FGM/C. However, other serious infections including HIV are also possible long-term sequelae as described in a 2013 systematic review.²⁹ More infections were identified in those with Type III FGM/C.²⁹

4. Mental health problems: Women living with FGM/C suffer from psychiatric disorders significantly more commonly than their peers without this history.³⁰ A small study of Senegalese women who had undergone FGM/C found that over 90% of women recalled their cutting as “appalling and extremely traumatizing” with 30% developing posttraumatic stress disorder and another 47% suffering from other psychiatric disorders.³¹ Appreciation of the potential psychiatric sequelae is vital to the approach to many women with FGM/C. However, it is also important for ICS specialists to consider that many women are capable of coping with the impediments and may regard the ritual as “normal” or even enhancing their gender identity or body image rather than a sickness. The experience and memories of FGM/C as well as coping strategies can differ according to the age, conditions, type and consequences of the practice. Diversity in interpreting

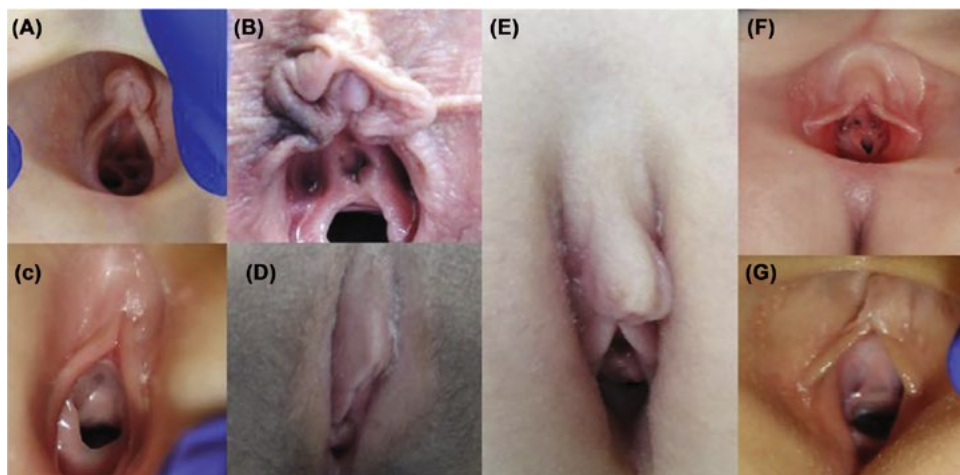


FIGURE 5 Observed clitoral anatomy in the pediatric population. Observed clitoral hood shapes: a) horseshoe; b) trumpet; c) coffee bean; d) tent; and examples of convergence of labia minora under glans and intersection with clitoral hood (e, f, g). Reprinted with permission from Journal of Pediatric Urology, 12/177.e1-177.e6. Brodie KE, Grantham EC, Huguete PS, Caldwell BT, Westfall NJ, Wilcox DT. Study of the clitoral hood anatomy in the pediatric population. pp e1-e6 (2016), with permission from Elsevier

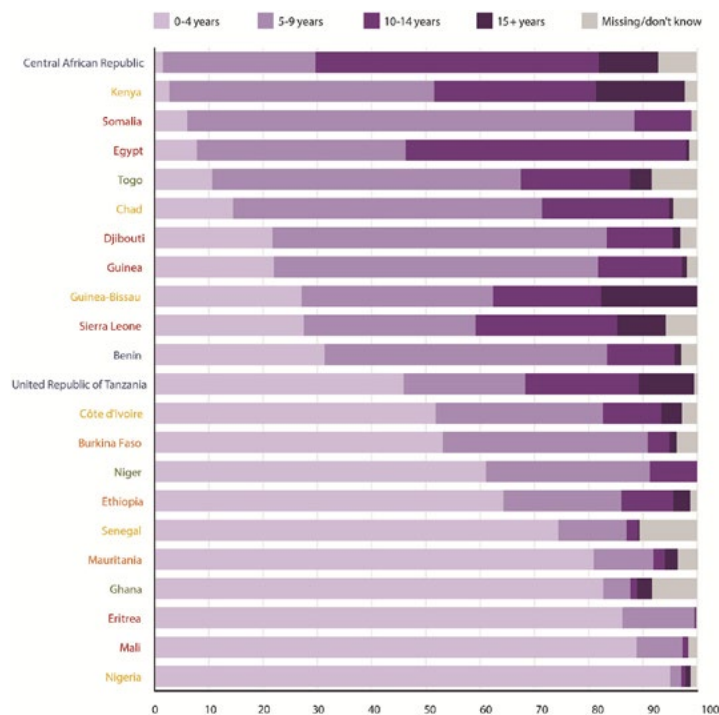


FIGURE 6 Percentage distribution of ages at which girls have undergone FGM/C (as reported by their mothers). United Nations Children's Fund, Female Genital Mutilation/Cutting: A statistical overview and exploration of the dynamics of change, UNICEF, New York, 2013

events and the level of remembrance is crucial for experiencing psychopathology.³² Migration and a different sociocultural setting can make women more aware of their FGM/C; a woman previously well adapted to her experience may then feel stigmatized, socially excluded or ashamed.³³ To avoid contributing to these feelings, ICS specialists will benefit women with FGM/C by approaching care in a neutral manner. Appropriate therapy interventions should be considered for those who are experiencing symptoms consistent with anxiety disorders, depression or post-traumatic stress disorder (PTSD).

5. Sexual Dysfunction:³⁴ There are many research gaps regarding sexual function after FGM/C, especially with regards to type of FGM/C and the specific effects of clitoral involvement.³⁵ A systematic review of sexual consequences of FGM/C representing 12 671 women reported that those with a history of FGM/C were 52% more likely to have dyspareunia and greater than twice as likely to lack desire versus women without a history of FGM/C.³⁶ Some forms of FGM/C involve excision of the glans or the glans and part of the body of the clitoris. However, the remaining tumescent sexual structures (the body or part of the body; the crura of the clitoris and the vestibular bulbs and the corpus spongiosum of the urethra) are not involved by the cutting. Because of this, women may still

experience sexual pleasure and orgasm, provided other physical or psychological effects do not interfere.³⁷ The presence and severity of sexual dysfunction can vary greatly and depends on the specific tissues involved, eventual complications, and on biopsychosocial factors that have to be addressed to treat sexual dysfunction after FGM/C. Dyspareunia among women with FGM/C type III can often be treated with defibulation. Clitoral pain and dyspareunia due to post-traumatic neuromas, cysts, adhesions/synechiae or obstetric trauma can be approached surgically. Pelvic floor muscle dysfunction can be treated with pelvic floor physical therapy. Culturally sensitive sexual health counseling (including education on anatomy and the sexual response) is recommended for both those living with FGM/C and their partners.

6. Other Gynecologic Problems: Dysmenorrhea can result from obstructed drainage. Infertility can result from ascending genital infection. Chronic vulvar pain can be a long-term outcome of FGM/C.

7. Effects of FGM/C on Men: FGM/C can also affect men negatively within a marriage, and thereby becomes an issue pertaining to them.³⁸⁻⁴⁰ A Sudanese study of married men ($n = 59$) found that most expressed difficulty with vaginal

penetration, wounds or infections on the penis, and psychosexual problems.³⁹ The majority perceived their wives' suffering as their own problem, and most stated they would have preferred to be married to "uncut" women. According to UNICEF, 67% of women in 29 countries and 63% of men in 18 countries, all aged 15-49 and who are aware of FGM/C believe it should stop.⁴¹ Wahlberg and Johnsdotter demonstrated that most Somali immigrants, including those newly arrived, opposed all forms of FGM/C with increased opposition over time after migration.⁴² O'Neill surveyed immigrants in three European countries and found that most men and women reported that FGM/C affected their sex lives in a negative way.⁴³

1.3 | Healthcare professionals should not perform FGM/C

The ICS stands firmly against all forms of FGM/C as defined at the outset—those non-consensual procedures mostly performed on minors (and less commonly unconsenting adults). This extends to medicalization¹ of FGM/C where such procedures may be performed by professionals with varying degrees of surgical training, with clean instruments and in safer settings. While it is probable that medicalization can reduce some FGM/C complications such as acute infection, it does not prevent the long-term complications. Most importantly, healthcare professionals should be the trusted promoters of prevention/abandonment of the practice and of sexual and reproductive health literacy as well as the healthcare of women and girls already affected by FGM/C.

The aim of the paper does not extend to address the complex and sometimes controversial issues surrounding adult women who request various forms of genital surgery, including reinfibulation and female genital cosmetic surgery. Several researchers are addressing these topics from a legal, medical, social and ethical perspective. Conflicts between the important principle of autonomy and concerns about coercion or social pressure are not easily resolved. The long-term consequences of such surgery are not easily identified and become more nuanced when taken in a sociocultural context. Male circumcision and the concept of "genital autonomy" in intersex conditions are similarly complex issues—the ICS recognizes these as important discussions but beyond the scope of this work.

1.4 | FGM/C complications should be screened and recognized, treated appropriately and ultimately prevented

1.4.1 | Screening for FGM/C

The first step in management is to screen and recognize the FGM/C and its eventual complications. In a study in Eastern

Sudan, only 7% of midwives could identify the four types of FGM/C correctly, whereas 81% had practiced the procedure, and in Alexandria, only 7% of nurses could identify the types; in both studies there was little knowledge among these practitioners regarding the medical consequences of the procedure and the majority planned to continue the practice.^{44,45} Similar findings have been reported in diaspora countries; therefore, it behooves ICS members to be aware of the condition and to be prepared to identify and care for these patients.⁴⁶ As mentioned above, women who have experienced FGM/C may not know what unaltered anatomy looks like, what type of FGM/C they have personally experienced, and the current symptoms may be so remote from the FGM/C that they do not associate the cause and effect.⁴⁷

1.4.2 | Treatment of FGM/C

The WHO Handbook "Care of Girls and Women Living with Female Genital Mutilation" (<http://www.who.int/reproductivehealth/publications/health-care-girls-women-living-with-FGM/en/>) provides excellent advice to the clinician managing FGM/C patients. However, there is a relative paucity of information in many areas. A primary role for the ICS lies in improving training of its members and in sharing research and expertise, workforce, and resources to improve the care of women with FGM/C. We envision:

- Working with providers in high prevalence areas and diaspora countries to design prospective clinical trials that will inform future care.
- Supporting high quality training for front-line ob-gyn, urologists, pediatricians, general practitioners, infectious disease specialists and surgeons in managing complications of FGM/C, offering defibulation and reconstructive techniques.
- Sharing knowledge through regional meetings and via on-line educational resources.
- For those who wish to submit educational material for ICS online content are invited to submit according to the Standard Operating Procedures for format: <https://www.ics.org/committees/education/icsops>

1.4.3 | Prevention of FGM/C

We need to understand the socio-cultural milieu that supports the practice of FGM/C if we are to prevent it. The most effective and durable change will arise from within the practicing societies rather than being imposed upon them. FGM/C stems from long-standing socio-cultural mores; therefore, efforts toward eradication must align

with cultural factors perpetuating the practice. The updated 2013 UNICEF statistical overview emphasizes the challenging dynamics of cultural change, noting according to social science research it “is difficult for individual families to stop the practice on their own. There is a social obligation to conform to the practice and a widespread belief that if they do not, they are likely to pay a price that could include social exclusion, criticism, ridicule, stigma or the inability to find their daughters suitable marriage partners.”⁵³ According to Mpofu and colleagues, the practice of FGM/C is deeply embedded in social and cultural traditions dating back generations. Over time, interventions have failed to understand the complexities surrounding the practice.⁴⁸ “Most campaigns against FGM/C have come about from a viewpoint of outrage, disgust and condemnation, and therefore are seen as a direct and aggressive attack on a people’s core values, beliefs and traditions which have been a part of their very existence for generations^{49–51}” and can lead to further stigmatization of girls and women who have already undergone FGM/C. “FGM/C is said to enhance marriageability, fertility, and to promote purity or virginity of a woman,^{52–54} and is also said to “. . . temper female sexual urges thereby preserving a girl’s virginity for marriage.”^{50,55}...The belief in the protection of female virtue goes hand in hand with upholding family status and dignity! When one is [circumcised], it is a symbol of entry into womanhood and marks that one fully belongs to a community.” Marriage and reproduction are essential to the long term economic and social security of most women, and FGM/C is regarded in many communities as a normal and acceptable part of raising the girl child.

Programs aimed at preventing FGM/C and its consequences must therefore:

- Be strongly based on facts and evidence as opposed to aversion and disgust
- Evolve from cultural understanding within the society rather than being imposed from outside.
- Avoid stigmatizing the girls and women who have already undergone FGM/C.

The evidence discussed above regarding the effects of FGM/C on men and the changing attitudes of many immigrants are promising, as they may allow strategies to lift the social obligation of FGM/C, once proper dialogue between genders and within community hierarchies can occur. UNICEF³ has been developing programs in consultation with communities. These participatory programs have a greater impact as individuals within the community state publicly they will not practice FGM/C, and they then educate others. According to WHO, however, programs that educate women and girls about

their bodies and their rights are very rare.⁵⁶ According to UN estimates, most young people lack access to education about their bodies and the impact of FGM/C.⁵⁷ WHO recommends that to have the most responsible impact, preventing unintended alienation and retraumatization, educational interventions should be evidence-informed and scientifically accurate, non-prejudicial, non-judgmental, sensitive and respectful, non-stereotypical, and when involving adolescents, geared toward their evolving capacities. A culturally integrated educational approach will favor these goals. Mpofu highlights select programs that emphasize the healthy portions of the coming-of-age rituals associated with FGM/C, teaching girls about the responsibilities associated with adult and married life, while omitting the FGM/C itself.

The fundamental question at hand remains: how can FGM/C be most effectively prevented? Although in decline, it remains distressingly prevalent. The Pan African Parliament (PAP) has recently joined the U.N. Population Fund (UNFPA) in an action plan to ban FGM/C for the whole continent. This is a promising legal and cultural statement on the part of the Parliament. The initiative includes legislation, community mobilization, advocacy, and recruitment of men to speak out against FGM/C.⁹ There is some evidence that changing hearts and minds at the community level will ultimately be the most effective strategy.⁵⁸

Looking more closely at specific countries country will highlight the complexity of changing the practice of FGM/C. The prevalence in Kenya decreased from 41% in 1984 to 11% in 2014 (however, these numbers differ from those in Mpofu’s study). In 2001, the Kenyan government outlawed the practice, passing the Children’s Act.⁵⁹ Further, in 2011 it passed the Prohibition of Female Genital Mutilation Act. Lastly, successful public education campaigns have led to relief of social pressures—for example, young men have had an impact by publicly declaring their preference to marry a woman who has not undergone FGM/C.⁶⁰ In 1990 Burkina Faso formed the Committee to Fight the Practice of Excision (Comité National de lutte contre la Pratique De l’excision, CNLPE). In November 1996 a penal code was adopted forbidding female genital mutilation, threatening imprisonment of 6 months to 3 years and large fine for all forms of FGM/C. In addition, special emphasis is placed on education of the girl so that in adulthood, she does not seek FGM/C for her daughters. The CNLPE instituted campaigns of sensitization regarding FGM/C; policemen were trained to intervene in keeping with the law; the subject of FGM/C became part of scholastic programs; and women who had endured complications linked to FGM/C were treated free of charge in certain health initiatives identified by CNLPE, in line with WHO Guidelines. A free telephone line called “SOS Excision” (SOS Female genital cutting), was set up to

gather real-time information on the acts of mutilation. According to UNICEFxi, the prevalence of FGM/C in Burkina Faso declined from 89% in 1980 to 58% in 2010 (however, not unlike Kenya, according to internal statistics, the prevalence of FGM/C may remain significant: 76 % [EDSBF-MICS IV 2010]).⁶¹ The persistent high prevalence, although decreasing and lower than some surrounding countries, is likely multifactorial—including the low level of population education (30% literacy), the persistence of traditional practices impacting the health of women overall (eg, beliefs impacting nutrition during pregnancy), and inadequate funding for the permanent implementation of the national strategy against FGM/C. The continued high incidence of FGM/C in Burkina Faso, Kenya, and other countries also calls into view the complexity of criminalization. It is possible that this strategy may have a diminished effect by driving the practice underground instead of into the light. It is certain that work across health care disciplines in cooperation with government and non-government organizations engaging community leadership will be required for optimal results.

Medical professionals can help prevent FGM/C by providing healthy, non-judgmental messages in every interaction. For example:

- offer health education on FGM/C during pregnancy (preparing for the issue to arise if the future child is a girl),
- primary doctors must build trusting relationships, including the father or other important family elders and exploring the beliefs of the family,
- pediatricians must discuss this issue with parents over time,
- doctors can provide safeguarding/protection measures according to the local laws in case of real and immediate risks.

2 | CONCLUSION

FGM/C is relevant to all who practice pelvic medicine, as understanding the unique health issues significantly impacts care for this population. The ICS position on FGM/C is that it should never be performed in any form on a girl or non-consenting woman. ICS members can educate themselves and others on the practice. Those with significant experience in caring for women with FGM/C can offer information, health education, reconstructive and rehabilitative services to women and girls with a history of FGM/C experiencing urogynecological, infectious, obstetric, sexual and functional pelvic floor consequences. A respectful, neutral, non-judgmental, non-stigmatizing and trained approach should be the tone of the individual patient interaction.

The International Continence Society is uniquely positioned to promote the care for women and girls living with FGM/C. Although a smaller percentage of our members have significant experience in managing patients with FGM/C, as a multidisciplinary, international society, we have significant reach with educational needs around the world. We can lend our expertise to many of the preventative and cure needs such as obstetric trauma, urogynecological and psychosexual consequences. Our expertise in education, research methodology, complex reconstructive surgery, nursing, physiotherapy, psychosexual issues can be of great value. We will start by providing educational opportunities to our members so that they can develop appropriate sociocultural, rehabilitative (including physiotherapy), medical and surgical knowledge of the topic.

ICS and its Members will lend support and act to:

1) Educate:

- Support the work of practitioners treating high volumes of patients with FGM/C throughout the world through assistance in creating, presenting, filming and distributing educational material (See www.ics.org/tv, <https://www.ics.org/committees/education/icssops>).
- Educate health care workers, patients, and communities regarding FGM/C—raising awareness, exploring medical, ethical and cultural issues, consequences of FGM/C, and management.
- Work within communities to engage women and men regarding the medical risks of FGM/C and to lift the myths perpetuating this practice.

2) Research:

- Lend our expertise to define the benefits and risks of post-FGM/C intervention, and to further characterize the health consequences.
- Support and/or conduct studies to define optimal care of those with FGM/C.

3) Provide Care:

- Provide neutral, clear, non-alienating information to women and girls who have experienced FGM/C regarding its meaning to her individual situation, and options for care.
- To provide holistic care always, high quality reconstructive surgery where appropriate, and to support colleagues in high prevalence areas of the world when opportunities arise.

4) Advocate:

- Partner with affected women and girls and other associations regarding FGM/C.
- Promote government support for medical care of women who have had FGM/C, including culturally fluent psychological care.
- Work within communities to promote the healthy coming-of-age rituals associated with FGM/C while removing the permanently damaging risks associated with FGM/C.

CONFLICTS OF INTEREST

No conflicts of interest.

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International Continence Society

Best Practice Statement for Use of Sacral Neuromodulation

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SACRAL NEUROMODULATION CONSENSUS STATEMENT

INTRODUCTION

Sacral neuromodulation (SNM) is an accepted therapy for refractory urinary urgency and frequency, urgency urinary incontinence (UI), non-obstructive urinary retention (NOR), and fecal incontinence (FI).

- These indications for SNM are approved by the FDA in the United States. In other parts of the world there are some other approved indications for various pelvic floor conditions.
- A need was identified for a comprehensive document reflecting best practices across indications related to SNM

A panel of experts from the fields of urology, gynecology, and colorectal surgery was convened to determine best practices for use of this therapy.

- Eight urologists, three colorectal surgeons and two urogynecologists, covering a wide breadth of geographic and specialty interest representation, met for two days in Chicago, Illinois, USA on January 19-20, 2017 to discuss best practices for neuromodulation. Suggestions for statements were submitted in advance and specific topics were assigned to committee members. Committee members prepared each assigned topic and presented supporting data to the group at which time each topic was discussed in depth. Best practice statements were formulated based on available data and expert opinion and then each member prepared a discussion section for each particular topic which reflected the current literature and expert opinion. Another urologist was added to the group during the initial writing process. After multiple rounds of editing within the group the highlights of the statements were presented at the ICS meeting in Florence, Italy in September 2017. This document was then circulated to multiple external reviewers after which final edits were made and approved by the group.
- The meeting and editing expenses were supported by the ICS. Funding to support this project was based on an unrestricted society-initiated grant made by Medtronic to the ICS.
- As many of the recommendations herein are based on expert panel consensus, the recommendations in this document, while meant to aid clinical decision-making, do not pre-empt physician judgment in individual cases.

The statements and recommendations included in this document pertain to SNM in its present form (Interstim, Medtronic) They may or may not have relevance for future SNM products or therapies which become available for clinical use.

- At the time this document was created, the only sacral neuromodulation device commercially available was the Medtronic Interstim (Minneapolis, MN). Thus, the data and statements discussed pertain to this device. However, it is clear that other sacral neuromodulation devices will be available in the near future. Accordingly, many of the concepts contained within this document will likely apply to newer devices as well.

- The panel used the International Consultation on Urological Diseases (ICUD) method when determining levels of evidence and grades of recommendation. Table 1 summarizes the criteria used for determining levels of evidence and grades of recommendation.¹

DEFINITIONS

SNM: a technique that electrically stimulates a sacral spinal nerve root to modulate a neural pathway with the aim of treating bladder and/or bowel dysfunction.

- The term neuromodulation vs. neurostimulation was preferred by the committee since SNM, through electrically stimulating nerves, effectively functions by modulating the lower urinary tract or bowels.

Neurogenic lower urinary tract dysfunction (NLUTD): includes all bladder/urinary sphincter dysfunction related to any relevant neurological disease

Peripheral nerve evaluation (PNE) lead: a monopolar, temporary lead which is always removed after an SNM test period and is not designed for long-term therapy.

Staged (tined) lead: a quadripolar lead which is designed for potential long-term use after a successful test period.

BACKGROUND

SNM is not indicated as a first line therapy for either urinary or bowel disorders.

- Typically, conservative measures (behavioral, physical therapy) and medical treatment are recommended prior to treatment with SNM.

In the absence of a comparative study with recommended doses of onabotulinum toxin A (BTX-A) and contemporary SNM tined leads, no recommendations can be made as to whether BTX-A or SNM should be used over the other for the management of refractory overactive bladder (OAB).

- *The Rosetta trial is a prospective randomized trial that compared SNM to Botulinum toxin.² It showed a slight short-term advantage to Botulinum toxin, however, it did not utilize currently recommended doses of Botulinum toxin (200u as opposed to the recommend 100u dose) or the currently available SNM lead technology and thus no conclusions can be drawn relative to contemporary practice.*

SNM is a minimally invasive technique with good long-term outcomes. SNM can be offered to patients with OAB with or without incontinence who fail to respond to or are intolerant of conservative and medical therapies. (Level of Evidence: I; Grade of Recommendation: A)

OAB Without Incontinence

The initial SNM prospective, randomized, 12 center study enrolled 51 patients for severe urgency-frequency syndrome. This group reflects the present definition of OAB “dry” (urinary urgency and frequency without urinary urgency incontinence). Subjects who demonstrated a satisfactory response to PNE were randomly assigned either to immediate treatment or implant following a 6-month delay (control group). At 6 months, voiding diary results demonstrated statistically significant

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improvements in the immediate implant group in comparison to the control group with respect to the number of daily voids, volume per void and degree of urgency.³ At 2 years follow-up, 29 urgency-frequency patients showed significant reduction in the number of voids per day, with 56% of patients showing 50% or greater reduction in the average voids per day, including 32% who returned to a normal range of 4 to 7 voids per day.⁴

OAB With Incontinence

The initial prospective, randomized, multicenter trial included 34 patients with severe urgency incontinence (OAB “wet”) who underwent immediate implantation of SNM after a positive trial test and 42 patients (delayed group) who received standard medical therapy (SMT) for 6 months and then were offered implantation. At 6 months, the number of daily incontinence episodes, severity of episodes and absorbent pads or diapers replaced daily due to incontinence were significantly reduced in the early stimulation compared to the delayed group. In the early stimulation group, 16 patients (47%) were completely dry and an additional 10 (29%) demonstrated a greater than 50% reduction in incontinence episodes 6 months after implantation. Efficacy appeared to be sustained for 18 months. Surgical revision was required in 32.5% of patients.⁵

In this cohort, the long-term efficacy of SNM for refractory urinary urge incontinence remained high. At 3 years, leaking was significantly reduced, with 59% of patients reporting 50% or greater reduction in leaks per day and 46% of patients reporting that they were completely dry.² As compared to baseline, the group of 96 implanted patients demonstrated significant reductions in urge incontinence symptoms at an average of 30.8 (range 12-60) months with respect to the number of urge incontinence episodes per day, severity of leaking, and the number of absorbent pads/diapers replaced per day due to incontinence. About 10% of patients underwent device explant due to lack of efficacy, pain or bowel dysfunction but no permanent injuries associated with the devices or therapy were reported.³ Others demonstrate that after 3 years, 59% of urinary urgency incontinent patients showed greater than 50% reduction in leaking episodes per day with 46% of patients being completely dry.² A single center study with median long-term follow-up of 50.7 months showed a success rate of 84.8% for urgency UI. Overall 39% of patients needed revision of the SNM neuromodulation implant.⁶ SNM showed superior subjective and objective results compared to pharmacologic–SMT treatment for OAB, at 6 months. SNM is shown to be a safe and effective treatment for OAB patients.⁷ Ultimately, a 2009 Cochrane review concluded that implantable neurostimulators have benefits for some patients with OAB symptoms, retention without organic obstruction, and in those for whom other methods of treatment have failed.

SNM is an effective treatment for Fowler’s Syndrome, voiding dysfunction and NOR. (Level of Evidence: I; Grade of Recommendation: A)

Non-Obstructive Urinary Retention (NOR)

The initial SNM prospective, randomized, 12 center study enrolled 177 patients for NOR. All patients had PNE and 38.4% eventually received the implant. Of the 68 patients who qualified for implantation 37 were randomly assigned to an immediate treatment and 31 to a 6-month delayed implant (control group). At 1.5-year follow-up 70% of 42 implanted patients (immediate or late) showed greater than 50% reduction in volume per catheterization.² Further publication of 18-month follow-up showed that of the patients treated with implants 69% eliminated catheterization at 6 months and an additional 14% had a 50% or greater reduction in volume per catheterization. Therefore, successful results were achieved in 83% of the implant group with retention compared to 9% of the control group at 6 months.

Temporary inactivation of SNM therapy resulted in a significant increase in residual volumes but effectiveness of SNM was sustained through 18 months after implantation.⁸ Extension of this study with 5-year follow-up showed significant reduction in the mean volume per catheterization and the mean number of catheterizations. The clinical success rate of 71% was observed at 5 years after implantation.⁹ In another single center study, out of 60 women implanted there was a spontaneous voiding rate of 72% over a mean follow-up of 4 years. After surgery, of the 43 women who voided, 13 required the continued use of clean intermittent self-catheterization up to twice a day, but this was less than before surgery. Women with abnormal EMG did better, with 76% of patients experiencing restoration of voiding.¹⁰ Another study confirmed that the presence of Fowler's syndrome is a positive predictive factor for SNM in female urinary retention.¹¹ Several single center studies reported good long-term outcomes between 73%¹² and 87%.⁵

SACRAL NEUROMODULATION FOR INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME

There is limited evidence supporting the role of SNM for patients with interstitial cystitis (IC)/bladder pain syndrome (BPS).

SNM is an option for IC/BPS non-responsive to conservative therapies after appropriate assessment. (Level of Evidence: III; Grade of Recommendation: C)

IC/BPS is a condition characterized by bladder, urethral and pelvic pain along with urinary frequency, urgency and nocturia.¹³ SNM may be considered for patients with IC/BPS who do not sufficiently respond to first, second or third-line treatments. However, SNM has approval for pelvic pain conditions in only a few countries, and is not approved specifically for IC in any nation. There is limited evidence supporting the role of SNM for patients with IC/BPS - typically small observational case series all reporting different criteria for success. Based on these small observational studies, the success rate for SNM for IC/BPS using intention to treat analysis was 48% to 72%.^{14,15,16,17,18,19}

Based on the available limited evidence, SNM may be an option for IC/BPS non-responsive to conservative therapies after appropriate assessment and multidisciplinary team review. The AUA IC/BPS Guidelines lists SNM as a 4th line therapy.²⁰

There is a lack of evidence supporting SNM as a treatment option for patients with non-IC/BPS chronic pelvic pain. (Level of Evidence: III; Grade of Recommendation: C)

Chronic pelvic pain is defined as "chronic or persistent pain perceived in structures related to the pelvis of either men or women. It is often associated with negative cognitive, behavioral, sexual and emotional consequences as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor or gynecological dysfunction. Pain must have been continuous or recurrent for at least 6 months".²¹

There is minimal evidence reporting the efficacy of SNM for chronic pelvic pain.²² Based on available evidence, SNM cannot be recommended as a treatment option for patients with non-IC/BPS chronic pelvic pain. However, pelvic pain is not necessarily a contraindication in patients with concomitant voiding symptoms such as frequency and urgency, if those voiding symptoms improve during the trial period and the patient endorses an associated improvement in quality of life.

SACRAL NEUROMODULATION (SNM) FOR NEUROGENIC LOWER URINARY TRACT DYSFUNCTION (NLUTD)

SNM is an option for symptom control in patients with NLUTD who are at low risk of upper urinary tract deterioration. (Level of Evidence: III, Grade of Recommendation: C)

SNM for NLUTD is of growing interest, although it is still as an “off-label” indication. There have been many reports of good outcomes in NLUTD but with a lack of standardized criteria in terms of patient selection, success definition, etc. Most of the evidence is focused on incomplete SCI and multiple sclerosis (MS) but patients with cerebrovascular accident, brain trauma, cerebral palsy, and Parkinson’s disease have been implanted as well with similar outcomes as in patients with non-neurogenic indications.^{23,24}

SNM has been utilized in the treatment of detrusor overactivity (DO), NOR, detrusor sphincter dyssynergia (DSD) and FI due to incomplete SCI. Although there are no clinical or urodynamic criteria to select ideal candidates for SNM in SCI, in one study ASIA D (incomplete injury with some preservation of motor function below the lesion) and E (normal sensory and motor functions below the injury level) lesions and sensation of bladder filling were associated with higher success rate during the test trial.²⁵ We recommend that in SCI patients, SNM should be limited to ASIA D and E patients with preserved bladder filling sensation.³³

The success rate of SNM in patients with upper motor neuron injury may be higher than in patients with lower motor neuron injury since the former preserves afferent integrity and contractility of the detrusor. One study demonstrated an improvement in bladder emptying with SNM in patients with acontractile or hypocontractile bladder, but the mechanism of action is unclear.²⁶

In patients with MS, SNM has demonstrated good results treating DO and NOR due to DSD but a low success rate in treatment of NOR has been reported in those with an acontractile or hypocontractile bladder.²⁷ Patients with MS being considered for SNM should have stable disease without an expected requirement for frequent or routine magnetic resonance imaging (MRI); patients with rapidly progressive MS typically should not have SNM systems implanted.

The most recent studies in SNM for NLUTD utilize longer periods of the test trial than for patients with idiopathic dysfunctions.²⁸ Longer test periods might be more appropriate for more complex conditions such as NOR²⁹ as well as NLUTD.

Since SNM is used after all other therapies have failed and prior to more invasive procedures, a 50% improvement during the trial period is adequate to define success. Most studies define success with the same parameters as in non-neurogenic patients, such as reduction of urinary frequency, urgency incontinence episodes, number of catheterizations, volume per catheterization and FI episodes.

NEED FOR URODYNAMIC TESTING PRIOR TO SNM

There is a lack of evidence to suggest that urodynamic testing can predict SNM outcomes. (Level of Evidence III, Grade of Recommendation C).

Patient characteristics such as age, sex, comorbidities, duration and severity of symptoms, and results of examination and testing such as cystoscopy, imaging and urodynamic studies (UDS) have shown insignificant value in predicting which patients will respond to a trial of SNM. Indeed, in some parts of

the world, UDS are commonly performed prior to SNM trial, whereas in other areas, they are not, without an obvious difference in outcomes.

With regard to clinical studies, while some case series³⁰ have shown that older patients and longer duration of symptoms are less likely to respond, others^{31,32} have contradicted this. One study suggested that combining traditional urodynamics and ambulatory monitoring might have additional predictive value³³ over conventional studies alone. None appear to be more sensitive, specific, or cost effective for the prediction of response to SNM as the screening trial, consisting of a PNE or a staged lead implant.^{34,35,36} There is however a single recent prospective study showing that children with bowel and bladder dysfunction who had detrusor overactivity on videourodynamic testing had significantly greater improvement in symptoms with 2 stage SNM implant.³⁷

The trial phase of SNM is the single most valuable tool for predicting the potential therapeutic success of SNM for urinary indications. (Level of Evidence II, Grade of Recommendation B).

Several large, multicenter trials have shown that the PNE⁴ and the staged trial⁶ predict which patients are likely to respond, and also which will likely have long term benefit from the therapy.^{1,8,9,39} A unique advantage of SNM is this inherent ability to predict which patients are likely to benefit with its own specific trial. **UDS is unlikely to add significant diagnostic benefit in the evaluation of routine idiopathic OAB.**³⁸

The index patient suffering from refractory OAB is female, has no neurologic disease, has not had prior pelvic surgery, and has no or minimal SUI. On physical exam there is no significant pelvic organ prolapse or urinary residual. She has failed first and second line options, and has significant bothersome symptoms. In this scenario, the panel agreed that there is scant evidence that the result of a UDS is likely to change the third line therapy options or outcomes. Patients with neurologic disease, an unclear degree of SUI or bladder emptying symptoms, significant prolapse, male patients, and prior pelvic surgeries including outlet reduction procedures (e.g. transurethral resection of prostate) and slings are more likely to benefit from UDS to aid in the correct differential diagnosis.

Pressure flow study or Video UDS may be valuable in the diagnosis of NOR. (Expert Opinion).

Urodynamics is particularly helpful to rule out obstruction when considering the diagnosis of NOR or incomplete bladder evacuation.^{39,40} Another study showed that SNM treatment response in male patients with impaired bladder emptying can be predicted with a bladder outlet obstruction (BOO)-contractility nomogram.⁴¹ In this study of 18 men, the authors found that only 20% of patients below the 10th percentile of contractility, but 86% of men between the 10 and 25th percentiles of the Maastricht-Hannover nomogram were treated successfully with SNM. All successfully treated patients voided without needing self-catheterization. Other studies have shown that EMG study of the external urethral sphincter may be helpful in defining Fowlers syndrome.⁴² In females, the combination of video imaging and real time urodynamic data has been determined to be the best method of defining BOO.⁴³ Video studies in men may also be useful in determining the level of obstruction, for example benign prostatic hypertrophy vs. pseudodyssynergia.⁴⁴

In cases where SNM has been tried and failed, UDS may be considered to further define the underlying disorder. (Expert Opinion)

Considering that the PNE or staged lead placement have the best predictive value for determining which patients will benefit from long term treatment with SNM, patients who fail screening, or those who have declining efficacy over time may benefit the most from initial or repeat urodynamic assessment, which may reveal bladder pathologies not amenable to SNM and direct another therapeutic course.

FECAL INCONTINENCE (FI)

SNM should be considered as a second line treatment option for bothersome FI in patients who have failed conservative measures. (Level of Evidence: 2, Grade of Recommendation: B)

Conservative medical measures are the first line treatment for FI, however, SNM should be considered as the second line of treatment in most patients with FI.^{45,46,47} Physicians should consider SNM if the patient has failed medical measures, as SNM has been shown to be superior to best medical management in a randomized trial.¹³ Results of pooled analysis has suggested that 79% of patients with permanent implant for chronic stimulation experience $\geq 50\%$ improvement in incontinence episodes in the short-term, while 84% achieve this endpoint with 3 years of follow-up.⁴⁸ Comparative studies are scarce. One study compared 23 patients randomized to SNM vs. 17 randomized to percutaneous tibial nerve stimulation.^{49,50} Though short-term outcomes were acceptable in both groups, the design of the study did not allow statistical comparison between groups. One study compared 15 patients treated with SNM to 15 historical controls treated with the artificial bowel sphincter. Postoperative incontinence scores were slightly better with the artificial sphincter, though constipation scores were worse.⁵¹ Importantly, both the artificial bowel sphincter and the magnetic sphincter, another recent option for FI, are currently unavailable. There are no comparative studies of SNM vs. sphincteroplasty, the major competing procedure for FI.

An anal sphincter muscle defect is not a contraindication for SNM. (Level of Evidence: 3, Grade of Recommendation: C)

There is a large and growing body of evidence that a defect of the internal or external sphincter is not a contraindication for SNM for FI.^{50,52,53,54,55,56,57,58,59,60,61} Though clinical success has been reported in patients with sphincter defects up to 180 degrees,^{13,57,62} most would agree that the size of the defect does not matter and should not affect decision making.^{50,54} This is likely because the proposed mechanism of action relies more on sensory nerve fibers and bowel motility than on muscular contraction.^{63,64} Given the extent of the available evidence stating that a sphincter defect does not impact the success of SNM, some authors have advocated using preoperative ultrasound only in selected patients with FI.⁶⁵

In a patient who is a good candidate for a sphincter reconstruction, typically in a younger woman with relatively recent obstetric injury, it is appropriate to have a full discussion of risks and benefits of a sphincteroplasty vs. SNM. Though there is no evidence to compare the outcomes of these two techniques, many young women with new onset obstetric sphincter defect may be good candidates for sphincter muscle repair.

Other factors such as pudendal neuropathy and the presence of a prior sphincter repair do not predict the outcome for SNM and should not be among the factors considered when deciding which patients to test for SNM.^{45,65}

Patients who have FI after Low Anterior Resection for rectal cancer may be a candidate for SNM test lead implantation if conservative treatment fails. (Level of Evidence: 3, Grade of Recommendation: D)

As treatment for rectal cancer has evolved and sphincter preservation strategies have emerged, many of these patients are cured of their disease, but as many as 50-90% will suffer at least some degree of bowel dysfunction.⁶⁶ Many patients will suffer from debilitating low anterior resection syndrome (LARS), a constellation of fecal urgency, clustering of bowel movements, and FI. As these patients have altered anatomy after resection of the rectum, it is unclear how much benefit SNM may play in achieving relief of symptoms. Two separate studies were conducted on the utility of SNS in LARS.^{67,68,69} Success was noted in 47-100% of patients subjected to a test implantation and QOL was generally improved.⁶⁷ The difficulty in interpreting this data is that the patient groups are heterogeneous. Some, but not all, of the patients had radiation for rectal cancer, and the rectal resections were done for different disease processes such as cancer or Crohn's disease. Additionally, LARS is a constellation of symptoms with many dimensions such as bowel movement clustering, urgency, and incontinence. Though most studies report on improvement in continence, further research should use a more comprehensive scoring system such as the LARS score⁷⁰ to determine which elements of the overall syndrome are improved by SNM. Though it is reasonable to consider SNM test stimulation in the clinical setting of LARS, conservative treatment such as medical bowel management and lifestyle modification should be attempted first.

SNM is the preferred therapy in an appropriate patient with combined urinary and bowel symptoms. (Level of Evidence: III, Grade of Recommendation: C)

Combined Urinary and Bowel Symptoms

Early studies of 14 patients with FI and associated urinary disturbances showed encouraging results with permanent SNM implant.⁷¹ A study of 24 female patients with combined FI and UI showed improvement in both symptoms after SNM implant in 31.8% of patients with a mean follow-up of 28 months. SNM may be beneficial in selected patients with FI and UI.⁷² A recent study showed improvement of bowel dysfunction in patients implanted with SNM for urinary urgency incontinence. There was significant improvement in mean urinary and bowel symptom scores, though only urinary quality of life (QOL) scores improved.⁷³

SNM for combined urinary and fecal incontinence has been also explored in children with a positive response. Based on prospective clinical data and patient-reported measures, 29 patients showed between 55% and 91% improvement in both bowel and bladder dysfunction.⁷⁴

SNM should be considered for combined urinary and FI after the work-up for both conditions has been completed.

OTHER BOWEL CONDITIONS

SNM for constipation should only be considered for patients who have had symptoms for more than one year and have failed conservative treatment, as results of clinical studies have been disappointing. There should be no mechanically correctable cause. (Level of Evidence: 4, Grade of Recommendation: D)

Reported outcomes of SNM in patients with constipation have been mixed,^{75,76,77,78,79,80} thus this remains an area of considerable debate. Success rates with test lead implantation have been reported at 42-100%, and extended testing periods of 2-3 weeks are often necessary.⁸¹ Contradictory studies have emerged, suggesting much lower rates of clinical success. A study by Graf et al⁸² indicated that only 11% of patients were improved at 24 months. A double-blind randomized trial of SNM vs. Sham indicated that only 28% of SNM patients met the criteria for device implantation and there was no benefit of this therapy over sham treatment.⁸³ Additionally, this therapy is not approved by the US Food and Drug Administration, and is not universally covered by insurers in Europe. Best evidence suggests that all less invasive medical and surgical measures should likely be taken prior to proceeding with SNM in these patients.

NEED FOR BOWEL TESTING PRIOR TO SNM

A 2-3-week bowel diary is necessary prior to SNM test for bowel dysfunction. Anorectal physiology testing (manometry, anorectal sensation, volume tolerance, compliance) can be considered to help define the elements of dysfunction and guide management. (Level of Evidence: 4, Grade of Recommendation: C)

It is difficult to identify from the literature the optimal work-up prior to SNM in bowel indications. Some clinicians even consider the PNE test itself as a part of the pre-SNM work-up in FI patients, as there is no known physiologic predictor of success of SNM in these patients.⁸⁴

However before embarking on an SNM trial, common bowel investigations are typically done to identify those patients for whom such a test could be of greatest potential benefit.⁸⁵ Typically, the patient proposed for SNM test has chronic, severe FI which is defined as more than “one leak per week, over a 3 to 4-week period, lasting for more than 6 months” and that has failed conservative measures. A 2-3-week bowel diary is the most important document prior to SNM test for bowel dysfunction. The following is recorded and will be compared with a similar diary done during the test phase: leaks (minor and major), normal evacuated stools, time to defer as a mean by day, and medications taken. The Bristol stool chart is useful to characterize the bowel habits and to allow exclusion of patients with diarrhea from SNM since a normalized stool pattern has not been reached.

Additional investigations **may** include the following:

- Anorectal physiology testing (manometry, anorectal sensation, rectal volume tolerance and compliance) can be considered to help define the elements of dysfunction and guide management. It is usually done before surgical decision-making, as part of the FI work-up and plays a role to guide pelvic floor retraining.
- Endoanal ultrasound is the recommended tool to assess the anal sphincter complex and to identify any sphincter defects. It would guide the discussion to proceed for repair vs. SNM trial according to the different aspects of the defect.

- Dynamic defecography, either standard or MRI, is nowadays also a test to consider prior to SNM trial.⁸⁶ This exam allows for identification of any posterior pelvic floor disorder including high-grade rectal intussusception, which can be clinically difficult to identify and a potential cause of FI. In such a case, many clinicians would first correct the rectal prolapse followed by an SNM trial if FI persists.
- Neurophysiology testing may be performed in some neurologic conditions, but is not part of the usual investigations.
- A/P and lateral views of the sacrum could exclude some abnormalities/malformations making the needle and electrode placement difficult for instance in the case of sacral agenesis associated with anorectal malformations.

SNM FOR THE PEDIATRIC POPULATION

SNM may be considered in children who have failed an extended period of behavioral modification, biofeedback, and pharmacologic therapy and should be considered before irreversible surgery.

Safety and effectiveness have not been established for pediatric indications. (Level of Evidence: III, Grade of Recommendation: C)

Anatomical differences and somatic growth make implantation technically more challenging (Level of Evidence: IV, Grade of Recommendation: D)

SNM has been reported to be effective in children in several single center pilot studies. In one, a total of 23 patients, ranging from 6 to 15 years old with presenting symptoms of dysfunctional voiding, enuresis, incontinence, urinary tract infections, bladder pain, urinary retention, urgency, frequency, constipation and/or fecal soiling were followed for a mean of 13.3 months after SNM. The overall patient satisfaction rate was 64%, while that of the caregiver was 67%. Explantation rate was 10%.⁸⁷ Another study with 30 children with refractory bowel and bladder dysfunction showed significant improvements.³⁷

There are only two prospective randomized trials utilizing SNM in children. The first study of 42 children with incontinence due to neurogenic LUTD showed subjective improvement in about half of children undergoing SNM, including improved bowel function in 9 children, resolution of urinary tract infections in 5 children, and improved bladder sensation in 6 children.⁸⁸ The other randomized study of 33 patients (24 boys) with mostly neurogenic LUTS and with a mean age of 12.2 years compared SNM to standard conservative treatment. Incontinence was mixed urinary and fecal in 19 cases, urinary only in 9 and fecal only in 5. Overall positive response rate was more than 75% for urinary and bowel dysfunction.⁸⁹

A study with longer follow-up (average 3.2 years) in consecutive children with UI, constipation, frequency and/or urgency, and nocturnal enuresis from a single center showed that nearly all children (99 of 105) experienced improvement of at least 1 symptom. Reoperations occurred in 56% of children, mainly for device malfunction. Explantation was performed in 35%, mainly for complete symptom resolution.⁹⁰ Of note, certain health preventive measures are of greater importance in children, mainly reduced radiation exposure. Also, anatomical differences and somatic growth must be considered with SNM implantation in the pediatric population.

CONTRAINDICATIONS FOR SNM IMPLANTATION

Absolute contraindications for SNM includes: Inadequate clinical response to a therapeutic trial, inability to operate the device with lack of supportive caregivers who could otherwise offer assistance, and pregnant patients (Level of Evidence: IV, Grade of Recommendation: C).

Relative contraindications for SNM includes: patients with severe or rapidly progressive neurologic disease, patients with established complete SCI, patients with known anticipated need for MRI of body parts below the head and patients with abnormal sacral anatomy (Level of Evidence: III, Grade of Recommendation: C).

The manufacturer of the currently most widely available system (InterStim II) has approved the safety of the current device for 1.5 Tesla MRI of the head. See manufacturer's website for further detail.⁹¹ Recent studies have shown that the risk of heating is low for clinical lumbar and pelvic MRI at 1.5-Tesla, both in an intact SNM system and with a fractured lead.⁹²

In pregnant women, no negative effects of SNS on the fetus, mother or device have been reported. However, further studies are needed to conclude if it is a safe practice to implant or to leave a device activated in a pregnant woman.^{93,94} Indeed, a recent review that included 16 Cesarean and 9 vaginal deliveries, comprising 25 pregnancies with SNM devices in situ (8 with device left on during gestation, 18 with device deactivated, typically between 3-12 weeks gestation) reported that post-delivery SNM dysfunction was present in 32%, with 3 after vaginal delivery and 5 after c-section. Ultimately, the authors suggested that "within the current limited evidence, the decision regarding SNM activation or deactivation should be individualized [in pregnancy]."93 Until more data is available, for example from a patient registry, the panel recommends not implanting a SNM device in a pregnant woman and deactivating the device when a patient already on SNM therapy becomes pregnant.

TIPS FOR INTRODUCTION OF SNM TO PATIENTS

SNM therapy should be discussed with all patients as part of their bowel or bladder control treatment pathway. (Level of Evidence: IV, Grade of Recommendation: C)

Surgeons should review the need for life-long follow-up, eventual battery replacement, complications, and expected symptom improvement. (Level of Evidence: IV, Grade of Recommendation: C)

SNM is classified as a 3rd line option for treating OAB symptoms,⁹⁵ and as a 2nd line therapy for FI. Medications and non-invasive interventions comprise first line therapy. It is known that many patients will not respond to initial therapies and will potentially be offered neuromodulation as an option. There is no documented 'best practice' for introducing SNM to patients, however at least one study showed that group-education visits made patients more informed and prepared for the test phase, which translated into improved patient-reported outcomes compared to those undergoing standard preoperative counseling, despite voiding diary outcomes being no different between the groups.⁹⁶ As no reliable predictor for patient response to more conservative therapies exists, it is our recommendation that all patients be informed of this therapy as early as possible in the treatment pathway. Similarly, for FI, where limited therapies exist beyond pelvic-floor therapy and modification of stool consistency, patients should be alerted that SNM therapy exists.⁹⁷ Patients with dual bladder and bowel disorders stand to benefit with respect to both symptoms,⁷³ which may direct the clinician

to educate the patient about SNM almost at the first encounter. This is discussed in further detail elsewhere in this consensus statement.

As patients are introduced to SNM it is important to review the limitations and implications of the therapy. Currently, the InterStim II device is labeled for an expected battery life of 3-5 years, though some have shown longer periods with lower energy settings.⁵ Long-term follow-up, the need for battery replacement, possible revision of the lead or programming changes are all important aspects of SNM therapy,⁹⁸ and should be communicated to the patient, in particular given that a recent study using contemporary technology found a 32% rate of surgical intervention at 3 years following implantation.³¹ Furthermore, while symptom improvement can be dramatic in some patients, the target response of >50% improvement both objectively and subjectively as the implant threshold indicates this is not a cure in most patients. Expectations for the patient are important and should be balanced against the known response to trial and long-term implant success.

PREOPERATIVE COUNSELING - ADVERSE EVENTS

Preoperative counseling prior to SNM should include a discussion of risks including implant site pain, infection, paresthesia, leg pain, and/or need for reprogramming or for device revision. (Level of Evidence: 3, Grade of Recommendation: C)

Though SNM is a relatively safe surgical procedure, adverse events do occur. The most complete report on adverse events comes from the North American Multi-Center trial, as investigators were required to report all adverse events. The most common adverse events were implant site pain (32.5%), paresthesia (19.2%), implant site infection (10%), leg pain (5.8%) or buttock pain (5.0%).⁹⁹ The 5-year clinical data on implants for bowel indications from Hull et al¹⁶ suggest that preoperative counseling and long-term follow-up are necessary, as 24.4% required revision or replacement by 5 years, and 19% were permanently explanted by 5 years. Close follow-up with programming parameter optimization, may increase clinical efficacy, while decreasing paresthesias and leg pain.¹⁰⁰

In a recent multicenter trial, the infectious complication rate was 3.3%.¹⁰¹ It may be helpful to distinguish between early (<1 month after implantation) vs. late (>1 month after implantation) infections. Wexner et al¹⁰² reported that in colorectal patients, 5/7 early device infections resolved with antibiotics, while all 4 late infections required device explantation. As testing strategies evolve over time, there is increasing interest in the percutaneous office approach to testing, as at least one publication suggested an overall infection incidence of 0% in patients tested via office PNE vs. 10.5% in patients who received a staged approach in the operating room (OR).¹⁰³

RATIONALE for PNE vs STAGED PROCEDURE

Both PNE and staged trial play a role in SNM. The advantages and disadvantages of each must be taken into consideration when selecting the approach. (Level of Evidence: II, Grade of Recommendation: C)

One of the unique aspects of SNM is that patients are allowed to undergo a trial period to evaluate whether the therapy is efficacious and provides adequate symptom relief.

Both PNE and the staged trial play a role in SNM. The advantages and disadvantages of each must be taken into consideration when selecting the approach.^{2,6,104,105} An ideal candidate for PNE is one who

is comfortable undergoing a procedure under local anesthesia (LA) and who is able to tolerate the potential, mild discomfort related to the procedure. Patients with heightened levels of anxiety or a low pain threshold may benefit from a staged procedure in the OR under monitored anesthesia care (MAC) sedation /local or general anesthesia (GA).¹⁰⁶

PNE is less invasive, less costly and can provide reliable sensory responses. (Level of Evidence: III, Grade of Recommendation: C)

This form of test stimulation may be required by insurance carriers and may also act as a bridge to therapy acceptance. However, PNE lead migration can be problematic, and there may be limitations in pediatric populations and patients with NLUTD. (Level of Evidence: II, Grade of Recommendation: C)

Overall, the PNE approach is less invasive, less costly if performed in an office setting, and can provide reliable sensory as well as motor responses.¹⁰⁷ As it is generally performed in the office setting, it may also be more convenient for the patient as it has the potential to avoid one trip to the OR. This advantage would reduce the risks associated with anesthesia and hospital admission by having only one procedure in the hospital vs. two. Additionally, this form of test stimulation may be required by insurance carriers as well as acting as a bridge to accepting therapy. However, there are issues with PNE lead migration, and it may have limitations in a pediatric population and patients with neurogenic voiding dysfunction.⁹³

Staged implant is superior to PNE with regards to conversion rates to chronic therapeutic stimulation in OAB and FI. (Level of Evidence: II, Grade of Recommendation: B)

This approach also has the advantage of a longer trial period.

However, this approach may be more costly, may require two trips to the OR and may be associated with a greater rate of adverse events.

The advantage of the staged implant is that there is a longer trial period, and the lead that is being tested is the lead the patient will use long-term. The patient is also allowed to trial multiple programs to achieve optimal outcomes. The conversion to permanent implant is consistently higher in the staged vs. the PNE at rates of 80% vs. 44-52%, respectively.^{2,93,94,103,108} Now with the use of fluoroscopy at the time of PNE lead placement, the PNE conversion rate may be higher, however there is no current data to support this supposition.

More data is needed to identify ideal candidates for PNE vs. staged implant. Reliable predictors of test stimulation success are currently lacking in both bladder and bowel dysfunction. (Level of Evidence: III, Grade of Recommendation: D)

For patients with FI who have continent periods of >5-7days punctuated by intermittent episodes of FI, a staged implant may be preferable to ensure an adequate trial period. (Level of Evidence: IV, Grade of Recommendation: D)

Since NLUTD is a complex condition and given the lower rate of positive tests using PNE, a staged procedure should be considered for the majority of NLUTD patients. (Level of Evidence: III, Grade of Recommendation: D)

In patients with underlying neurological conditions, since NLUTD is a complex condition and given the lower rate of positive tests using PNE, a staged procedure should be considered for the majority of NLUTD patients. The majority of studies recently published in this area reported exclusively on the use of tined lead electrodes for the test trial in NLUTD patients.³⁶ Even though these studies do not report comparative results between the two techniques it has been demonstrated that PNE testing has disadvantages compared to the staged procedure such as lead migration 11-18%,² lower rate of positive tests 46% vs 88%¹⁰⁹ (9) and different responses between temporal and definitive lead – up to 20%.

SCREENING FOR SUCCESS DURING THE TEST PERIOD

Patients who achieve ≥ 50% improvement in one or more of their bothersome urinary or bowel parameters during PNE or Stage 1 test period may be offered a full system implantation.

For both PNE and stage 1 trials, both objective and subjective measures of improvement should be assessed. Success during the SNM trial is defined as at least 50% improvement in one or more of the bothersome parameters.⁹ Patients who achieve this benchmark should be offered full implantation.

PNE duration is typically 7 days for bladder indications. As the PNE leads are not anchored with tines, there has historically been concern regarding lead migration causing an inconclusive trial; thus, PNE trials are typically not done for more than about 7 days. However, some implanters do utilize longer PNE trials with little ill effect (in particular European implanters for bowel indications).

PNE test stimulation period is typically 7 days for bladder and 10-21 days for bowel indications. (Level of Evidence: III, Grade of Recommendation: 3)

PNE duration for urinary urgency/frequency and urgency incontinence is typically 7 days. This can be extended in cases of NOR. The period for SNM trial recommended by the manufacturer is two-weeks for bowel indications. It has been strictly applied in the US with a 10-14 day trial in the major published studies.¹⁶ However, in Europe this is considered too short a duration as stated in the published consensus statement based on a Delphi process in 2015.⁵⁴ Assuming the lead remains viable without significant migration, a 3-week trial period has been chosen as an empirical compromise.¹¹⁰

Thus, for bowel indications, it is suggested that SNM test duration last from 10 days to 4 weeks, allowing for testing of various stimulation programs, which may be beneficial when a satisfactory result is not immediately achieved.¹¹¹ Ultimately, the goal of any trial (whether PNE or staged), is to provide an adequate duration to determine whether at least a 50% improvement in symptoms has been achieved.

Stage 1 test period duration is typically 2-3 weeks.

Stage 1 testing can be attempted if PNE is inconclusive, particularly if a longer test period is required for screening.

A repeat stage 1 test may be performed at the physician's discretion.

Stage 1 duration is typically 2-3 weeks. There are some experts who do utilize up to four weeks, in part to avoid any possible placebo effect, or in instances when it is unclear if the patient has met the 50% improvement criterion, or for patients with incomplete emptying.¹¹² Kessler and colleagues followed a series of 44 patients who underwent prolonged tined lead testing for a median of 30 days,

with 70% proceeding to full implantation. The complication rate was 5% during the prolonged tined lead testing, but none of these were attributable to the extended testing itself.¹¹³

Patients should be encouraged to adjust the stimulation settings during their test period to optimize the trial.² If PNE testing is inconclusive, it is reasonable to consider a Stage 1 trial, in particular if a longer duration of testing is required. Stage 1 trials are typically not repeated, but can be attempted at the physician's discretion in select circumstances.

REMOVAL OF SCREENING LEAD

PNE electrode(s) removal preferably occurs in the clinician's office, but may be removed by patient/family at home.

Stage 1 tined leads can be removed under local anesthetic (in the office or OR) with or without sedation to ensure patient comfort during removal of all components.

There are no published studies regarding removal of the PNE lead at home by the patient versus in the office by the clinician. Removal at home is convenient for patients, especially those who travel a great distance to their clinician's facility; however, removal in the office allows for both confirmation that the lead was removed intact, as well as an opportunity to review outcomes of the trial (though this could also be done via phone in conjunction with home lead removal). The panel agrees that removal of a PNE lead can likely be safely performed in either setting

Stage 1 tined leads should be removed by a physician.¹¹⁴ These can be removed under local anesthetic in the office or the OR setting, with or without sedation, as needed to ensure patient comfort.

PREVENTION OF SURGICAL SITE INFECTION (SSI)

A perioperative antibiotic aimed at coverage of skin flora should be given intravenously within 60 minutes of incision for both bowel and bladder indications.

The specific antibiotic of choice should be guided by the local antibiogram and the patient's allergy profile. (Level of Evidence: IV, Grade of Recommendation D)

The most significant complication after SNM device implantation is wound infection. Reported wound infection rates range from 2–11% and are most commonly caused by *Staphylococcus aureus*.¹¹⁵ A recent large multicenter trial reported a wound infection rate of 3.3%.¹¹⁶

No defined perioperative or postoperative antibiotic protocol is uniformly agreed upon for neurostimulator implantation; instead, this decision should be guided by the local antibiogram and surgeon discretion. For the staged procedure, preoperative intravenous antibiotics should be given within 60 minutes prior to the incision and aseptic techniques should be closely followed.

The AUA Best Practice Statement for perioperative antibiotic prophylaxis recommends the use of a first-generation cephalosporin for open surgical procedures that do not involve entry into the urinary tract and does not recommend prolonged antibiotic usage, since there is no evidence to support it.¹⁰¹ Prostheses implantation surgeries are recommended to receive prophylaxis with an aminoglycoside plus a first-/second-generation cephalosporin or vancomycin. It is debatable how to categorize the SNM procedure because it is an open surgical procedure not entering the urinary tract as well as an implanted procedure.

In a study done by Haraway et al,¹⁰⁴ the use of cefazolin as the preoperative antibiotic was the only significant risk factor for subsequent infection and explanation of the SNM device. Indeed, cefazolin was less effective than vancomycin with or without gentamicin in preventing infection in this study, likely due to resistant organisms.

Antibiotic recommendations for bowel and bladder indications are similar. The European consensus statement for sacral nerve stimulation for FI and constipation recommends a single dose of prophylactic antibiotics before both the tined lead and the IPG implantation procedures, and suggests that routine postoperative antibiotics are not required.⁵⁴

Chlorhexidine-based skin prep is commonly used for perioperative cleansing of the patient's back and upper buttocks, but this varies between clinicians. Care should be taken in preparation of the buttocks and anus. If the implanter chooses to visualize the anus during test stimulation to observe the anal sphincter contraction, it should be covered with a separate plastic drape until visualization is required during surgery.

Other investigators suggest minimizing the risk of SSI with a preoperative shower with antiseptic, as well as allowing the dressing to remain in place for 48 hours postoperatively following stage 2 procedures.¹¹⁷

IDEAL ANESTHESIA

No data suggest superiority of local anesthesia (LA) with IV sedation vs. general anesthesia (GA) for a successful staged neuromodulation trial.

Muscle relaxants with GA and regional anesthesia causing neuromuscular blockade must be avoided.

LA is preferred for PNE, and LA with IV sedation for IPG implant. GA may be considered.

There are two current methods for trialing SNM to screen for efficacy.

The first is the PNE, which is generally done in the office under LA. There is the option to perform the PNE in an ambulatory surgical center (ASC) or even in the hospital and provide monitored anesthesia care (MAC) or GA. The second method is the staged approach, which is typically done in an ASC or hospital setting under MAC or GA. When SNM was first approved, this involved a PNE screening trial, and if the patient was determined to be a success, they then underwent implant of the long-term device. This required a large cut-down to the posterior aspect of the sacrum and was routinely performed under GA with high success rates. This suggests that the use of GA does not negatively impact the success of SNM.

In general, LA is considered to be safer than MAC, which is itself considered safer than GA. There is no current data that suggests any type of anesthesia is superior over another in terms of outcomes for SNM. As one of the parameters for determining a successful implant is appropriate motor response (bellows and great toe flexion), the use of a paralytic agent should be avoided if using GA. ***(Level of Evidence: V, Grade of Recommendation: C)***

LA is preferred for PNE if patients are able to tolerate it, and LA with IV sedation (MAC) for tined lead and IPG implant. GA may be considered under certain circumstances according to physician discretion,

however there is no evidence that the choice of anesthesia impacts outcomes (**Level of Evidence: II, Grade of Recommendation: B**).^{9,97}

IMPLANT TECHNIQUE

The clinician should strive to achieve appropriate motor and/or sensory responses on all 4 contacts at stimulus amplitudes of <2 volts. (Level of Evidence: II, Grade of Recommendation: B)

The concept of “Optimal Lead Placement” derives from the notion that while the overall success of SNM is excellent,¹¹⁸ there is a potential for an individual patient to experience an incomplete benefit, or a “false negative” response due to technique and imprecise lead positioning². Although it remains to be proven scientifically, logically it is hard to dispute that the quality of the interface between the neuromodulation device and the nervous system is of general importance to the therapeutic outcome of SNM. The current 3023 tined lead is an electrode array, consisting of four equally spaced contacts in a flexible assembly. By taking readily reproducible steps to steer the lead into position it is often possible to follow the course of the sacral nerve target, and achieve similar motor and sensory responses at each individual contact.^{119,120,121} Some have demonstrated more accurate placement with the curved lead.¹²¹ These electrode contacts may then be employed singly or in combination to achieve neuromodulation for clinical benefit.

The closer the lead is to the intended target, the lesser is the amount of energy that will be required to obtain a neuromodulation response. On one level, effective programing at lower thresholds is more efficient, and is likely to result in longer lasting battery life and less frequent need for replacement thus increasing the cost efficacy of the therapy and reducing risks related to re-operation.^{122,123} On another, electrode placement near the nerve means that the chance of stimulation of unwanted tissues (ie, the piriformis muscle), which may trigger uncomfortable stimulation or paresthesias, will be minimized. In turn, the need for reprogramming or re-operation to resolve uncomfortable stimulation should be lessened.

Leads that require higher thresholds or offer responses at fewer than 4 contacts can be successful. (Level of Evidence: II, Grade of Recommendation: B)

Sub-optimal lead placement can be therapeutically beneficial. Initial techniques for chronic lead placement were performed in a “blind” fashion, guided only by anatomical landmarks, without the routine use of fluoroscopy.⁴ The depth of lead placement, lead direction, and even the final sacral level of placement was not standardized. Many subsequent series have shown excellent symptom benefit before the concept of lead optimization was widely suggested. However, it is unknown if the overall degree of symptom relief could potentially have been greater, and the rate of screen failure, re-operation, or eventual therapy abandonment might have been reduced within these study populations, had lead optimization been a standard.^{124,125} Another unknown is whether the demands for precise lead placement may differ for various indications. An example of this concept is the notion that the target for lead placement for the indication of FI seems to be more robust, with a relatively large neuromodulation target (S3 or S4), while placement for urinary frequency and urgency without urge incontinence, and with a component of pelvic pain, may require hitting a narrower target (S3 or pudendal lead placement).

S3 is the preferred target for SNM. Bellows and toe dorsiflexion are the motor responses consistent with S3 placement. Thresholds for bellows should be lower than for toe. Leads placed in S4 may be appropriate in some cases. S2 should be avoided due to the risk of aberrant sensation and motor response in the leg. (Level of Evidence: 3, Grade of Recommendation: C)

From the initial studies on SNM, S3 is the preferred target for SNM. A typical S3-mediated response is a contraction of the pelvic floor along with plantar flexion of the first and second toes, whereas S4 stimulation does not produce any toe response.¹²⁶ There is individual variation in composition of the sacral roots. A direct ventral sacral root electrical stimulation study measuring bladder contraction by means of intravesical pressure showed that in 100% of the patients, bladder pressure increase was measured upon stimulation of the S3 anterior sacral root, but also in 60%, upon stimulation of S4, 40% on S2 and around 15% at S5. There is an individual difference in distribution of bladder efferent fibers.¹²⁷ It is unknown if the distribution of motor nerves activated directly by neurostimulation is similar to the distribution of the rootlets stimulated for the indirect neuromodulation effect.

In a retrospective study on patients with FI however, there was no difference in success rate upon S3 or S4 stimulation during a 3-week PNE test.¹²⁸ These findings are also supported by reports of accidentally or deliberately implanted leads in S4.

S2 stimulation produces outward rotation of the leg and sensation running down the leg.¹¹⁶ These effects may bother the patient, and S2 stimulation should therefore be avoided.

The clinician should consider both sensory and motor responses important for success. (Level of Evidence: IV, Grade of Recommendation: C)

The most readily quantifiable responses are motor (bellows and toe) with the patient under sedation. It is easier to obtain sensory responses than motor during a PNE, when the patient may not be able to relax and is fully conscious.^{116,129} A purported mechanism of action of SNM is sensory afferent neuromodulation, so the sensory side of the response may be meaningful. Indeed, given that sensory responses are used when reprogramming, having appropriate sensory responses during initial placement may help guide successful reprogramming and eliminate the need for revisions.

Motor responses alone may be utilized in patients who undergo GA. (Level of Evidence: IV, Grade of Recommendation: C)

With patients under heavy sedation or GA, sensory responses are unlikely to be elicited. The pattern of motor responses can be helpful in predicting where paresthesias will be felt. For example, all bellows and no toe, or toe only at a significantly higher threshold than bellows, is likely to be associated with anal sensation, while bellows followed by toe response immediately or at slightly higher thresholds is more likely to be associated with genital sensation. Toe movement at a lower threshold than bellows is likely to be associated with uncomfortable sensation down the leg.

Sensation down the leg or in the buttock and discomfort in the anal, perianal, or genital areas should be avoided. (Level of Evidence: II, Grade of Recommendation: B)

Although sub-sensory thresholds are potentially associated with good patient outcomes, generally patients tend to do better when the stimulation is comfortable. One of the most common adverse events of SNM is uncomfortable stimulation.¹⁰⁵ Most patients find stimulation in the buttocks or down the leg less comfortable, than in the anal, perineal, or genital areas.¹¹⁶

Patients are more likely to require reprogramming when stimulation is uncomfortable.¹⁰⁵ It is unclear whether anal, perineal, or genital sensations are associated with higher success in individual patients or between patient groups depending on diagnosis, ie, FI vs. urinary frequency with or without a component of pelvic pain.

Standard frequency and pulse width settings of 10-20 Hz should be used. (Level of Evidence: II, Grade of Recommendation: B)

Other frequencies and pulse widths can be used during troubleshooting procedures. (Level of Evidence: IV, Grade of Recommendation: D)

There are no studies which show definitive advantages of specific programming settings over others for a condition or indication. Low frequency stimulation of 10-20 Hz, with pulse width between 180-210 μ s, has been associated with therapeutic success for all the indications approved for SNM. These settings should be used initially. If patient comfort or therapeutic efficacy is not achieved, it is reasonable to experiment with alternative programming, though consistent success is anecdotal.

ROLE OF FLUOROSCOPY

Fluoroscopy is recommended for staged lead positioning to control depth of foramen puncture and optimize placement of the lead. (Level of Evidence IV, Grade of Recommendation D)

Fluoroscopy may be used for PNE to confirm proper lead placement. Alternatively, use of bony landmarks to determine lead placement is acceptable if fluoroscopy is not available. (Level of Evidence III, Grade of Recommendation C)

Fluoroscopy is a key element underlying quality tined lead placement, allowing the surgeon to control both depth of puncture and the placement of the lead. In many countries, labeling of the therapy indicates that fluoroscopy must be used for tined lead placement. Fluoroscopy may also be used during PNE, but not all clinicians do this during their office procedures.

Siegel and colleagues first described fluoroscopic lead placement in 1992.¹³⁰ Their description is still useful today, and very much in keeping with the modern technique; however, they described an open surgical procedure, which contrasts with the modern, minimally-invasive approach to tined lead placement. The role of fluoroscopy has become even more crucial following conversion to the minimally-invasive placement technique, as it allows for consistent, reproducible and optimal positioning of the lead in the foramen, as well as confirming curvature along the path of the S3 nerve, plausibly avoiding multiple punctures, minimizing bleeding, infection risk, post-operative pain and surgical time.

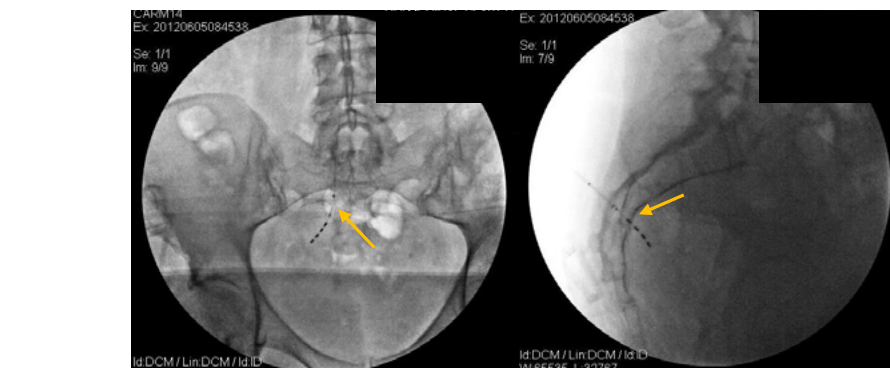
- **Active lateral fluoroscopy should be used during final tined lead deployment.**
- **The distal end of the lead introducer should be placed only ½ to 2/3 through the sacral bone table.**
- **The motor and sensory responses and the stimulus amplitude at which they occur, along with AP and lateral x-ray images associated with final deployment, should be recorded in the medical record.**
- **Radiographic appearance consistent with ideal lead placement entails:**

- In the lateral view, the lead parallels the fusion plane between third and fourth sacral segments, enters above the hillock, and curves caudally. Distal lead contacts appear to be spaced more closely together than proximal contacts.
- In the AP view, the lead starts close to the medial edge of the foramen, and curves out mediolaterally. Proximal contacts appear to be spaced more closely together than distal contacts.
- The curved stylet may be able to increase the number of responding contacts at lower stimulus amplitudes. (Level of Evidence IV, Grade of Recommendation C)

There remains debate regarding optimal lead placement, and no prospective studies exist to correlate clinical response (in bowel or bladder conditions) with lead positioning. Jairam et al¹³¹ from Maastricht retrospectively reviewed lead placement in 189 patients, and found no correlation between the position of the tined lead in the Stage 1 trial, with regard to depth, angle, and deflection, and the number of active electrodes, and the likelihood of a successful trial in either the OAB group or the NOR group. Nonetheless, expert consensus dictates that placement close to the nerve may reduce voltage used and improve programming options and long-term battery life.

Figure 1a: A/P image demonstrating medial placement in the S3 foramen (arrow)

Figure 1b: Lateral image demonstrating 3 contacts below the sacral plate



IPG PLACEMENT

IPG buttock placement in the lateral upper quadrant is preferred but abdominal placement may be required in some cases. (Level of Evidence: 3, Grade of Recommendation: C)

IPG should be placed above the muscle layer, no deeper than 2.5 cm (1 in). (Level of Evidence: 3, Grade of Recommendation: C)

When SNM was first introduced, the IPG was placed in the anterior abdominal wall. This required repositioning of the patient during surgery and prolonged the procedure, and, of note, the lead extension required for this type of placement is no longer manufactured. Buttock placement of the IPG was described by Scheepens et al¹³² in 2001. This technique simplified the procedure and reduced

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operative time in all 39 trial patients by approximately 1 hour, given that no repositioning of the patient was required during surgery. Pain was reduced and there were no infections.¹²¹ It is, however, difficult to assess the true advantage of buttock vs. abdominal placement, since no direct randomized trials have been published. In some patients with very limited fat, an abdominal placement might be utilized.

Because of the distance limitation of the wireless communication with the programmer, the IPG should be placed no deeper than 2.5 cm (1 in). [Product information data]

POST PROCEDURAL PATIENT RESTRICTIONS

PNE test stimulation is associated with a risk of lead migration. Limited physical activity during the trial is advised to reduce this risk. (Level of Evidence: 3, Grade of Recommendation: C)

Risk of lead infection is greater with Stage 1 testing than with PNE. Operative dressings should not be removed during the test period, unless permitted by the surgeon. (Level of Evidence: 3, Grade of Recommendation: C)

Following Stage 1 and Stage 2 procedures, patients should be encouraged to minimize vigorous activity for several weeks to allow the tined lead to scar in place and prevent lead migration. (Level of Evidence: 3, Grade of Recommendation: C)

Besides the manufacturer's recommendations (Manual InterStim 3889, 3058, etc.) very limited data has been published regarding specific post procedural patient restrictions. However, the two main risks to the implants are infection and dislodgement.

For test stimulation with temporary leads, which are only secured by external dressing and not by internal fixation like the tined lead, secure fixation with splash-resistant, transparent dressing allowing for washing and showering after disconnection of the external pulse generator is advised.¹³³ Patients should be instructed to avoid strenuous physical activities, which result in tension on the electrode.

For test stimulation with a tined lead, the risk of dislodgement appears to be less;¹³⁴ however, the risk of infection becomes more relevant. In a retrospective review of 669 SNM procedures, one group did find substantial decreases in infection rates after instituting an at-home chlorhexidine washing protocol.¹³⁵ The removal of the dressing throughout the test period should, however, still be avoided unless the physician has concern upon inspection of the dressing for infection or bleeding. There is no consensus on the use or efficacy of continued antibiotics during the trial period.

In one study¹³⁶ of 235 patients, lead migration occurred 1 subject when using a tined lead. In another study, with 2 years follow-up after tined lead implantation, there was a 10% rate of lead migration following tined lead implantation.¹³⁷ Regardless, after implantation, vigorous activity and excessive bending or twisting at the waist should be avoided for sufficient time to allow scarring and fixation of the implanted device.

POST-OPERATIVE AND FOLLOW-UP CARE

Routine follow up should include a clinical examination, symptom evaluation, system check of the stimulation device and confirmation that it is functioning. (Level of Evidence: III, Grade of Recommendation: C)

In patients with urinary retention, a post-void residual should be assessed.

Suggested routine follow up consultations during the first year should occur at 1, 6 and 12 months postoperatively, then annually thereafter. (Level of Evidence: IV, Grade of Recommendation: D)

Follow up consultations on demand should also be available. (Level of Evidence: IV, Grade of Recommendation: C)

The purpose of post-operative follow-up care is to confirm adequate functioning of the therapy and to address potential complications/side effects. Different patterns of follow up visits have been described.¹⁰⁰

It is recommended that the initial follow-up visits and subsequent follow-up visits should be spaced at least 1 month apart because full evaluation of setting changes may not be meaningful if the interval is less.¹³⁸ Based on the experience that a proportion of patients requires reprogramming in the early phase of follow-up, more than one follow-up visit in the first year is recommended.^{100,139}

Subsequent yearly follow-up visits are advised by international expert groups,^{100,125} but no consensus on the timing and interval of follow-up was determined on recent systematic review.⁵⁴ Follow up visits are uniformly recommended when problems occur.^{54,100,125} A clinical evaluation of the efficacy of SNM (eg, bowel and bladder diaries, scoring of the severity of symptoms, measurement of the impact of symptoms on QOL) and evaluation of the correct functioning of the neurostimulation device (eg, stimulation settings, impedances and side effects) are considered minimum requirements of follow-up.¹⁰⁰

Radiological imaging of the tined lead is advised at final implantation, which allows for comparison and evaluation of lead migration in case of dysfunction or unexpected loss of efficacy. (Level of Evidence: 3, Grade of Recommendation: C)

Whether postoperative radiological imaging after temporary lead insertion may be helpful to confirm the position remains controversial.⁵⁴ Intraoperative fluoroscopic monitoring/documentation during the implantation phase and/or postoperative documentation of the implanted hardware is recommended to document positioning of the electrode in the sacral foramen. Post-implantation radiological imaging at routine follow up is not required, unless there is loss of efficacy potentially due to electrode dislodgement or breakage.¹⁴⁰

SUCCESSFUL OUTCOME—BLADDER AND BOWEL

A patient who is satisfied with the treatment is considered to have a successful treatment outcome. (Level of Evidence: III, Grade of Recommendation: C)

For SNM, the most commonly used criterion for successful test stimulation is an improvement in the patient's bothersome symptoms of $\geq 50\%$ during the period of observation monitored by bladder or bowel diaries.^{54,100} Some data suggest that greater improvement during test stimulation may predict better long-term outcomes.^{141,142,143} Regardless, the symptom improvement should be associated with concomitant patient satisfaction before pursuing full implantation.

For patients with voiding dysfunction or NLUTD, further evaluations may be necessary to ensure long-term safety of the urologic tract. (Level of Evidence: III, Grade of Recommendation: C)

Of note, in patients with voiding dysfunction in the setting of NLUTD, further evaluation may be necessary to ensure the long-term safety of the upper urinary tract. The clinical evaluation of patients' LUT symptoms often includes a bladder diary, uroflowmetry followed by measurement of post-void residual urine volume in spontaneous voiders, urinalysis, renal-bladder ultrasonography, assessment of renal function, quality-of-life measurements and sometimes urodynamic investigations and/or cystoscopy.¹⁴⁴ UDS, with or without fluoroscopy, can at times be essential in these patients as a means to assess detrusor and bladder outlet function and give fundamental information about detrusor pressure and thus the risk factor for upper tract damage.¹⁴⁵ Additional interventions, ranging from oral medication or intradetrusor BTX-A injections, to augmentation cystoplasty or even urinary diversion, may be required and are not contraindicated in the setting of SNM.

SNM INFECTION

Explantation of the IPG and lead and debridement of the infected tissue is recommended in instances of SNM infection. The wound should be irrigated and a course of oral antibiotics can be considered. (Level of Evidence: III, Grade of Recommendation: C)

Infection rate of SNM is low at 2-11% for urinary indications,² as well as for FI.¹⁰² In one large investigational trial of SNM for FI, in which patients were followed for an average of 28 months (range 2.2-69.5), 10.8% of subjects reported infection with SNM implant. One infection spontaneously resolved and five were successfully treated with antibiotics. Seven infections (5.8%) required surgical intervention, with infections in six patients requiring full permanent device explanation.¹⁰²

A study of staged SNM implantation revealed lead infection in 12% and IPG infection in 11%. The only significant difference in clinical/surgical characteristics between infected and non-infected patients was a longer operative time for Stage 2 in infected patients.¹⁴⁶ A prolonged first stage implant trial with permanent quadripolar electrode has shown colonization in 13/34 electrode extension leads with the mean stage 1 SNM evaluation period of 52.3 (27–116) days but this was not associated with an increased risk of wound infection. The most frequent colonization was with *Staphylococcus epidermidis*, *Staphylococcus capitis*, *Peptostreptococcus* spp., *Enterococcus faecalis* and *Micrococcus luteus*.¹⁰¹ In the urinary literature, one study demonstrated that Cefazolin alone was less effective in preventing infection compared with the other antibiotic regimens, with 88% of infections that required explantation stemming from *Staphylococcus aureus* species resistant to cephalosporins.¹⁰⁴

There are no specific published reports regarding treatment of SNM device infections. Based on common general surgical principle, guidelines and expert opinion the infected device must be removed in its entirety, the wound irrigated/drained and oral/systemic antibiotic therapy started. The choice of the antibiotic should depend on local institutional guidelines. In very rare instances, removal of only one component of SNM implant may be contemplated with adequate antibiotic coverage. The choice to close the wound primarily or allow it to heal by secondary intention should be decided on a case by case basis. Other techniques to combat infection can be considered.¹⁴⁷

A 3-month waiting period prior to reimplantation is advised and use of the contralateral side for the IPG pocket should be considered. (Level of Evidence: IV, Grade of Recommendation: D)

There is no reliable data regarding the waiting period for reimplantation after removal of the infected device. The recommendation of a 3-month waiting time is based on expert opinion.

TROUBLESHOOTING DEVICE MALFUNCTION – LOSS OF EFFICACY & PAINFUL STIMULATION

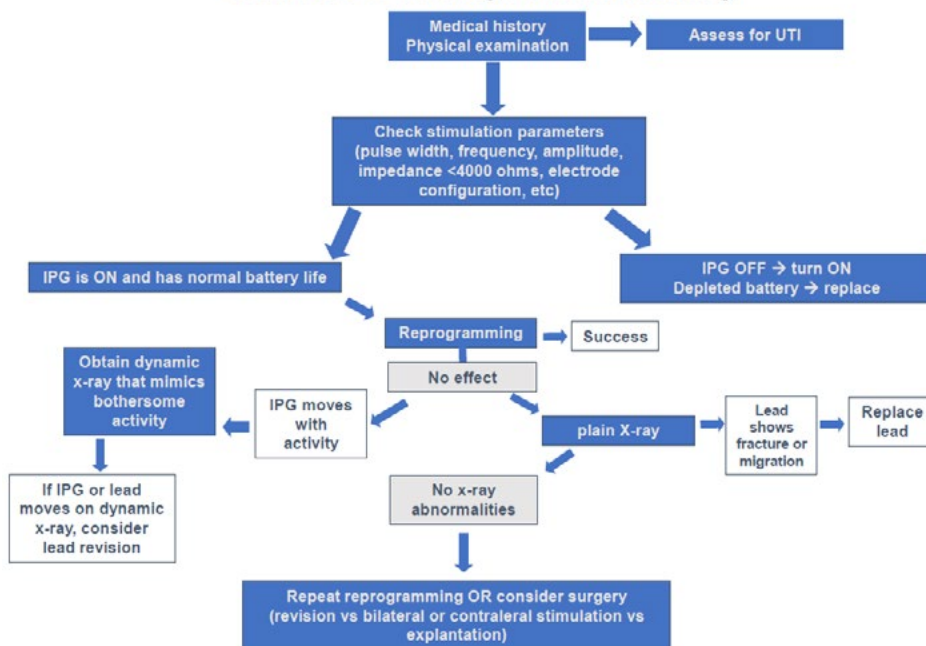
Patients with declining efficacy or painful stimulation should undergo device assessment. Turning off the device will differentiate painful stimulation vs. local pain at site of IPG. Changing program voltage or lead configuration may correct painful stimulation prior to attempting lead revision. (Level of evidence III, Grade of Recommendation C)

After permanent implantation, patients should be followed considering their primary reason for implant and clinical effect obtained at the time of their trial. Common complaints include discomfort at the site of the IPG, painful stimulation, recurrence of symptoms, absent stimulation, and stimulation in non-target areas.^{5,148}

Such complications can be related either to the device, implantation technique, or parameters of stimulation. The most recent prospective, controlled data with 3 year follow-up is now available,³¹ reporting a global device-related adverse event rate of 16%. Concerning the IPG, 47% of patients in the series reported adverse events, of which 91% were resolved at the time of analysis. These included an undesirable change in stimulation (49/272, 18%), implant site pain (34/272, 13%) and lack of efficacy (16/272, 6%). Loss of efficacy may develop either due to failure of the therapy to achieve significant clinical improvement of symptoms (> 50%) or due to a depleted battery.

Little has been published regarding the troubleshooting of sacral neuromodulation systems since the description by the Cleveland Clinic in 2005. As such, the following algorithm is recommended:

SNM loss of efficacy: troubleshooting



When a patient presents with a side-effect which may be related to stimulation, such as declining efficacy, painful stimulation, or aberrant neurological stimulation, the first action by the clinician should be to turn off the IPG. Should symptoms disappear, the IPG may be turned back on and reprogrammed, trying to avoid return of the presenting symptom. Pain related to stimulation should disappear when turning off the IPG and reprogramming, which may include decreasing voltage, decreasing frequency and/or changing the lead configuration. This can be done by the physician, or by a physician assistant or dedicated nurse if they are adequately trained in programming as well as clinical analysis of patient complaints. If pain persists after the IPG is turned off, the pain is may be due to the position of the IPG itself and IPG repositioning may be required, or it may be unrelated to the device. At minimum, other etiologies should be considered.

Device programming should be performed by experienced clinicians targeting comfortable low sensory thresholds to the perineum. (Level of Evidence IV, Grade of Recommendation C)

Follow-up of patients undergoing permanent SNM depends somewhat on the local health care system. As most of the adverse events require the clinician to analyze symptoms and then try to correlate those symptoms with any device malfunction, office evaluation (rather than a telemedicine visit) is usually required.

Patients given a complement of programs should try a new program for at least 1 week, unless it is not tolerable secondary to unpleasant stimulation or severe worsening of symptoms. (Level of Evidence IV, Grade of Recommendation C)

Since voiding and bowel disorders are not always constant over time, any new program should be tested for at least one week unless the patient experiences side effects from the new program. In a recent prospective trial¹¹⁸ 22% of patients needed reprogramming due to an undesirable change in stimulation, decrease in therapeutic efficacy, or pain, within 5 years of implantation.

If reprogramming does not improve the patient's symptoms, radiographic imaging should be performed to assess for lead breakage or migration. (Level of Evidence IV, Grade of Recommendation C)

X-ray images can reveal lead fractures or migration of system components that subsequently necessitate replacement of the system. Moreover, impedances > 4000 ohms are also diagnostic of a lead fracture or microfracture (which may not be visible on imaging) and likely requires lead replacement, although evidence from a large retrospective series shows many abnormal impedances can be programmed around to salvage a lead.⁹⁸

WHEN TO STOP SNM TESTING/THERAPY

SNM testing or therapy should be discontinued if the patient no longer wishes to proceed, or if in the judgment of the clinician, further testing/lead revision will not lead to symptom improvement. (Level of Evidence: III, Grade of Recommendation: C)

The only documented predictor for treatment success is the response to a trial of stimulation. Since implanted patients may experience declining efficacy over time,³⁹ therapy may need to be altered. As outlined elsewhere in this text, patients may elect to undergo device interrogation, re-programming, or surgical revision when symptoms are not well controlled with SNM. If at any time the patient does not desire to continue with SNM, or would prefer to transition to other 3rd line treatments, then therapy should be discontinued. Furthermore, once a patient has exhausted the possible revisions and alterations of therapy (lead location and side, programming options) and the clinician determines that no further benefit can be expected, then SNM should be discontinued.

DEPLETED IMPLANTABLE PULSE GENERATOR (IPG)

Exchange of IPG should occur when end of service is confirmed and the patient has maintained a successful response to SNM prior to battery depletion.

Check the impedance of the lead and, if indicated, replace the lead when exchanging the IPG. (Level of Evidence: III; Grade of Recommendation: C)

Patients with a depleted IPG battery (end of service) will usually present with loss of SNM stimulation and/or loss of efficacy of SNM. Occasionally, increased stimulation may be experienced. When patients present with a depleted IPG battery, confirm end of service by running a battery check with a physician programmer. Exchange the IPG when the end of service is confirmed and the patient has maintained a successful response to SNM prior to battery depletion. Check the impedance of the lead and, if indicated, replace the lead when exchanging the IPG.

NON-FUNCTIONING SYSTEM

When patients present with a non-functioning system, confirm impedances by checking all combinations with a physician programmer. If all of the combinations are non-functional, then the IPG should be turned off to conserve battery life and the lead replaced. The lead should also be replaced if there is a therapy-limiting number of programming options. (Level of Evidence: III; Grade of Recommendation: C)

Patients with a non-functioning lead will usually present with loss of SNM stimulation and/or loss of efficacy of SNM. When patients present with a non-functioning lead, confirm by an impedance check all combinations with a physician programmer. At least one functioning lead electrode is required for a lead to operate unipolar and two functioning leads for bipolar stimulation. If all of the combinations are non-functional, the IPG should be turned off and the lead replaced.

When assessing the lead with the physician programmer, run an impedance check at 2.0 volts to deliver sufficient energy for a complete check and assess all the seven possible circuit combinations. A non-functioning combination will return a reading above 4,000 ohms or 0 ohms. If all of the combinations are non-functional, the IPG should be turned off and the lead replaced (consider a trial of unipolar stimulation if only one electrode is functioning). If not all of the combinations are non-functional then, by a process of elimination, the non-functioning electrode(s) can be identified and not used in future programming. Many devices with non-functional electrodes can be salvaged and used to provide continued therapy after programming around the broken lead.⁹⁸

Before replacing a non-functioning lead, the clinician should discuss the implications of lead removal, including the risk of retained fragments. Confirmation of the lead site should be sought, in the form of a sacral X-ray if the prior operative reports or intraoperative films are not available. It is recommended that the lead be removed through the pre-sacral incision. When removing the lead through the pre-sacral incision, use gentle traction in a straight-line direction with respect to the lead tines. If too much resistance is encountered during lead removal, further dissection through lumbosacral fascia and pre-sacral periosteum may be required. The prevalence of lead breakage during lead removal is 1-3.6%.^{103,149,150} Of note, some anecdotally report successful lead removal through the buttock incision using gentle traction on the lead. Nonetheless, leads left in for prolonged periods of time may be more challenging to remove this way and strong consideration should be given to midline removal.

RESIDUAL LEAD FRAGMENTS FOLLOWING LEAD REMOVAL

Patients with residual lead fragments should be advised of the presence, nature and safety of the residual fragments. Current evidence suggests it may be safe for residual lead fragments to remain long-term. (Level of Evidence: III, Grade of Recommendation: C)

Patients with residual lead fragments should be advised of the presence, nature and safety of the residual fragments. This should include providing patients with information regarding composition, size and location of residual lead fragments. Although not reported for SNM, migration, infection, and injury to surrounding structures from residual lead fragments are theoretical risks. Current evidence suggests it is generally safe, for residual lead fragments to remain *in situ* long-term, including in patients undergoing MRI.⁸⁵

BILATERAL AND PUDENDAL LEADS

During PNE testing, bilateral temporary lead placement is recommended to reduce the risk of test failure due to lead migration. (Level of Evidence: III, Grade of Recommendation: C)

There is no published evidence that bilateral tined lead placement is more efficacious than unilateral placement. (Level of Evidence: 3, Grade of Recommendation: C)

For PNE test, a non-tined electrode is used. The currently available version is a thin wire without any anchoring system and is prone to migration. The risk of migration is related to the duration of the test and thus only a few days of reliable stimulation are possible. Placing bilateral PNE leads increases the possibility of a correctly placed lead, and increases the possibility of a successful test. Tined leads are more expensive than non-tined, and it may be difficult in some countries due to insurance to place bilateral tined leads for testing. In a retrospective study of 55 patients with unilateral tined leads and 69 with bilateral tined leads, 76% of patients with bilateral leads went on to full implantation, versus only 58% of those trialed with a unilateral lead. It should be noted that in patients with bilateral leads, both leads were consecutively stimulated—not simultaneously.¹⁵¹

Theoretically, bilateral stimulation may be more efficacious than unilateral. This hypothesis is supported by animal experiments which demonstrate that with bilateral stimulation more nerve fibers can be stimulated enhancing the neuromodulatory effects.¹⁵² However, in a prospective randomized trial on 25 patients, no beneficial effect was found with bilateral PNE lead stimulation compared to unilateral stimulation.¹⁵³ In patients with loss of efficacy, adding a contralateral PNE lead to achieve bilateral stimulation resulted in a significant decrease in the number of voids and pads per day. However, no benefit was found between bilateral or contralateral stimulation.¹⁵⁴ In FI, a study exploring the benefit of bilateral over unilateral sacral neuromodulation had to be discontinued prematurely after an interim analysis of 20 patients demonstrated no additional benefit in symptom score, quality-of-life score, or findings on anorectal manometry.

Placement of pudendal leads can be considered as an alternative option if SNM fails after sacral lead positioning and programming has been optimized, especially if the IPG is already in place or if the patient is refractory to other minimally-invasive treatments. (Level of Evidence: III, Grade of Recommendation: Grade C)

The currently available system for SNM can be used off-label for pudendal stimulation. However no long-term data are yet available. A retrospective study in a mixed patient group including OAB wet/dry, NOR and painful bladder syndrome showed successful responses upon pudendal stimulation in 93% of patients failing SNM.¹⁵⁵ In two prospective studies, patients (OAB wet/dry; painful bladder) were implanted with leads at both S3 and close to the pudendal nerve. Of the patients responding successfully to the test, 78% subjectively favored the pudendal lead for chronic stimulation; however, it should be noted that the pudendal leads were placed with EMG guidance, while the sacral leads were not.^{156,157}

MRI CONSENSUS STATEMENT

For current devices, manufacturer labeling should be followed for MRI imaging of the head or extremities. (Level of evidence: Grade IV, Grade D)

MRI imaging is used to diagnose and monitor an increasing number of conditions. There are three magnetic fields during MRI that can react with implanted neuromodulation devices including mechanical force and torque induced by a static magnetic field, induced voltages and current on leads by a pulsed gradient field, and current induced into the generator body by the radiofrequency magnetic field.^{158,159,160} These forces could potentially result in local tissue injury or damage to the implanted devices. Until the development of MR conditional neuromodulation systems, it is necessary to consider explantation of entire systems in order to perform MRI, exposing the patient to loss of therapy benefit, additional surgical risks, and costs.

According to the manufacturer's labeling (2012 manufacturer's instructions for use [IFU]), non-clinical testing has demonstrated that InterStim Therapy systems have been found to be MR Conditional. If a patient is implanted with an InterStim II Model 3058 Neurostimulator or an eligible serial number of an InterStim Model 3023 Neurostimulator (when implanted as a system including a neurostimulator, lead, and extension as applicable), MRI examinations of the head only may be safely performed under the following conditions:

- 1.5-Tesla (T) horizontal closed bore
- Maximum spatial gradient of 19 T/m (1900 gauss/cm)
- RF transmit/receive head coil only (no RF transmit body coil)
- Gradient slew rate limited to 200 T/m/s
- Normal operating mode (Scanning frequency of approximately 64 MHz only)
- If possible, do not sedate the patient
- Model 3058 and eligible Model 3023 Neurostimulators: Turn the neurostimulator off
- Eligible Model 3023 Neurostimulators only: Disable the magnet switch

According to the manufacturer, scanning under different conditions may result in severe patient injury or device malfunction, and is currently not recommended by FDA labelling. As a matter of course, implant surgeons and radiologists should recognize these guidelines.

There appears to be an increasing body of evidence that axial MRI imaging can be performed safely with present devices under certain circumstances. (Level of Evidence: II, Grade of Recommendation: B)

Two separate studies have shown that MRI studies of the extremities other than the head and body MRI scanning including the lumbar spine and pelvis can be performed safely with earlier and current InterStim devices. Elkelini¹⁴⁷ as well as Chermanski¹⁶¹ reported the results from individual small series of patients studied without event using the interstim I device, using 1.5 and 0.6 Tesla machines. In one case, a generator (IPG) was found to be damaged after study due to leaving the magnet switch on, and both studies recommended setting the amplitude to zero and turning the magnet switch off.

In an ex vivo phantom model simulator study of the contemporary InterStim II device,¹⁶² there was no significant heating, defined as an increase in temperature of $>1^{\circ}\text{C}$, found using an intact system or with a 5cm distal lead fragment meant to simulate a retained lead fragment after partial extraction. Significant heating was found when a full-length lead, not connected to an IPG, was evaluated. Based on these findings, a prospective in vivo study was performed¹⁶³ wherein a pelvic or lumbosacral MRI was performed on a series of eleven patients with their devices in situ, and turned off (no magnet switches as part of these devices). No serious adverse events were reported during the MRI study and there were no changes in the devices after, though two patients did report a sensation of warmth at the IPG site during the scan, which resolved afterward. A caveat is that the patients were studied on

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the same MRI machine used to study the phantom model, and they were not willing to generalize to other machines and specific locations.

Alternative forms of imaging should be considered carefully before device removal for MRI imaging. (Level of Evidence: IV, Grade of Recommendation: D)

Although it appears that less restrictive use of MRI may be safe in certain clinical settings, it is recommended that implanting physicians and radiologists follow the manufacturer's guidelines at the present time. Thoughtful discussion and planning with radiologists may be helpful in obtaining MRI imaging of extremities that are geographically separate from the pelvis, using the principles outlined in the manufacturers' IFU for study of the head only. It remains prudent to consider imaging modalities that can serve as a substitute for MRI whenever appropriate; indeed, a study by Lloyd et al suggests that up to 24% of patients who undergo SNM device removal for MRI ultimately do not go on to receive an MRI study, and that only 56% of MRIs lead to a change in clinical management, emphasizing that it is of paramount importance to confirm the necessity of MRI before removing a functional SNM device.¹⁶⁴ Clearly, full body MRI conditional safety will be a highly valuable feature if and when it becomes available with future systems and devices.

FUTURE RESEARCH

Future research, including newer technologies, mechanisms for patient-response driven programming, and techniques for optimal lead placement, is needed.

This research will be aided by a better understanding of the mechanism of action of SNM

Attention should also be directed toward the development of better composite measures of therapy outcomes.

This consensus statement highlights the complex nature of neuromodulation therapy. Broadly, we have a low level of evidence for many of our recommendations. Patient selection is based on symptoms, not biochemical or functional testing. Pelvic floor, urinary and bowel studies have not reliably predicted the best candidates for SNM, nor have patient symptoms.¹⁶⁵ One study has shown an association of treatment satisfaction with pudendal nerve terminal motor latency in FI¹²⁸ and another suggests that strong toe responses at as many electrodes as possible intraoperatively may reduce the risk of future lead revision,¹⁶⁶ but only response to a trial of stimulation can currently predict response to treatment. This opens the door to newer technologies which incorporate the lead trial into long-term therapy, possibly with a one-step implant if costs can be contained. The current IPG (InterStim, Medtronic) is costly which is the reasoning behind a staged-implant approach. Other perceived weaknesses of this device, including lead fracture, battery life, clinician-dependent programming, and MRI compatibility, need to be addressed, as does the long-term effect of SNM on bladder and bowel physiology.

Surgical technique has not changed much since the introduction of the tined-electrode, which eliminated the need to suture directly to the periosteum. There remains debate regarding how precisely the lead must be positioned. Some studies suggest that only one active electrode is needed for a clinical response¹¹⁴, though most advocate for 4-electrodes targeted at low voltages.¹⁶⁷ CT guidance has been used for those with complex anatomical findings,¹⁶⁸ while others have shown intra-operative EMG to be of help.¹⁶⁹ Nevertheless, further outcomes-based research is needed to clarify the best method for placing the lead. ***(Level of Evidence: III, Grade of Recommendation: C)***

Furthermore, there are no specific programming recommendations besides the 4-program settings and patient selection based on perceived symptom improvement. More novel approaches may incorporate a patient's "vote" for a program or a setting based on bowel/bladder diaries kept in real time. There are already available smart-phone applications for patients to track their symptoms which may be utilized in device programming.¹⁷⁰

Economic modeling suggests that SNM becomes cost-effective relative to intradetrusor botulinum toxin injections for idiopathic OAB after about 5 years of treatment.¹⁷¹ At 10 years, models suggest that SNM is also cost-effective relative to oral medical therapy for OAB.¹⁷² There is little data on SNM cost-effectiveness relative to other treatments for urinary retention and fecal incontinence. Such studies would need to incorporate patient reported outcome measures to best characterize therapeutic benefit versus the cost of therapy.

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TABLE: International Consultation on Urological Diseases (ICUD) modification of The Oxford Centre for Evidence-Based Medicine guidelines on the levels of evidence that generate the subsequent grades of recommendations

Level of Evidence	Criteria	Grade of Recommendation	Criteria
I	Meta-analysis of RCTs or high-quality RCT	A	Usually consistent with level I evidence
II	Low-quality RCT or good-quality prospective cohort study	B	Consistent level II or III evidence or "majority evidence" from RCTs
III	Good-quality retrospective case-control study or cohort study	C	Level IV evidence or "majority evidence" from level II or III studies, Delphi processed expert opinion
IV	Expert opinion	D	No recommendation possible because of inadequate or conflicting evidence

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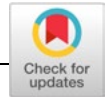
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The clinical role of LASER for vulvar and vaginal treatments in gynecology and female urology: An ICS/ISSVD best practice consensus document

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BACKGROUND: The clinical role of LASER for vulvar and vaginal treatments in gynecology and female urology is controversial.

AIMS: In this best practice document, we propose recommendations for the use of LASER for gynecologic and urologic conditions such as vulvovaginal atrophy, urinary incontinence, vulvodynia, and lichen sclerosus based on a thorough literature review.

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

MATERIALS & METHODS: This project was developed between January and September 2018. The development of this document followed the ICS White Paper Standard Operating Procedures.

RESULTS: Most of the available studies are limited by their design; for example they lack a control group, patients are not randomized, follow up is short term, series are small, LASER is not compared with standard treatments, and studies are industry sponsored. Due to these limitations, the level of evidence for the use of LASER in the treatment of these conditions remains low and does not allow for definitive recommendations for its use in routine clinical practice. Histological evidence is commonly reported as proof of tissue regeneration following LASER treatment. However, the histological changes noted can also be consistent with reparative changes after a thermal injury rather than necessarily representing regeneration or restoration of function. The use of LASER in women with vulvodynia or lichen sclerosus should not be recommended in routine clinical practice. There is no biological plausibility or safety data on its use on this population of women.

DISCUSSION: The available clinical studies do not present convincing data regarding the efficacy of LASER for the treatment of vaginal atrophy or urinary incontinence. Also, while short-term complications seem to be uncommon, data concerning long-term outcomes are lacking.

CONCLUSION: At this point, LASER is not recommended for routine treatment of the aforementioned conditions unless part of well-designed clinical trials or with special arrangements for clinical governance, consent, and audit.

KEYWORDS

genitourinary syndrome of menopause, ICS, ISSVD, LASER, lichen sclerosus, urinary incontinence, vulvovaginal atrophy, vaginal laxity

1 | INTRODUCTION

“Light Amplification by Stimulated Emission of Radiation” (LASER) has been widely used in gynecology and urology for more than 40 years. It is well established in the management of HPV-related genital lesions, prostate vaporization, and lithotripsy.^{1,2} More recently the use of trans-vaginal or vulvar LASER has escalated to be used as a panacea for several urological and gynecological conditions, such as: lichen sclerosus, vulvodynia, “vaginal laxity”, overactive bladder, and pelvic organ prolapse.

Limited ex-vivo studies have suggested that LASER has the potential to modify tissue characteristics. Clinically it has already been adopted for tissue remodeling of non-mucosal scars and wrinkles with relative success. These findings have led to the concept that LASER technology could be used in the treatment of vaginal atrophy³ and has already been utilized and marketed as a “treatment” or therapy for vaginal “rejuvenation” and “Designer LASER Vaginoplasty” by the aesthetics industry.

Several published studies have suggested that fractional microablative CO₂ and Er:Yag LASER effectively treat not only atrophic vaginal mucosa (2014)(3), but also improve urinary incontinence (2015).⁴ From the initial studies, the jump to aggressive marketing and widespread adoption of the LASER technology was quick. However, the studies failed to provide definitive evidence of its safety and effectiveness. Flaws of these studies include short follow-up time, absence of control groups, lack of standardized outcome measures, and the involvement of industry sponsorship.

Vaginal atrophy related to hypoestrogenism is recognized as a prevalent and significant cause of morbidity in the postmenopausal population.⁵ In 2014 it was integrated into the broader definition of “genitourinary syndrome of menopause” (GSM).⁶ GSM classifies an extensive list of signs and symptoms common to the natural process of female menopause as a syndrome. This umbrella term also carries the risk of classifying true disease (ie, lichen sclerosus) as GSM.⁷

Despite the lack of a true functional or anatomical definition, the use of the term “vaginal laxity” has become more widespread.⁸ The term has been defined by the International Urogynecological Association (IUGA) and the International Continence Society as a feeling of vaginal looseness,⁹ a woman’s subjective sensation of vaginal “looseness.” “Vaginal rejuvenation” with LASER is targeted to women with “vaginal laxity” as a procedure to improve the sensation of laxity and thus enhance sexual function in those with decreased vaginal sensation.¹⁰

In 2007 the American College of Obstetrics and Gynecology (ACOG) included “vaginal rejuvenation” and “designer vaginoplasty” in a list of procedures that were “not medically indicated” due to a “lack of evidence confirming safety and effectiveness.”¹¹ However the US Food and Drug Administration (FDA) licenced the CO₂ LASER systems for “incision, excision, ablation, vaporization, and coagulation of body soft tissues and was used by specialities such as aesthetics (. . .), otolaryngology (. . .), gynecology, neurosurgery, and genitourinary surgery” in 2010.¹² Other LASER manufacturers requested FDA approval in 2014, with similar licence terms approved.¹³ Er:YAG LASERs were licensed for dermatologic uses: coagulation, vaporization, ablation, or cutting of skin in dermatology and plastic/aesthetic surgery (2011).¹⁴ The Nd:YAG had a similar approval in 2014.¹⁵

Treatment of vaginal atrophy and other gynecological disorders with LASER devices gained popularity and was marketed for this purpose. In response to this surge, ACOG issued a warning in 2016 clarifying that the FDA had not approved the use of these devices for the treatment of vulvovaginal atrophy.¹⁶ Despite this announcement, claims that the devices had received FDA approval for such conditions were circulated.^{17,18}

Several authors^{19,20} and groups, such as the International Society for the Study of Vulvovaginal Disease (ISSVD)¹⁰ and the Society of Obstetricians and Gynecologists of Canada (SOGC),²¹ have raised concerns about the lack of evidence sustaining the use of LASER technologies for these gynecological indications. Finally, on the July 30th, 2018, the FDA issued a warning that the effectiveness and safety of energy-based devices (LASER and radiofrequency) for urinary incontinence, vaginal “rejuvenation” or cosmetic vaginal procedures has not been established.²²

The executive council of the International Society for the Study of Vulvovaginal Disease (ISSVD) and the board of trustees of the International Continence Society (ICS) acknowledge the need to establish scientifically based recommendations on the new uses of LASER in their fields. This best practice document has therefore been developed to provide guidance on the use of LASER for the treatment of gynecological and urogynecological conditions and to educate providers about the weaknesses of the available data.

2 | MATERIAL AND METHODS

The ISSVD and the ICS identified and invited members to develop this project; participants were assigned a specific topic to be thoroughly researched and summarized in order to produce recommendations. The project was developed between January and September 2018. The development of this document followed the ICS White Paper Standard Operating Procedures.²³

Literature searches were performed using Pubmed, Google Scholar, Ovid, Cochrane, and Embase to identify relevant papers. Search results were limited to papers written in English and published prior to June 2018.

Search strings for each topic were:

1. Vaginal atrophy/“rejuvenation”:
 - a. “genitourinary syndrome of menopause,” “vulvovaginal atrophy,” “atrophic vaginitis,” “vaginal atrophy,” “vaginal rejuvenation,” “menopause” and “LASER.”
2. Urinary incontinence and/or pelvic organ prolapse:
 - a. “urinary incontinence,” “incontinence,” “prolapse,” “POP,” “pelvic organ prolapse,” “cystocele,” “rectocele,” “hysterocele,” and “LASER.”
3. Vaginal laxity:
 - a. “vaginal tightening,” “vaginal laxity syndrome,” and “LASER.”
4. Vulvodynia:
 - a. “vulvodynia,” “vestibulodynia,” and “LASER.”
5. Lichen sclerosus:
 - a. “lichen sclerosus” and “LASER.”
6. Other possible uses of LASER:
 - a. “bleaching,” “whitening,” “brightening” “labiaplasty,” “labioplasty,” “nymphoplasty” and “LASER.”

Evidence was graded according to the Center of Evidence Based-Medicine’s “Levels of Evidence for Therapeutic Studies” and recommendations according to the American Society of Plastic Surgeons’ “Grade Practice Recommendations.”²⁴

After discussion and consensus among all participants, the final version of the text was approved by the Executive Council of the ISSVD and the Board of Trustees of the ICS.

3 | BASIC SCIENCE EVIDENCE

3.1 | Proposed mechanism of action of LASER on skin and vaginal tissue

Human skin is comprised of three layers: the epidermis, the dermis, and the subcutaneous fat.²⁵ Currently, the hypothesized mechanism by which the LASER rejuvenates the vaginal mucosal epithelium has been developed based on the effects of LASER on epidermal skin epithelium. The LASER is believed to induce controlled injury to the epithelial layer of the skin, which stimulates tissue repair and remodeling.²⁶

Wound repair in skin epithelium is a well-defined process characterized by inflammation, proliferation leading to tissue restoration, and tissue remodeling.²⁷ LASER is believed to normalize the cycle of collagenesis and collagenolysis^{28–30} by inducing break down of disorganized collagen fibrils,³¹ creating more organized collagen bundles, and decreasing collagen bundle thickness and density.³²

Similar to skin, the vaginal wall is composed of three histologically unique layers. The most superficial layer of the vaginal mucosa is made up of stratified squamous epithelium but, unlike the skin epidermis, is devoid of keratinocytes and is therefore non-keratinized. Also unlike skin, vaginal tissue undergoes a number of discrete histologic changes during menopause. Thinning of the vaginal epithelium, reduced vaginal blood flow, diminished lubrication, increased pH, and a change in the vaginal microbiome, as well as decreased elasticity of the vaginal wall can occur.³³

Neocollagenesis and restoration of the trabecular architecture of collagen is the proposed basis for vaginal rejuvenation with CO₂ LASER treatment. Investigators have hypothesized that the molecular and histologic changes demonstrated in the skin in response to LASER treatment can be recreated in the vaginal wall. However, given the differences in anatomy as well as histologic changes in response to hormone balance, such as those seen during menopause, it is unclear whether the effects of the LASER on skin could be expected for the vaginal wall.

In 2011, Gaspar et al³⁴ demonstrated that vaginal fractional CO₂ LASER treatment increased the thickness of the vaginal epithelium and increased the fibrillary component of the extracellular matrix. In 2015, Salvatore et al³⁵ described fibrillogenesis and neocollagenesis of vaginal tissue following vaginal LASER treatment in postmenopausal women. Zerbinati et al³⁶ in 2015 carried out a similar study and examined the tissue of postmenopausal patients with severe symptoms of GSM following CO₂ LASER treatment. They concluded that the histological changes seen support the theory that the LASER stimulates fibroblasts to produce collagen. It is unclear, however, if these histologic changes following LASER treatment can be directly correlated with improvement of clinical symptoms, as no control group was used (discussed in section 3.2).

TABLE 1 The use of LASER in the vagina for the treatment of atrophy/rejuvenation

	Level of evidence	Grade of recommendation
The mechanism of action of LASER on vaginal tissue in normal or diseased states is not known and cannot be used to justify treatment results	3b/4	C

Current published literature on the specific use of LASER in the vagina for the treatment of GSM is limited in the basic science results as well as clinical outcomes and the potential correlation to the histology findings (level of evidence 3b/4, grade of recommendation C). Thus, clinical conclusions drawn from these studies are highly speculative (Table 1).

3.2 | Histological effects

There is little known about the histology of the vaginal mucosa after LASER therapy for vaginal rejuvenation or functional remodeling. What is reported is based on small studies of patients over a short period of time.

Salvatore et al³⁷ described a single case, with a post-treatment biopsy performed 1 hour after the CO₂ fractional LASER treatment. The biopsy showed superficial epithelial desquamation. In comparison, animal skin burn studies report signs of injury to include desquamation. Desquamation therefore cannot be interpreted as beneficial remodeling.³⁸

In a prospective study from the same group,³⁵ the authors compared treated vaginal mucosa with mucosa out of the field of therapy from the same patient. They noted neovascularization, neocollagenesis, and restoration of the trabecular architecture of collagen in the treated mucosa, which was interpreted as remodeling changes. These biopsies however were taken at the time of the LASER procedure, which would have provided insufficient time for remodeling to occur. In comparison, skin studies have shown changes of wound healing in the first few days after LASER therapy, while restorative changes ensue weeks later.³⁹ The histology images in the paper mentioned show denuding of the epithelium and different degrees of tissue coagulation, which are consistent with thermal injury.

Zerbinati et al³⁶ biopsied five patients before vaginal treatment, and at 1 and 2 months after treatment, which would allow early changes to be appreciated. At 1 and 2 months, changes were similar, noting thickened epithelium with superficial shedding, increased dermal papilla with elongated capillaries, giving the epidermal-dermal junction an undulating pattern, increased glycogen in the epithelial cells, and an increase in fibroblast activity. Increased collagen and ground substance have also been described in existing studies.^{35,36} The illustrations in Zerbinati's paper show epidermal thickening with acanthosis, and some show parakeratosis and increase in dermal chronic inflammatory cells.³⁶ These changes are consistent with repair, as might be seen in lichen simplex chronicus, and alone do not indicate functional remodeling.

Histology changes to the vaginal mucosa following intravaginal LASER therapy have also been compared to a healing vaginal wound at the 2-month time point. A lack of significant capillary density and the increase in cellularity of connective tissue is consistent with this. It has not been confirmed if these changes are favorable for functional

TABLE 2 The histology of vaginal LASER “rejuvenation”

	Level of evidence	Grade of recommendation
The histological changes present after LASER therapy are consistent with reparative changes after a thermal injury. They do not necessarily represent restoration of function, and cannot be used to justify treatment results.	4	C

remodeling or if they would be sustained at the 6 and 12 month marks.²¹

Interpretation of available studies overall is limited by the lack of long-term follow-up, and hence complications such as scarring may not have been detected.⁴⁰ In addition, in a review of the literature on LASER therapy for treating GSM, the authors noted that in one pilot study, the maturation index (a ratio obtained by performing a random cell count of the three major cell types shed from the vaginal squamous epithelium: parabasal, intermediate, and superficial cells) was not considered.^{3,40}

In summary, the histology of vaginal LASER “rejuvenation” is not well studied. Only small series have been published, with short follow-up. The changes present after therapy are consistent with reparative changes after a thermal injury. Whether they represent restoration of function has not yet been demonstrated by the histology. Further study is needed (level of evidence 4, grade of recommendation C). Further study is needed (Table 2).

3.3 | Impact on the vaginal microbiome

In postmenopausal women, lactobacilli concentration and diversity tend to be lower, while there is a higher diversity of other species.^{41–43} These changes have been correlated to the severity of vulvovaginal atrophy symptoms with normalization using hormonal replacement therapy (HRT) associated with symptom improvement.⁴⁴ Based on the limited and controversial evidence demonstrating that vaginal LASER improves sexual health, vaginal glycogen, and vaginal epithelial thickness, its impact on the vaginal microbiome was evaluated in two studies.

Athanasiou et al⁴⁶ enrolled 53 women with at least one moderate or severe symptom of GSM. The methodology is insufficient as it assumes that one symptom can be used as a surrogate of an entire syndrome⁴⁵ and does not describe which scale of severity was used.

Following vaginal LASER treatment, the authors report a significant decrease in vaginal pH, but only one third reached a pH lower than 4.5. This decrease was accompanied by an

TABLE 3 Impact on the vaginal microbiome

	Level of evidence	Grade of recommendation
LASER cannot be recommended as a means to improve the vaginal microbiome.	2b	B
The use of CO ₂ LASER does not negatively impact the vaginal microbiome.	2b	B

increase in the number of lactobacilli although the techniques used to estimate the lactobacilli population are known to produce an inaccurate estimation. Interestingly, with an inclusion criteria of vaginal pH in the range 4.5–5 at baseline, nearly half of the women had normal vaginal flora according to Nugent and Ison-Hay scores. Following treatment and at the end of the study, this increased to approximately 90%. Colonization by *Candida* was very low (1.9%) and remained stable. The vaginal maturation index improved, but no changes regarding the presence of leukocytes in the vagina were noted.

Becorpi et al⁴⁷ studied the vaginal microbiome in 20 breast cancer survivors treated with two sessions of CO₂ LASER. The study reported an almost unchanged microbiome following treatment. The authors suggested that any possible benefits would be derived from a possible anti-inflammatory effect.

While LASER cannot be recommended as a means to improve the vaginal microbiome, it does not seem to have a deleterious effect on it (level of evidence 2b, grade of recommendation B) (Table 3).

4 | “GENITOURINARY SYNDROME OF MENOPAUSE” AND VAGINAL ATROPHY

GSM and vulvovaginal atrophy (VVA) are commonly seen in women after menopause. Nearly 50% of postmenopausal women report a vaginal symptom.⁴⁸ These symptoms have a significant impact on the quality of life, interfering with the ability to be intimate, and enjoy sexual intercourse in 60–70% of sexually active postmenopausal women.^{49,50} However, many women consider their symptoms to be a natural part of aging. A survey of American women with a median age of 58 years revealed that 81% did not think VVA was a medical condition, of whom 71% had never sought treatment.⁵

A total of 24^{51–74} clinical studies were identified that investigated transvaginal LASER in women with GSM/VVA. Two studies appeared to include the same study population (separate analyses).^{55,67} The vast majority of the studies used

either Er:YAG or fractional, micro ablative CO₂ LASER. Some studies used ablative Er:YAG LASER.⁶² All studies but four were prospective or retrospective case series without a control group. There was one randomized placebo/estriol controlled study⁷⁴ (level of evidence 2b) and three prospective, non-randomized studies using estradiol gel (or lubricant) as the comparative arm (level of evidence 3b).^{51,53,69}

The clinical outcomes measured were inconsistent throughout the studies. Both subjective non-validated outcome measures and validated clinical outcomes scores were used to assess symptoms, quality of life impact, and general health. Samples taken varied from vaginal punch biopsy after treatment in one study,⁷⁵ to cytology, and pH evaluation⁶⁶ in others. Most studies had a follow up period of less than 12 months, although three studies presented 18-24 month follow up data. In addition, conflicts of interest were not always clearly specified and adverse events were rarely specifically outlined.

LASER treatment for women with a history of breast cancer and vaginal atrophy was investigated in one paper. In this group of women hormonal treatment is either contraindicated or patients are reluctant to take low dose topical estrogens for symptoms of GSM. This limited study drew similar conclusions to those reached for other women and was hindered by similar study design flaws.^{70,71,76}

Recent developments for the use of LASER in women with GSM/VVA include an international multicenter observational study aiming to evaluate 1500 women treated with vaginal Er:YAG LASER.⁷⁷ There is also an ongoing randomized study comparing the effects of CO₂ LASER to vaginal estrogen treatment. This study aims to enrol nearly 200 patients and is expected to finish by the end of 2018.⁷⁸ However there is still a need for a prospective randomized controlled trial with a placebo or sham control arm to understand the differences. For example a recent meta-analysis demonstrated that 67.7% of the treatment effect for female sexual dysfunction is accounted for by placebo.⁷⁹

The available studies on the use of LASER to treat vaginal atrophy have overall not provided sufficient evidence of efficacy and long term safety (level of evidence 2b/3b, grade of recommendation C) (Table 4).

TABLE 4 “Genitourinary syndrome of menopause” and vaginal atrophy

	Level of evidence	Grade of recommendation
There is currently not enough scientific data demonstrating efficacy and safety of LASER for treating vulvovaginal atrophy.	2b/3b	C

5 | STRESS URINARY INCONTINENCE AND/OR PELVIC ORGAN PROLAPSE

Some evidence on the role of vaginal LASER exists for its use in urinary incontinence and pelvic organ prolapse.^{4,34,77,80–86}

The data on its use in stress urinary incontinence comprises mainly short-term observational studies. Participants varied from 19 to 205 women. Treatment response was usually assessed with validated questionnaires and showed favorable outcomes in terms of improvement of symptoms, but only one study followed patients for 24 months. None of the studies had a control or placebo group.^{4,34,80–83}

There is minimal published data on the use of LASER in treating female pelvic organ prolapse. Its use has been described in women with grade II (prolapse to the hymen) to IV (maximum descent) cystoceles and follow up at 12 months has demonstrated an improvement in prolapse grade, with some patients sustaining the effect at 36 months.⁸⁶

While the use of LASER to treat stress urinary incontinence and/or pelvic organ prolapse may seem appealing, the lack of good quality evidence in the form of multi-center randomized placebo-controlled trials is concerning.

Use of LASER may lead to serious adverse events such as vaginal burns, scarring, dyspareunia, and chronic pain. Although reports of adverse events in the literature is minimal, the sample sizes are small hence minimal reassurance can be taken from this.⁸⁷ The histological effects of LASER to the vaginal wall remain unclear leaving further questions regarding the effect of LASER therapy on surgical dissection and outcomes in women who may eventually require reconstructive pelvic or anti-incontinence surgery.

A recent review article looking at the evidence relating to the risks and benefits of intravaginal LASER technology in the management of stress urinary incontinence confirmed that despite the short-term observational studies of small patient numbers demonstrating improvements, there is still insufficient evidence to offer it as an effective modality for the treatment of stress urinary incontinence over alternative managements, such as pelvic floor physiotherapy, incontinence pessaries, or continence surgery.²¹ Similarly there is insufficient evidence to offer intravaginal LASER therapy for vaginal prolapse (level of evidence 4, recommendation grade D) (Table 5).

6 | VAGINAL LAXITY SYNDROME

Vaginal laxity as a subjective patient complaint has been described by IUGA and ICS as a feeling of vaginal looseness.⁹ Its anatomical definition, quality of life impact and treatment are poorly understood⁸⁸ and not widely recognized. “Vaginal laxity syndrome” (VLS) or even

TABLE 5 Stress urinary incontinence and/or pelvic organ prolapse

	Level of evidence	Grade of recommendation
There is limited evidence supporting the use of LASER for stress urinary incontinence	4	D
There is limited data concerning the safety of LASER for stress urinary incontinence	4	D
The evidence supporting the use of LASER for pelvic organ prolapse is limited	4	D
The data concerning the safety of LASER for pelvic organ prolapse is limited	4	D

“vaginal hyperlaxity syndrome” are concepts and marketing terminology with a lack of a standardized definition.

Some believe that VLS is an evolution of the aesthetic designation of “vaginal rejuvenation.”⁸⁹ It is described as a disorder derived from the excessive laxity of the vaginal walls, leading to a sensation of looseness, diminished sensation of penile friction, and may be associated with urinary incontinence (urgency or stress).⁶¹ VLS is considered a consequence of aging and related to having had vaginal deliveries. The term VLS and therefore its therapy, vaginal rejuvenation, is not endorsed or formally defined by the leading gynecological societies.¹¹ However, management of the symptoms have evolved from techniques involving sutures and the adaptation of traditional urogynecological procedures to the use of LASER^{61,90} and radiofrequency procedures.^{91–99}

In 2011, there was an attempt to restore the *rugae* of the vagina in postmenopausal women (“vaginal rugation rejuvenation”), by vaporization of the vaginal wall in order to create parallel grooves. The procedure was performed in women with a sensation of a loose or smooth vagina. In a small observational trial (10 patients in each arm), there was an apparent improvement of sexual function and no complications. The design and small sample size did not allow the authors to draw conclusions from the study.⁹⁰

In 2014, Lee evaluated two different protocols (15 patients in each arm), using Er:YAG LASER. Women in both groups were evaluated 2 months after the procedure. There were no complications or adverse effects, although mild heating of the vagina and ecchymosis were reported. There was an objective (perineometer) and subjective improvement for 70% of the subjects with 76.6% of their partners reporting an improvement in sexual function. No validated scales were used for evaluation of the sexual function. A histological improvement was also suggested, but no analysis was shown in Ref.⁶¹

TABLE 6 “Vaginal Laxity Syndrome”

	Level of evidence	Grade of recommendation
There are no data supporting the recommendation of performing “vaginal rugation rejuvenation” or showing its safety	4	D
Er:YAG LASER for vaginal looseness or laxity has not been shown to be safe or efficacious	4	D

In total, two small studies on the use of LASER in vaginal relaxation syndrome comprising 51 women showed non-validated patient-reported improvements in sexual experience after LASER treatment but follow up was short term.^{84,85} We could not find any study in the literature evaluating the role of CO₂ LASER for vaginal tightening specifically. Several studies have arisen using radiofrequency. The available data, in comparison to that for LASER use, are more robust and sustained by studies with a better design. So far, there has been no comparison between the different types of energy. There are no data supporting the recommendation of performing “vaginal rugation rejuvenation” or showing its safety (level of evidence 4, grade of recommendation D) (Table 6).

7 | VULVODYNIA

Vulvodynia is a chronic, complex pain disorder of multifactorial aetiology that can be difficult to manage. It is common, affecting more than 4–16% of women and can occur at any age, including postmenopausal women, particularly among those who remain sexually active.^{100,101}

In 2015, the ISSVD, the International Society for the Study of Sexual Health of Women (ISSWSH) and the International Pelvic Pain Society (IPPS) adopted new terminology for vulvar pain and vulvodynia.¹⁰² It is classified according to the site of pain (generalized or localized), the need of a stimulus (provoked, not provoked [spontaneous], or mixed), and the onset (primary or secondary). Treatment is difficult, and rapid resolution is unusual even with proper treatment. Decrease in pain may take weeks to months and may not be complete. No single treatment is successful in all women.¹⁰³ The vulvodynia treatment algorithm includes vulvar skin care guidelines, topical, oral, and injectable medications, pudendal nerve block, biofeedback, physical therapy, dietary modifications, cognitive behavioral therapy, sexual counseling and surgery, as well as alternative therapies such as acupuncture and hypnotherapy.¹⁰⁴

Few studies have been conducted evaluating the usefulness of LASER therapy in the treatment of vulvodynia.^{59,105,106}

A retrospective study indicated less pain with sexual intercourse among 24 of 37 women treated with LASER pulse therapy for vestibulodynia. However, 35% of the patients in the study required a vestibulectomy to control the symptoms.¹⁰⁵

In 2016, in a study involving 70 patients who underwent fractional micro-ablative CO₂ LASER treatment for vestibular pain plus vestibulodynia ($n = 37$) or menopausal patients (age > 50 years) who presented with vulvar pain secondary to GSM/VVA ($n = 33$), showed statistically significant improvement of dyspareunia and pain scores, with gradual improvement over each time point persisting through 4-month follow-up. Average overall vestibular health index score (a non-validated score, that intends to assess vestibular atrophy) improved significantly in the two groups after each of the three individual treatments. There was no statistically significant difference in outcomes between the two study groups.⁵⁹

More recently, a placebo-controlled, double-blinded, randomized clinical trial involving 34 women aged 19-46 years old using low-level LASER therapy (LLLT) versus placebo showed *Clinical Pain Report* improvement in 78% in the LLLT group and 44% in the placebo group. Nevertheless, other measurable parameters (Q-tip test, intercourse pain on the Visual Analog Scale, and tampon tests before and after treatment, severity of discomfort in daily activities and/or in daily pain intensity) did not show a difference between groups. Although none of the patients reported side effects during the study, recurrence of pain was evidenced in 33% of the LLLT group.¹⁰⁶

Interestingly, LASER (pulse or scan), used to treat vulvar mucosa disease (warts or vulvar HSIL) has been shown to be a possible cause of chronic vulvar pain.¹⁰⁷

The few available studies concerning the treatment of vulvodynia with LASER have not proven it to be efficacious or safe, therefore its use should not be considered in these patients (level of evidence 2b, grade of recommendation B) (Table 7).

TABLE 7 Vulvodynia

	Level of evidence	Grade of recommendation
LASER therapy cannot be recommended as a means to improve pain in vulvodynia.	2b	B
The use of low-level LASER does not negatively impact symptoms in vestibulodynia.	2b	B

8 | LICHEN SCLEROSUS

Lichen sclerosis (LS) is a complex chronic inflammatory autoimmune dermatosis that can be found in patients of any age and race.¹⁰⁸ It is 10 times more common in females.¹⁰⁹ The incidence rate is around 10 per 100 000 woman-years, rising to over 30 per 100 000 woman-years in women older than 55.¹¹⁰ The main symptoms are itching, burning, and dyspareunia, with impact on health-related quality of life.¹¹¹

Vulvar LS (VLS) clinical aspects can vary significantly. Differentiated (dVIN), the HPV-independent pathway to vulvar carcinoma, must be suspected and biopsied promptly in treatment-resistant cases, and in the presence of erosion or hyperkeratotic plaques in a field of VLS.¹¹² The risk of vulvar cancer in VLS is estimated to be 2-5%, with higher risk in older women and with longer duration of disease.^{110,113,114} Long term therapy, however, seems to be protective.^{115,116} Current guidelines recommend the use of super-potent topical corticosteroids as first-line. Both the risk of cancer and the need of long term follow up must be taken into account when new treatment options are presented for LS, given the proven efficacy of topical corticosteroids.¹¹⁷⁻¹²⁰

In 1991 a Canadian study reported seven women with LS refractory to topical testosterone who became asymptomatic following LASER ablation (600-900 W/cm² depth of tissue destruction 2 mm under general anesthesia). No biopsy after treatment was performed to confirm histological changes.¹²¹ Similar results and depth of tissue vaporization was described by Kartamaa and Reitamo¹²² in two patients with VLS. The aim to "remove the epithelium and papillary dermis involved in LS" for resolution of symptoms was reported in another two cases study in the absence of post treatment biopsies.¹²³

In a recent case series,¹²⁴ five women underwent fractional CO₂ LASER treatment for hyperkeratotic VLS not responding to topical clobetasol. After 1-3 treatments with CO₂ LASER, energy 140-170 MJ and treatment depth 150 μm, symptoms had complete resolution in three, partial in one, and one was asymptomatic before treatment. Median follow up was 9 months (range 6-48). Re-epithelialization occurred in 3-4 weeks in all cases. Hyperkeratosis recurred after 6-8 months. In all patients, maintenance treatment was clobetasol. The objective to ablate the improper function of dermal epidermal zone, creating a new zone with proper function, is not supported by the published data.

All the papers considered are studies with very small series of patients, who did not undergo randomization, with short follow-up time. Neither visual acuity scale (VAS) for symptoms, nor details of pre/post treatment vulvar lesions were reported. The lack of description of the corticosteroid regimen utilized is another common weakness in the reported studies that prevent correct analysis of CO₂ LASER-treated patients and interpretation of its true efficacy. Furthermore, injuries (mechanical, chemical, burning, etc.) can be a cause

TABLE 8 Lichen sclerosus

	Level of evidence	Grade of recommendation
There are no data supporting the use of CO ₂ LASER in VLS	4	C
There are no data concerning the long term safety of the use of CO ₂ LASER in VLS treatment	4	C

of isomorphic or Koeber phenomenon in LS patients.¹²⁵ Currently, there is no evidence that fractional LASER is exempt from this risk in LS patients. Up to now the description of CO₂ LASER as a safe and effective therapy for recalcitrant VLS has no evidence within the literature data (level of evidence 4, grade of recommendation C) (Table 8).

9 | OTHER POSSIBLE USES OF LASER (VULVAR BLEACHING/WHITENING/BRIGHTENING, LABIAPLASTY)

While the labia tend to be more pigmented than the surrounding structures, some women have the desire to whiten it. It can represent up to 6.8% of the patients consulting a gynecological aesthetical unit.¹²⁶ This procedure, using LASER, is commonly offered, but there are no studies showing its efficacy or safety. We could only find reference to it in one study, but LASER was done in combination with other procedures, such as labiaplasty, augmentation of the labia *majora*, *mons pubis* liposuction, or vaginal tightening.¹²⁷ Of note, even the use of LASER for hair removal has been related to serious urogynecological complications, such as labial adhesion with cryptomenorrhea, and acute urinary retention.¹²⁸ In one survey, 85.9% of physicians stated that there is no medical indication for the performance of such procedures.¹²⁹

Labiaplasty is one of the most performed female cosmetic genital procedures worldwide. There are several techniques described, some with the use of LASER. Despite the misleading anatomical description, the procedure coined "Designer LASER Vaginoplasty" is also a form of labiaplasty.¹³⁰ Of note, this procedure has been considered unethical by the American College of Obstetricians and Gynecologists, due to the lack of supporting evidence.¹¹

In 2006, the use of Nd:YAG LASER for the treatment of hypertrophy of the labia *minora* was reported. In a series of 55 women (including 4 children 10-15 years old), of whom 11 (20%) lacked the authors' established criteria of hypertrophy of the labia *minora* (>2 cm of width), there were no intraoperative complications, dehiscence occurred in 5.4%, and there was no pain after 7 days. Satisfaction rates were very high (>90%).¹³¹ In another series, comprising 231

TABLE 9 Other possible uses of LASER (vulvar bleaching/whitening /brightening, labiaplasty)

	Level of evidence	Grade of recommendation
There is no medical indication for the use of LASER for vulvar bleaching	4	C
There are no data concerning the safety of the use of LASER for vulvar bleaching	4	C
Nd:YAG and CO ₂ LASER appear to be safe options for labiaplasty	3b	C
There is no data supporting the use of LASER labiaplasty to enhance sexual function	4	C

women who underwent reduction of the labia *minora* using CO₂ LASER to make a lambda shaped incision, a 100% satisfaction rate was reported, along with a low complication rate (11 wound dehiscence, 3 hematomas, 1 acute bleed requiring return to the operating room); however, there is no reference to the duration of follow up.¹³² More recently, in a study involving 112 women aged 15-62 years old using CO₂ LASER, improvement in overall satisfaction and comfort during intercourse were reported. The rate of complications and the duration of follow-up were not mentioned.¹³³

None of the studies have included a control group. In at least two of the studies children were enrolled. In at least one study, women did not meet the (controversial) study definition of hypertrophy of the labia *minora*. There appears to be no sufficient good quality data showing the safety of or justification of the use of LASER for cosmetic indications.

There is no universally accepted definition of hypertrophy of the labia *minora*; some authors have described it as a width superior to 4 or 5 cm, or protruding beyond the labia *majora*.¹³³ There is no correlation between the size of the labia *minora* and the ability to feel sexual pleasure or orgasm.¹³⁴ Brodie et al evaluated normal adolescents and pointed that there can be significant variance in the size of labia *minora*, according to being stretched or non-stretched (1-13 mm), that asymmetry is common (>50% of adolescent women), and that the mean width of labia *minora* was 10 mm (3-70 mm) (unstretched) and 20.5 mm (5-62 mm) (stretched).¹³⁵ If those definitions were applied to adolescents, a significant number would be considered "abnormal"!

There appears to be no sufficient good quality data showing the safety of or justification of the use of LASER for gynecological cosmetic indications in general (level of evidence 4, grade of recommendation C). It appears, however, to be safe for labiaplasty (level of evidence 3b grade of recommendation C) (Table 9).

10 | CONCLUSIONS

Advances in science, including medicine, are often questioned. However, as science evolves, we must remain committed to maintaining a high ethical standard. The four pillars of ethics—autonomy, beneficence, non-maleficence, and justice¹³⁴—must guide medicine in both clinical practice and research.

The lack of quality studies regarding the use of trans-vaginal and vulvar LASER for gynecology and urology raises the question of whether such therapy provides beneficence and absence of maleficence; its use also hinders the patient's autonomy and choice. In order to give truly informed consent, there is need for clear and definitive information. Many questions remain unanswered from the safety profile of the therapies, comparison to current treatments, and long-term effects on tissues. Interestingly, the majority of LASER research carried out so far has been industry-funded, leading to significant risk of bias. There is an attraction to this office procedure which is profitable to the individual provider, however this should not drive un-guided practice.

Controversial applications regarding the use of LASER that have been promoted recently without rigid scientific validation, regulation, or oversight include the reconstructive therapy for “vaginal rejuvenation,” and design LASER vaginoplasty.¹³⁰ The deceptive marketing of unproven treatments may not only cause injuries but may also keep patients from accessing appropriate and recognized therapies. It is imperative that providers protect patients from potential unknown harm due to the understudied clinical application of LASER technology and protect themselves from potentially indefensible lawsuits.

While there is potential for utilization of LASER to treat some proposed clinical conditions, most commonly vaginal atrophy and stress urinary incontinence, the scientific evidence remains exploratory. The existing literature is almost all post-marketing, in the setting of daily practice, rather than within controlled clinical trials. As with other innovations this is unacceptable, as safety must be proven before reaching the consumer. LASER has been available for use and disseminated among clinicians before sufficient data regarding quality, safety, and efficacy were provided.¹³⁵ Use of this technology prior to rigorous scientific examination may end in adversity, as has been demonstrated by previous technologies such as vaginal mesh for prolapse repair and power tissue morcellation.¹³⁶

Although LASER technology seems promising for select indications, long-term efficacy and safety data are lacking. In order to elucidate its optimal clinical application, LASER therapy must be evaluated in rigorous, well-designed studies that are of appropriate time scale, randomized and sham-controlled, to evaluate safety and efficacy. Therefore, despite its appeal to clinicians and women, assumptions cannot yet be made regarding the durability of this treatment nor its long-term effects, either positive or negative to date. Until further literature emerges, this technology should be considered experimental and

remain within the domain of clinical trials or with special arrangements for clinical governance, consent, and audit.

11 | RECOMMENDATIONS

Based on the available scientific evidence, with no supporting long term follow-up data, the use of LASER should, at present, not be recommended for the treatment of vaginal atrophy, vulvodynia, or lichen sclerosus. The data for the role of LASER for stress urinary incontinence and vaginal laxity are inadequate to draw any conclusions or safe practice recommendations. Therefore based on the available scientific evidence and on the lack of long term follow-up, the use of LASER should, so far, not be recommended for the treatment of vaginal atrophy, vulvodynia, lichen sclerosus, stress urinary incontinence, vaginal prolapse, or vaginal laxity.

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CONFLICT OF INTEREST

No conflicts of interest to declare.

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Terminology report from the International Continence Society (ICS) Working Group on Underactive Bladder (UAB)

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KEYWORDS

International Continence Society, lower urinary tract function, standardisation, terminology

1 | INTRODUCTION

This report presents definitions of the symptoms, signs, urodynamic observations, and conditions associated with detrusor underactivity (DU) and the potentially associated lower urinary tract symptom complex of the underactive bladder (UAB), relating to DU in all patients groups from children to the elderly. It is important to emphasize that in the past the use of the term UAB has been used in a non standardized and imprecise fashion.

Detrusor underactivity (DU) may be an aspect of (or contributor to) lower urinary tract symptoms (LUTS),

especially in later life. While DU is a urodynamic definition describing the detrusor voiding contraction, the clinical component of the definition—reduced urinary flow rate and/or an increased post-void residual (PVR)—have often and imprecisely been described as “underactive bladder” (UAB).^{1,2} In contrast to overactive bladder (OAB) and detrusor overactivity (DO), UAB and DU have remained largely unrecognized and poorly researched.^{1,2} There is a paucity of data regarding the pathogenesis and treatment of DU, and the definitions of DU and UAB remain imprecise, with a variety of definitions and diagnostic criteria found within contemporary literature.^{1,2} This lack of uniformity creates difficulties in characterizing UAB, in researching its effect on patient quality of life, and in evaluating possible treatments.

John Heesakkers led the peer-review process as the Associate Editor responsible for the paper.

The symptoms associated with UAB are common³ and likely to impact on quality of life.⁴ In the absence of a specific consensus-based definition of UAB, the true burden cannot be fully appreciated, nor can appropriately robust clinical trials be conducted.¹⁻⁴ In this report, we discuss a new definition for UAB that could be used as a platform for future discussion and research.

Although DU is an increasingly recognized urodynamic observation contributing to LUTS in both men and women, there has been a lack of research into all aspects of this dysfunction, and as yet, no effective treatments exist. DU can be diagnosed only on the basis of an invasive urodynamic study. An international consensus group met at the International Consultation on Incontinence-Research Society (ICI-RS) and International Continence Society (ICS) annual meetings in 2014 and again at these meetings in 2015 to consider the feasibility of developing a working definition of a symptom complex associated with DU. Drawing an analogy to detrusor overactivity (urodynamic observation) and overactive bladder (clinical diagnosis based on a symptom complex), the aim of this document is to help identify affected patients of all ages and to facilitate further clinical and epidemiological research.

2 | METHODS

The definitions restate or update those presented in previous International Continence Society Standardisation of Terminology reports.⁵⁻¹⁴

As far as possible, the definitions are descriptive of observations, without implying underlying assumptions that may later prove to be incorrect or incomplete. By following this principle, the ICS aims to facilitate comparison of results and enable effective communication by investigators who use urodynamic methods.

This document was developed according to the published methodology of the ICS Standardization Steering Committee.⁵ The group commissioned for this report developed an outline of proposed content and revised this in the light of a workshop held at the 4th International Neuro-Urology Meeting in Zurich, Switzerland in August 2015. The subsequent text was reviewed by the working group before a final draft was discussed at a workshop during the ICS meeting in Montreal in October 2015.

3 | DEFINITIONS

LUTS are defined from the individual's perspective who is usually, but not necessarily, a patient within the healthcare system. Symptoms are either volunteered by, or elicited from, the individual or may be described by the individual's caregiver.

LUTS are divided into three groups: storage, voiding, and post micturition symptoms.

LUTS are not disease specific. The symptoms of hesitancy, straining to void, and a slow urinary stream can be characteristic of both bladder outflow obstruction (BOO) and detrusor underactivity (DU).

Storage Symptoms are experienced during the storage phase of the micturition cycle.

- **Increased daytime frequency** is the complaint by the patient who considers that he/she voids too often by day.
- **Nocturia** is the complaint that the individual has to wake at night one or more times to void.
- **Urgency** is the complaint of a sudden compelling desire to pass urine which is difficult to defer.

Voiding Symptoms are experienced during the voiding phase. Since UAB is a disorder of emptying these seem to be the predominant ones but voiding symptoms may also be associated with storage symptoms in case of incomplete bladder emptying.

- **Slow stream** is reported by the individual as his or her perception of reduced urine flow, usually compared to previous performance or in comparison to others.
- **Intermittent stream (intermittency)** is the term used when the individual describes urine flow which stops and starts, on one or more occasions, during micturition.
- **Hesitancy** is the term used when an individual describes difficulty in initiating micturition resulting in a delay in the onset of voiding after the individual is ready to pass urine.
- **Straining** to void describes the muscular effort used to either initiate, maintain, or improve the urinary stream.
- **Feeling of incomplete emptying of the bladder** during voiding
- **Terminal dribble** is the term used when an individual describes a prolonged final part of micturition, when the flow has slowed to a trickle/dribble.

Post Micturition Symptoms are experienced immediately after micturition.

- **Feeling of incomplete emptying** is a self-explanatory term for a feeling experienced by the individual after passing urine.
- **Post micturition dribble** is the term used when an individual describes the involuntary loss of urine immediately after he or she has finished passing urine, usually after leaving the toilet in men, or after rising from the toilet in women.

Symptom syndromes suggestive of lower urinary tract dysfunction

In clinical practice, empirical diagnoses are often used as the basis for initial management after assessing the individual's lower urinary tract symptoms, physical findings and the results of urinalysis and other indicated investigations.

- Urgency, with or without urgency incontinence, usually with frequency and nocturia, can be described as the overactive bladder syndrome, urge syndrome, or urgency-frequency syndrome. These symptom combinations are suggestive of urodynamically demonstrable detrusor overactivity but can be due to other forms of urethro-vesical dysfunction. These terms can be used if there is no proven infection or other obvious pathology.
- **Lower urinary tract symptoms suggestive of bladder outlet obstruction** is a term used when a man complains predominately of voiding symptoms in the absence of infection or obvious pathology other than possible causes of outlet obstruction
- **Underactive bladder** is characterized by a slow urinary stream, hesitancy and straining to void,^a with or without a feeling of incomplete bladder emptying sometimes with storage symptoms.^b (NEW)

4 URODYNAMIC OBSERVATIONS AND CONDITIONS

In the context of urodynamics we would affirm the ICS standardisation report definitions:

Detrusor function during voiding

- Normal detrusor function

Normal voiding is achieved by a voluntarily initiated continuous detrusor contraction that leads to complete bladder emptying within a normal time span, and in the absence of BOO. For a given detrusor contraction, the magnitude of the recorded pressure rise will depend on the degree of outlet resistance.^c

- **Abnormal detrusor activity** can be subdivided:

- **Detrusor underactivity** is defined as a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span^d.
- **Acontractile detrusor** is one that cannot be demonstrated to contract during urodynamic studies.

- **Post void residual (PVR)** is defined as the volume of urine left in the bladder at the end of micturition.^e

Abnormal detrusor activity in the voiding phase does not exclude the presence of **detrusor overactivity** in the storage phase. This may then be described as, for example, storage phase detrusor overactivity combined with voiding phase detrusor underactivity.

5 | CONCLUSIONS

DU is diagnosed urodynamically and has a pressure/flow-based ICS definition, however, it is not feasible to utilize urodynamics outside a secondary care centre. DU is characterized by an absent or low-pressure, and/or poorly-sustained detrusor contraction in combination with low urinary flow. In contrast, UAB has no ICS definition but we would propose UAB as the clinical syndrome that includes DU. Because UAB is largely undefined in the literature, there is, in our view, the need for a new symptomatic definition.

For the sake of symptom quantification in much-needed research moving forward, it appears that a crystallized definition of UAB would be of definite value. In properly defining UAB, it will be important to consider the entire symptom complex, describing the sensation of incomplete or impaired voiding that may include hesitancy, straining to void, incomplete bladder emptying, slow or prolonged stream, or intermittent stream, without implying any specific urodynamic/functional findings or causative physiology.

Properly defined, UAB could be to DU as OAB is to DO, where treatment according to a symptom-based diagnosis would be possible if the diagnosis was sufficiently robust. Patient choice, practical, and cost reasons often necessitate treatment without a pressure/flow-based diagnosis

We propose that this definition should now be tested to check its validity. In particular the factors to be considered are the influence of gender, age, and origin (neurogenic versus non-neurogenic), combining the interpretation of symptoms along with bladder diaries, flow rates, PVR volumes, and urodynamic data. It is hoped that this suggested definition may be used as a springboard for future UAB research and discussion, in terms of both qualitative research to look for characteristic symptoms, and quantitative research in urodynamically-defined DU patients.

CONFLICTS OF INTEREST

CRC is a researcher, author, consultant and/or speaker for Astellas, Boston Scientific, GlaxoSmithKline, and Pfizer. PA is a consultant for Astellas, Ferring, and Ipsen, a researcher for Astellas, and a speaker for Astellas, Pfizer, and Ferring. MO is a researcher and/or speaker for Apogepha, Astellas, Bayer, Duchesnay, Ferring, GlaxoSmithKline, Lilly, Pfizer and Recordati. MJD is a researcher and speaker for Allergan, Astellas and Ferring. GvK is a consultant and/or researcher for

Astellas, Solace therapeutics, Boston Scientific, Allergan and Medtronic. NO has received speaker fees and travel grants from Astellas. OY is a researcher and/or a speaker for Astellas, Ferring, Pfizer, Hisamitsu and Asahikasei. AW is a consultant/advisor to Avadel, Allergan, Axonics, Valencia, Urovant, and Medtronic. VN is a researcher for Allergan, Astellas, and Medtronic.

ENDNOTES

^a FOOTNOTE a) Underactive bladder occurs in association with diverse pathophysiologies and based on current knowledge there is no single distinguishing symptom.

^b FOOTNOTE b) Storage symptoms are varied and may be highly prevalent, including nocturia, increased daytime frequency, reduced sensation of filling and incontinence. Underlying mechanisms of storage symptoms are diverse, and are often related to a significant post voiding residual urine volume.

^c FOOTNOTE c) In women voiding symptoms are usually less likely to be caused by anatomical bladder outlet obstruction, therefore, detrusor underactivity and functional causes of outlet dysfunction are more likely (such as dysfunctional voiding).

^d FOOTNOTE d) A urodynamic study is essential to differentiate between Bladder outlet Obstruction and Detrusor Underactivity. A normal detrusor contraction will be recorded as: high pressure if there is high outlet resistance, normal pressure if there is normal outlet resistance or low pressure if urethral resistance is low.

^e FOOTNOTE e) If after repeated free uroflowmetry no residual urine is demonstrated, then the finding of residual urine during urodynamic studies should be considered an artefact, due to the circumstances of the test.

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5. ICS EDUCATION MODULES

An ICS Education Module is an endorsed, evidence based, standardised module designed to teach best practice in the clinical or basic science of urinary, bowel and pelvic floor disorders. The module represents the gold standard of education for the ICS and is proposed and planned according to ICS Standard Operating Procedure.

The module includes a 3-part format:

- Official ICS-consensus PowerPoint available for download
- A studio-quality video (hosted on the ICS website) and
- A peer-reviewed published article published in NAU

These modules represent the highest level in the ICS educational mission: ICS seeks to develop and distribute high quality global health educational modules; define standards and competencies in health education; and address the needs of students, educators, and trainees as they seek to gain the skills and knowledge necessary to become healthcare leaders. All ICS modules are created to be used by educators around the world who can download the ICS module and present this to their students/colleagues. It is also expected that when an ICS speaker is invited to speak at an educational course or guest lecture the educational modules are used to provide the standardised educational content. The outcome of these modules is that educators around the world, and ICS faculty, can download the ICS module and present this to their students/colleagues. Additionally, if people are unable to attend a course on the topic the video can serve as an excellent educational tool.

All of the modules can be found on ICS TV: www.ics.org/tv

If one clicks on the module one will see the text below the video- click 'show more' and this will include the PPT slide and publication.

ICS Education Module Standard Operating Procedure (SOP)

ICS Education Modules are created according to SOP:

www.ics.org/education/icsstandardoperatingprocedures/videosops/icseducation3partmodule



Elise De
ICS Education Committee Chair

ICS Teaching Module: Ambulatory Urodynamic Monitoring

A Digesu, C Gargasole, C Hendricken, M Gore, E Kociancic, V Khullar & P Rosier



International Continence Society
Teaching Module

1

ICS teaching module

- To assist clinicians in performing and interpreting AUM
- This teaching module should be used together with the manuscript: 'ICS teaching module: Ambulatory Urodynamic Monitoring (AUM)'
- This manuscript includes the best available evidence but also contains experts' opinions reported as "eo" if reliable evidence is unavailable
- This module can, only in its complete form, freely be used for teaching purposes

ICS Teaching Module

2

Introduction

- A summary of the published literature on the role of AUM in clinical and research practice.
- Indications
- Technique and Protocol for AUM
- Troubleshooting
- Interpretation of AUM traces
- Advantages and disadvantages of AUM compared to laboratory cystometry (routine saline urodynamics)

Philosophy & Pathophysiology

- AUM has been recognized by the ICS as a useful tool to investigate LUTS in patients with inconclusive urodynamics diagnoses (19% to 44%)

Philosophy & Pathophysiology

ADVANTAGES

- Natural (orthograde) filling of the bladder
- Less embarrassing test since the patients are fully dressed
- The pressure are recorded for several hours (3-4)
- The patients able to leave the urodynamic room
- Increased diagnostic accuracy in the detection of DO

Philosophy & Pathophysiology

DISADVANTAGES

- Time-consuming test
- It requires trained and dedicated personnel
- It requires specialized equipment
- A high rate of abnormal detrusor contractions using AUM in asymptomatic controls

Catheters

- Catheter-mounted microtip transducers:
 - silicone-covered braided metal makes them very flexible
 - low stiffness and the circumferential configuration
 - allow greater patient's mobility
 - low incidence of artifacts ⁽⁶⁰⁾
- Fluid-filled catheters: possible but use not yet proven
- Air - charged catheters: possible but use not yet proven

Single use Catheters

- The use of single use catheters would be ideal as:
 - it would reduce the costs
 - save the time needed to reprocess/clean the multi-use electronic microtip transducers catheters
- Although recent studies have shown promising results in performing AUM with water filled catheters (for Pves/Pabd) scientific evidence is still lacking

Pressure sensor systems

- Tiny airtight capsules inserted into the bladder and rectum which then communicate with a portable recorder attached to the body to reduce artifacts
- The clinical use has not been proven & validated yet

Recording systems

- Gaeltec Devices
 - the oldest systems using electronic catheters-mounted microtip transducers
 - large recorder box which is very awkward to carry around
 - Lack of a patient event-marker capability to capture the patient sensation data and timing for urgency, voids, accidents, etc.

Recording systems

- Goby, Laborie Medical or Luna, MMS:
 - Newer systems
 - Small remote control attachment to capture data
 - Compatible with water, air and microtip catheters

Patient preparation

- Information leaflets explaining the test are posted to patients prior to the appointment
- Comfortably full bladder
- A uroflow and a urine analysis are performed
- AUM test can be performed if there are no signs of urine infections (nitrates and leucocytes)
- Wearing comfortable clothes (preferably gown for women)
- Empty bowel if possible

Technique

- Similar to laboratory cystometry
- Catheters are inserted into the bladder and the rectum
- Sufficient catheter length into bladder/rectum
- Catheters should be securely taped adjacent to the anus and external urethral meatus to reduce the risk of catheter's falling out as well as to reduce artifacts
- Transducers set to zero
- The patient can then dress and the catheters can be connected to the AUM recording system

Zero setting: water filled catheters

- Transducers must be set to zero at the atmospheric pressure
- Two three-way taps can be attached to the vesical and rectal transducers
- 10 ml syringe is used to flush fluid through the tubing system to eliminate bubbles from the transducers and catheters
- Transducers and the open end of the three-way tap must be at the same horizontal level of the symphysis pubis after having excluded the syringe by closing the tap where the syringe is attached

Zero setting: Air-charged & microtip transducers catheters

- Set zero prior to recording
- Before or after insertion into the bladder & rectum
- Not necessarily at the atmospheric pressure

Technique

- Prior to commence recording the patient is asked to cough to check the intravesical, abdominal and subtracted detrusor pressures
- AUM can be started if there is a similar increase of the intravesical and abdominal pressures and the subtracted detrusor pressure does not change
- Any problem must be rectified!

Technique

- Before the patient leaves the urodynamic room it is mandatory to ensure that the patient:

1. Understands and is able to follow instructions
2. Records on a diary all the urinary symptoms reported during AUM test

Since symptoms are compared against the pressures recorded, an accurate recording of symptoms and the times when they occur is essential for the final AUM diagnosis

Technique: recording urine leakage

- Method has not yet been standardized
- This may be recorded by:
 - An electronic pad
 - A remote control with event marker button
 - Completing a urinary symptom diary
 - All the above

Instructions to the patient

- To record episodes of urgency, incontinence, pain, voluntary voids, time and volume of fluid intake, feeling of catheter displacement, any provocative maneuvers (running, washing hands, coughing etc)
- How to use the event buttons on the AUM device
- To drink about 200-400 ml/hour or a fluid load up to 1 litre drunk over 30 minutes (unless a fluid load is contraindicated the AUM time would take longer ^{eo})

Instructions to the patient

- To return to the urodynamic room:
 - Every hour to check the system is recording the pressures correctly and subtraction is accurate
 - If need to void
 - If one of the catheter falls out (if a diagnosis has not be revealed the pressure transducers would need to be re-inserted, re-zeroed and the test will be re-started thus the length of the test will be altered from the suggested standard)
 - If the patient needs to defecate the catheter would need to be removed and reinserted accordingly

Quality control assessment

To ensure a good quality control it is important to check the signal quality by:

- Setting each transducer to zero prior to commencing to record the pressures or during the test if needed;
- Ensure that the intravesical/abdominal pressures are similar by asking the patient to cough prior to commencing the test and every hour
- Asking the patient to cough before and after each void when pressure flow studies are recorded (LE 2a)

Quality control assessment

- Ensure that all the catheters are securely taped on the patient's thigh, the catheter's length is reduced to the shortest length possible to avoid accidental displacement during the test
- If filled fluid catheters are used, ensure that there is no air in the system that may affect the quality control
- Provide information to patients advising to attend the appointment with an empty bowel if possible

Analysis and interpretation of AUM trace

- Assessment of the quality of data (signal) recorded:
 - Is the trace “active”?
 - Is the baseline static or highly variable?
 - Are the cough tests regularly present?
 - Is the subtraction adequate?
- At the end of the test, hourly or if any problem arises, to reduce the risk of missing or uninterpretable data
- The use of a detailed patient diary or event markers on the newer AUM systems is strongly recommended to improve the analysis of events occurring during AUM ^(14 eo)

Contraindications

- Poor patient mobility
- Cognitive impairment
- Inability to follow instructions
- Severe constipation
- Active urinary tract infection
- Medical conditions which limit patient’s participation (clinician’s discretion)

Recommendations

- AUM is most sensitive for the detection or exclusion of detrusor overactivity compared to laboratory cystometry (LE 2a¹⁶)
- AUM is valuable when all other diagnostic tests have failed to detect the underlying cause of LUTS and/or LUTS do not correlate to laboratory cystometry diagnosis (LE 2a)
- Stress urinary incontinence is better detected by laboratory cystometry than AUM ⁽¹⁵⁾ (LE1B)
- UTI must be excluded prior to commencing the test

Scientific Evidence

- No scientific evidence demonstrating that routine antibiotic cover before and after the test is needed
- Post procedure broad spectrum antibiotic cover may be considered in patients with:
 - Diabetes
 - Recurrent urinary tract infections
 - High post micturition residual^{eo}
- Although there is no scientific evidence supporting the use of routine bowel evacuation agents before AUM test (as they can cause rectal activity and/or abdominal discomfort) an impacted bowel should be avoided
- To date there is no clear LE about AUM role in the assessment of neurogenic LUTS

Conclusions

- AUM is a valuable and effective second line test where laboratory cystometry has failed to give a satisfactory diagnosis (LE2a)
- AUM improves the outcome of continence surgery by unmasking preoperative underlying DO (e^o, unpublished data)
- AUM is a more time consuming test than laboratory cystometry
- AUM requires expertise as well as specialised equipment
- To make the most of its diagnostic capability and to avoid over diagnosis of DO, a detailed record of urinary symptoms during the test is always recommended



ICS Teaching Module: Ambulatory Urodynamic Monitoring

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Aim: To present the ICS Teaching Module on ambulatory urodynamics monitoring (AUM). **Methods:** This teaching module has been developed by the ICS Urodynamics Committee to assist ICS members in their routine clinical practice. A detailed literature search on studies published on the clinical role of AUM as well as expert opinions have been considered. A slide set on AUM has been developed, approved by all members of the ICS Urodynamics Committee and is available to the ICS membership on the ICS website. The final approved teaching module has been presented at the ICS Annual Scientific Meeting in Brazil 2014. **Results:** The scientific evidence on the clinical role of AUM in patients with lower urinary tract symptoms is summarized. The catheters and recording systems used, the patient preparation for the test, the technique, the instructions to the patient, the analysis, interpretation, and quality control assessment of AUM trace as well as the contraindications for AUM are described. **Conclusions:** The clinical role of AUM is still controversial. The scientific evidence on the usefulness of AUM is still limited but the ICS Urodynamics Committee recommends its use as a second line diagnostic tool when office laboratory urodynamics have failed to achieve a diagnosis. AUM has been showed to be more sensitive than laboratory urodynamics in diagnosing detrusor overactivity but the level of evidence for this measurement is not high. This manuscript summarizes the evidence and provides practice recommendations on AUM for teaching purposes in the framework of an ICS teaching module. *NeuroUrol. Urodynam.* 36:364–367, 2017.

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Key words: ambulatory urodynamics; ICS teaching module; inconclusive urodynamics; lower urinary tract symptoms

INTRODUCTION

Ambulatory Urodynamic Monitoring (AUM) has been mentioned in International Continence Society (ICS) standards.^{1–2} AUM may be considered a useful tool to investigate lower urinary tract dysfunction (LUTD) in patients with lower urinary tract symptoms (LUTS) and inconclusive results on laboratory urodynamic testing.^{3,4} The clinical sensitivity and specificity of AUM are not very well established and the specific technical demands and the technical reliability are deliberated.^{1–2,5} To date there is no clear consensus about the role of AUM in the assessment of LUTD.^{6,7} Although the here above mentioned standards suggest some practical aspects, they do not cover all issues arising with clinical testing. The ICS Urodynamics Committee presents the teaching module “Ambulatory Urodynamic Monitoring” to serve as a standard education of Good Urodynamic Practice for everyone involved in indicating, performing, and analyzing urodynamic testing in general and more specifically, performing AUM. The teaching module consists of a PowerPoint presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base for the ICS PowerPoint presentation, which is available via <http://www.icsoffice.org/eLearning>. The presentation explains testing requirements, clinical workup, and analysis. The presentation and this manuscript are based on the highest-level available published evidence, graded according to the modification of the Oxford Center for Evidence-Based Medicine levels of evidence as also used by the 5th International Consultation on Incontinence. Where evidence is unavailable, experts’ opinion has been used and the sentence is marked as “eo” (experts’ opinion). The aim of this ICS Teaching Module is to provide a summary of the published literature on the role of AUM in clinical research practice, including indications. Furthermore the technique and

a practice protocol for AUM including troubleshooting and interpretation are presented.

Evidence and Philosophy of AUM

Conventional urodynamics is the standard clinical tool to investigate LUTD.^{2,8} However, it has been reported that it can fail to precisely demonstrate the cause of (storage) LUTS in 19–44% of the cases.^{2–4} This may be due to the shorter duration of the test, thus abnormalities are not detected before the end of recording. Lack of correlation between abnormalities detected and symptoms reported by patients may also play a role since it is well known that in LUTD, signs and symptoms are neither very specific nor sensitive towards the dysfunction.⁹ When conventional urodynamics is inconclusive, AUM may be helpful in diagnosing the cause of the symptoms and guiding more appropriate management of patients. In particular, AUM has been observed to have an increased detection of detrusor overactivity.^{10–16} However, the fact that AUM shows abnormalities, especially detrusor overactivity, in healthy volunteers may also be considered a sign of lesser specificity, apart from the fact that a person’s perception of LUT function may be “false negative.”^{17–20} There is single center expert retrospective evidence that stress urinary incontinence became detectable during AUM with a leakage

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detector¹⁵ (LE3). The sensitivity and or specificity of AUM towards voiding dysfunction or abnormalities is at present unknown.

AUM is performed in a similar way to conventional cystometry but differs in some specific elements: It uses natural (orthograde) filling of the bladder (the patients are usually asked to drink extra) and testing lasts for approximately 2–4 hr. Patients are fully dressed after the initiation of the test and are able to leave the urodynamic room, which may reduce embarrassment.^{11,12} Disadvantages of AUM may be that the test and analysis are time-consuming and require specialized equipment with trained and dedicated personnel.

Catheters

The majority of the reported studies on AUM have used catheter-mounted microtip transducers since they allow greater patient mobility and have a lesser incidence of movement artifacts.^(e0) Although it is possible to measure pressures during AUM with fluid-filled lines, with intravesical capsules or with air filled catheters, the evidence of their usefulness has still to be proven.¹⁰

Recording Systems

The oldest systems (Gaeltec Devices Ltd, Isle of Skye, Scotland) are mostly known for their catheters, made of flexible silicone-covered braided metal, with mounted electronic microtip transducers. The main disadvantage of this system is the large recorder box which has been awkward to carry around. The newer systems (i.e., Goby, Laborie Medical, Canada or Luna, Medical Measurement Systems, Mississauga, Canada) have a smaller remote control attachment that also allows data capturing of the important physiological events. These newer systems can also accommodate water filled, air filled, and electronic (microtip) options. (Comparative) evidence about the clinical or technical reliability of each system or combination is lacking.

Patient Preparation

The patient is asked to come to the department with an empty bowel if possible, with a comfortably full bladder and wearing comfortable (not too tight) clothes. If the rectum is loaded with feces at the start this may need to be sorted prior to commencement to prevent “fecal urgency” during the test. Active urinary tract infection must be excluded prior to commencing the test. There is no scientific evidence demonstrating that routine antibiotics before and or after the test are needed nor evidence supporting the use of routine bowel evacuation agents before AUM. Furthermore, laxatives can cause rectal activity and/or abdominal discomfort and therefore hinder the representativeness of the test.^{e0}

To record episodes of urgency, incontinence, pain, start and end of voluntary voids, time and volume of fluid intake, feeling of catheter displacement as well as any provocative manoeuvres (running, washing hands, coughing, sneezing etc) a remote control might be useful. Information leaflets explaining the test should be made available for patients prior to their appointment to explain what the test involves and how they can cooperate with the test. Preferably a uroflow and post void residual urine test are performed before AUM is started. If there are no signs of urinary tract infection the AUM test can be performed.

Technique

Before the test is started it is mandatory to ensure that the patient understands and is able to follow some important

instructions (described more in detail in the following section) and will be able to record on a diary all the (LUT) signs and symptoms perceived during the AUM test. Since symptoms are compared against the pressures recorded, an accurate recording of symptoms and the times when they occur is essential for the final AUM diagnosis.^{21–23}

Similar to conventional cystometry the catheters are inserted into the bladder and the rectal canal. Air-filled or microtip transducers catheters need to be zeroed prior to insertion at the atmospheric pressure by having the open end of three-way taps, attached to the catheters, at the level of the symphysis pubis. Via these three-way taps some gentle fluid flush can eliminate entrapped air and debris from the catheters and can also check them for leaks. Sufficient catheter length should be inserted into the bladder/rectum and the catheters must be securely taped adjacent to the anus and external urethral meatus to reduce the risk of catheters falling out as well as to reduce movement artifacts. The patient can then dress and the catheters can be connected to the AUM recording system.

Prior to commencing recording the patient is asked to cough to check the intravesical, abdominal, and subtracted detrusor pressures. If there is a prompt and steep increase of the vesical and abdominal pressures during cough and the subtracted detrusor pressure does not change then the test can be started. Otherwise any problem must be rectified.

The method of recording urine leakage has not yet been standardized. An electronic pad and/or the patient using a remote control and pressing an event marker button and/or completing a urinary symptom diary are possibilities. No evidence exists for any of the methods being more specific, predictive, or reliable.

Instructions to the Patient and AUM Test

As stated above, during AUM the bladder filling is accomplished with the patient's own urine production instead of filling the bladder through a catheter. The test may last from 2 to 4 hr. Patients should receive instructions prior to leaving the urodynamic room (See Table 1) in an easy to understand manner. In order to maximize AUM diagnostic power, the use of a detailed patient diary is strongly recommended to improve the analysis of events occurring during AUM.^{14,e0} However the availability of event markers on the newer AUM systems may replace the use of the diary allowing more freedom, ease, and flexibility for the patient.

Usually patients are instructed to drink extra during the test, to be able to record some storage to voiding cycles in a reasonable amount of time. Forced diuresis may unmask/provoke detrusor overactivity, however voiding an equivalent of 4 L/24 hr may be an unusual challenge for the LUT.²⁰

The patient instruction includes advice to return to the urodynamic office in case of problems. If a catheter is displaced or evacuated, or the system is malfunctioning, the trace, the recorded pressures, subtractions, and quality of the trace the test duration may need to be reviewed. If a diagnosis has not been revealed, in case of malfunction and test prolongation the pressure transducers would need to be re-zeroed, re-inserted, and the test re-started.

Quality Control Assessment

There is risk of losing signal quality associated with AUM. Therefore, there are a number of additional precautions to consider while performing AUM compared to conventional cystometry. Obviously it is relevant to ensure that all the catheters are securely taped adjacent to the meatus and the

TABLE I. Outline of Patient Instructions for Ambulatory Urodynamic Test
How to you use the event buttons on the AUM device

Drink about 200–400 ml per hour or a fluid load up to 1 L drunk over 30 min.
 If a fluid load is contraindicated the AUM time would take longer.⁶⁰
 Register urgency, incontinence, pain, start and end of voluntary voids, time and volume of fluid intake.
 Register activity and maneuvers that (usually tends to) provoke symptoms like example drinking, running, lifting weight, washing hands, coughing, sneezing etc.
 Return to the urodynamic room every hour to allow to check the system is recording the pressures correctly.
 Return to the urodynamic room whenever you need to void.
 This may allow recording up to three pressure flow studies during the whole study.⁶⁰
 Return to the urodynamic room when a catheter (or both) falls out, or is expelled during voiding (or defecation).

anus. The catheter's length should be fixed to the lower abdomen (stay inside the pants) and the rest of the length to the monitor box should be as short as possible and secured underneath the clothes to further avoid accidental displacement during the test.

To ensure good quality control it is important to check the signal quality by setting each transducer to zero prior to commencing to record the pressures and to ensure that the intravesical and abdominal pressures are similar by asking the patient to cough. Thus it can be checked that the subtracted detrusor pressure is within the normal range prior to commencing the test and this may be checked every hour to make sure that the pressures are correctly recorded and that the catheters are not displaced. The instructions should also preferably ask the patient to cough before and after each void when pressure flow studies are recorded (LE 2a).

Analysis and Interpretation of AUM Trace

The first step in the analysis of an AUM trace is the assessment of the quality of data (signal) recorded and to judge whether the trace appears "active" with clearly visible coughs and pressure variations due to the movement of the patient. A dead (flat) signal in one or both of the pressures indicates a problem and depending on the duration the test may not be evaluable. If both pressures have been recorded for a sufficient amount of time, the detrusor pressure should be evaluated. Evaluation of detrusor pressure is possible for the period that the movement and cough responses have been "balanced," without causing significant positive or negative deflections in this pressure; though inevitably rectal activity may play a role in (negative) deflections of detrusor "pressure" and these must be recognized.

Analysis and interpretation of the trace should be performed immediately following the test to allow discussion of the findings and management options with the patient, thus avoiding unnecessary repeat visits.⁶⁰

Contraindications for AUM

Poor patient mobility, cognitive impairment, or inability to follow instructions are relative contraindications for AUM. Severe constipation and active urinary tract infection may need to be treated before the test.

CONCLUSIONS

AUM may be performed when conventional urodynamic tests have failed to detect any underlying cause of LUTS and/or may be useful when conventional cystometry diagnosis does not explain the symptoms. AUM is a more time consuming test than conventional cystometry and requires expertise as well as specialized equipment. In order to make the most of its

diagnostic capability a standardized workup and systematic analysis by a skilled physician is mandatory. Analysis should be built on an as reliable as possible measurement including a detailed record of lower urinary tract signs and symptoms. For this reason, it is also very relevant to ensure patient cooperation. We have presented an evidence based teaching module to support good clinical practice regarding AUM with recommended elements of standardization for the physician as well as for the instructions to the patient.

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ICS Teaching Module: Analysis of voiding; Pressure flow test (Basic module)

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International Continence Society
Teaching Module

1

ICS teaching module

- This teaching module should be used together with the manuscript:
 - 'ICS teaching module: Analysis of Voiding; Pressure Flow Analysis' published in: Neurourology and Urodynamics
- The manuscript provides the scientific background and the evidence base of pressure flow analysis as well as the references.
- This teaching module contains expert opinion recommendations to compensate for lacking evidence where necessary. Expert opinions are marked with 'eo' in the title of the slide.
- Reference to this presentation and teaching module:
 - NeuroUrol Urodynam 2014 ##### (33) ###
- This teaching module contains 25 slides and can, only in its complete form, freely be used for teaching purposes.

Normal lower urinary tract function

- Bladder filling begins (Storage LUT function -phase)
- Nervous system maintains relaxed detrusor
 - and ensures low intravesical pressure
- Distension activates muscle stretch receptors
 - Perception (proprioception) of fullness develops
- Cortical determination of desire to void
- Voiding (Voiding LUT function -phase)
 - Until bladder emptied
- Bladder filling, again

Normal voiding

- Voiding is desired (and socially acceptable)
- Pelvic floor relaxes by will..
 - ...subsequently and autonomically the...:
- ...urethral sphincter relaxes and (antagonistic) detrusor-dome contracts;
- Detrusor pressure forces the (relaxed) bladder neck, the urethra and pelvic floor to open;
- Urine flow begins;
- Detrusor contraction ends;
- Urethral sphincter and pelvic floor contraction resume.

Control of lower urinary tract function

- Central control and influence
 - Cognition
 - Social
 - Emotional
- Central & peripheral pathways
 - Afferent (sensory)
 - Somatic
 - Autonomic/visceral
 - Efferent (motor)
 - Somatic
 - Autonomic/visceral
- While testing: (sub-) conscious central influence may (in comparison to storage phase) play a larger role in voiding function.⁰⁰

General principles of urodynamic testing*

Well informed patient

- Appropriate environment
 - Physical (warm, least uncomfortable position...)
 - Emotional (adequate draping, private...)
- Antiseptic procedure
 - Urinary tract infection as a result of urodynamic testing should be prevented
 - (Not 'corrected' with prophylactic antibiotics)

* See also: Basic module 'cystometry'

Voiding: pressure flow test(s)

- Because the pressure flow test may be more influenced through the patient's emotion:
 - Ask patient (after voiding):
 - 'Was this voiding -almost- as usual?'
 - 'Was the bladder 'uncomfortably' full?'
 - You have:*
 - Indicated on cystometry: first sensation of filling
 - Indicated on cystometry: normal desire to void
 - Indicated on cystometry: strong desire to void > end of filling AND
 - Indicated on cystometry: permission to void
 - The 'permission to void' separates the storage and voiding LUT phases!
 - Compare with free (without catheter) flow!

* See also: Basic module 'cystometry'

Voiding: pressure flow test(s)

- Negative influence on voiding:
 - Uncomfortably large intravesical volume at the start of voiding^{eo}
 - Very unrepresentative urgency at the start of voiding^{eo}
 - Extreme inhibition of overactive detrusor contractions before the start of voiding^{eo}
 - Rectal catheter hindering pelvic muscle relaxation

Voiding: Pressure flow test(s)

- Be aware that the transurethral catheter:
 - Causes (some) passive effect
 - May be obstructive (esp. when stricture exists)
 - May 'stent' kinking urethra in female
 - Causes active effect (hinders normal behaviour)
 - alters voiding sensation
 - Anaesthetic (lidocaine) gel
 - (fear for) pain during voiding
 - May –partially- slip out

Set up for the test

- (ICS-) Good urodynamic practice:
 - See also ICS module: Cystometry
- Ensure balanced intravesical and intra abdominal (intra rectal) pressure recording.
- Couch (pressures balance) check before and after voiding.
- Ensure correction of flow curve for the systematic delay between (recorded) flow and pressure.
 - depending on the meatus to flowmeter distance
 - before a pressure flow analysis is done

Set up for the test

- Best possible (= most comfortable for patient), position during voiding.
- Flowmeter as close as possible to the meatus.
 - Minimize time delay between flow at meatus and entering flowmeter
- No hindering of stream between funnel and beaker or spinning disk.
 - (e.g. No (long) tube between funnel and beaker or disk.)
- Use thin transurethral catheter.
- Use thin rectal catheter.
- Tape catheters alongside meatus / anus.

Mechanics of voiding

- Detrusor pressure (cmH₂O) generates flow (ml/s)
 - Intravesical pressure minus intra-abdominal pressure
- Urethra (normally) functions as a tube...
 - with passive distension (until Q_{max})
 - and passive collapse (after Q_{max})
- Flow (Q_{max}) is limited by the 'flow controlling zone' (FCZ)
 - The FCZ is the virtual (! by definition) point in the urethra that gives the highest resistance to flow
 - Increased resistance drives detrusor to higher pressures to generate flow
- Urethral catheter (8F) causes ±10cm H₂O increase of detrusor pressure
 - (Systematic) increase of measured outlet obstruction.
 - Should be corrected for if suprapubic catheter is used.

Mechanics of voiding: phases

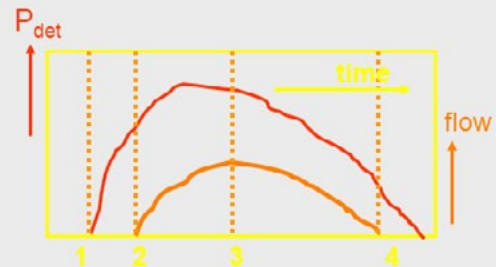
Start of pressure flow = end of storage: Indicated by 'permission to void'.

After voluntary pelvic floor relaxation after

- Permission to void *

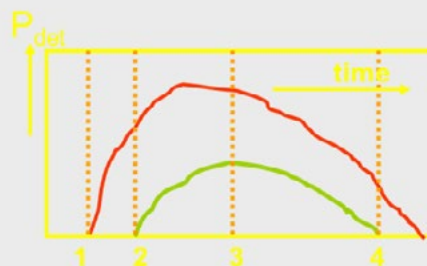
The voiding reflex starts and:

- Detrusor pressure rises (1)
- Outlet relaxes and becomes distended
 - Passive distensible....
- 'Detrusor opening pressure' when flow starts (2)
- 'Maximum flow' when distension is maximal (3)
 - Limited by FCZ
- Steady state /balanced forces until...
- Outlet collapses
 - ... collapsible tube
- 'Closing pressure' (end of flow) (4)



Voiding phases

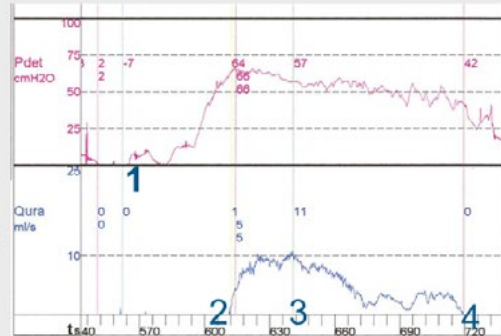
- start of voiding = detrusor pressure rise (see graph): 1 >>
- >> distension of outlet = opening pressure>start of flow: 2 >>
- >> maximum flow = beginning of 'steady state outlet'*: 3 >>
- >> end of flow = collapse of outlet: closing pressure: 4



* During a normal voiding there exist a balance between the forces outside and inside the bladder outlet (urethra) between 3 and 4.

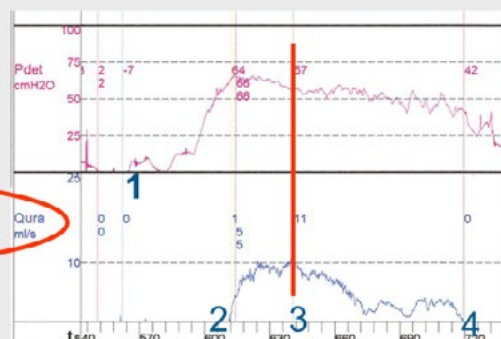
ICS terms

- Pre -micturition pressure (1)
- Opening detrusor pressure (2)
- Opening time
- Maximum detrusor pressure
- Maximum flow (3)
- Detrusor pressure at maximum flow (4)
- Closing detrusor pressure (4)
- Minimum voiding detrusor pressure
- Flow delay time



ICS terms

- Pre -micturition pressure (1)
- Opening detrusor pressure (2)
- Opening time
- Maximum detrusor pressure
- Maximum flow (3)
- Detrusor pressure at maximum flow (3)
- Closing detrusor pressure (4)
- Minimum voiding detrusor pressure
- Flow delay time



- Detrusor pressure at maximum flow (PdetQmax) and maximum flow (Qmax) are, in combination, the most relevant for the analysis of LUT voiding function

Provisional ICS method for definition of obstruction

- Easy way to grade pressure-flow result*:
- On the basis of:
 - Detrusor pressure at maximum flow ($P_{detQ_{max}}$) and maximum flow (Q_{max})

- calculate $P_{detQ_{max}} - 2 \times Q_{max}$ (#)

- (pressure at maximum flow minus 2 times maximum flow rate)
- use cmH₂O for pressure & ml/s for flow rate

Provisional ICS method for definition of OBS

* See also ICS modules: Pressure flow testing: Advanced analysis

Provisional ICS method for definition of obstruction

- p-ICS method is 'clinically calibrated' for elderly male patients with an enlarged prostate
 - if p-ICSmethod < 20: No BOO
 - if p-ICSmethod > 40: BOO
 - if p-ICSmethod 20 to 40: Equivocal/ intermediate
 - Might be interpreted for male patients with an enlarged prostate as*: (eo)
 - No BOO: des-obstruction will not change the voiding very much
 - BOO: des obstruction will likely be effective to improve voiding
 - Equivocal: the result of 'des -obstruction' is not predictable (50% chance of symptomatic improvement)

* this does not take filling phase abnormalities into account

Quality control

- Before:
 - Is the patient adequately informed and instructed?
 - Is anything changed after the indication for UDI testing was settled?
- During:
 - Are sterile catheters and filling medium used?
 - Are antiseptic procedures applied?
 - Is the patient clothed/covered as much as possible?
 - Is the patient comfortably positioned?
- (Especially if male:) Preferred position for voiding?
 - Has everyone who is unnecessary left the site of testing?
- After:
 - Is the patient instructed to drink \pm 0,5-1liter immediately after the test?

Quality control (p/Q analysis)

- Ask the patient:
 - Was this voiding more or less as usual / as at home?
 - If not: clinical urodynamic diagnosis may be irrelevant
 - E.g: Not being able to void does frequently (but not always) not represent the real function and is therefore situative during UDI
- Observe the tracings (of the entire cystometry)
 - Are the pressures in the physiological range
 - Are the intravesical and intra abdominal pressures reacting synchronous on patients' movements and coughing (balanced pressures), also after the voiding?
 - Is permission to void adequately marked /indicated?

Quality control (continued)

- Observe pressure and flow:
 - Is the time lag (meatus to flowmeter) adequately corrected?
 - May be a standard time correction per institute
 - Are flowrate artefacts visible/correctable/corrected?
 - Are pressure artefacts visible/correctable/corrected?
 - (compare cough -pressure- test before and after voiding)
 - Is post void residual urine measured?
 - Is it possible to make an adequate, complete and relevant diagnosis of lower urinary tract voiding function?
 - If not: repeat the test
- Is a pressure flow plot analysis needed? *
 - Quantification of BOO may be less reliable with (severe) underactive contraction
 - Is a physiologically plausible pressure flow 'loop' recognizable?
 - Can the lower pressure border be recognised?
 - Did automated analysis produce plausible and valid results?

* See ICS modules: Pressure flow testing: Advanced analysis

Clinical Quality

- Patients unable to void because of the test situation:
 - Might be not unexpected ('shy voiders / shy bladder/ paruresis')
 - Allow more time; ensure absolute privacy; dim the lights
 - Allow something (cold water) to drink
 - (Sound of) running tap –water
 - Some contraction is seen but no, or very little voiding:
 - not acontractility, not representative, BOO impossible to 'calibrate'*
 - No contraction is observed and no voiding:
 - If patient is usually able to void:
 - not definite acontractility; not representative*
- *patients tend to start straining; usually not productive and not representative!
- Formal pressure flow analysis and diagnosis (outlet or contractility) of voiding (other than 'shy') is impossible now.

Clinical Quality: Pressure flow analysis

- For (elderly) men (with a larger prostate):
 - Pressure flow (relation and) analysis is straightforward
 - Clinically applicable limits for (grading of outlet properties) exist
- For young men, women and children: (eo)
 - Basic principles of voiding and p/Q analysis are known and applicable
 - Universally agreed clinical grading of outlet properties does not exist
- Dynamic outlet obstruction/dysfunctional voiding: (eo)
 - No (standard) grading of outlet dynamics is available
 - No urodynamic (pressure flow relation) criteria
- Neurogenic dyssynergia or neurogenic dynamic outlet obstruction: (eo)
 - No (standard) grading is available
 - No urodynamic (pressure flow relation) criteria
 - However (detrusor) Leak Point Pressure is relevant

Pressure flow analysis: concluding

- Flow relates to pressure and is determined (or limited) by outlet properties
 - Representative voiding and clinically relevant pressure flow analysis depends on good urodynamic practice and properly ascertained patient cooperation
 - A very unrepresentative voiding and -or significant underactive detrusor contraction limit the validity of the pressure flow analysis
- Pressure flow starts: after permission to void
- Bladder outlet obstruction can be graded by:
 - p-ICS-method = $P_{\text{det}} Q_{\text{max}} - 2 \times Q_{\text{max}}$

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ICS Teaching Module: Analysis of Voiding, Pressure Flow Analysis (Basic Module)

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Aims: To present the evidence background for an ICS teaching module for the urodynamic analysis of voiding.

Methods: Literature analysis and expert opinion are combined to collate an outline and explanation of a preferred and good urodynamic practice. **Result:** Patient's preparation, pathophysiology, technique and principles of pressure flow analysis are summarized in this manuscript. **Conclusions:** This manuscript serves as scientific background for a slides set, made available on the ICS website to teach the basic and practical elements of pressure flow analysis. *NeuroUrol. Urodynam.* 35:36–38, 2016. © 2014 Wiley Periodicals, Inc.

Key words: bladder outlet obstruction; diagnosis; pressure flow analysis; review; teaching module; underactive detrusor; voiding

INTRODUCTION

The ICS Urodynamics Committee presents the teaching module Analysis of Voiding; Pressure Flow Analysis-basic module to serve as a standard education of Good Urodynamic Practice for everyone involved in indicating, performing, and analyzing urodynamic testing in general and more specifically, performing analysis of voiding. The teaching module consists of a presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base, for the ICS Power Point presentation; available via <http://www.icsoffice.org/eLearning/>. The presentation explains normal physiology, testing requirements, pressure flow analysis methods, and introduces the nomograms. The presentation and this manuscript uses experts opinion where evidence is, especially for the clinical practice aspects, unavailable and is marked with:^{eo} (experts' opinion).

PREPARATION OF THE PATIENT

Urodynamic testing requires an optimally informed patient, after adequate relevant medical history, systematic symptoms analysis, laboratory, and clinical (neuro-gyneco-urological) exam and, preferably, at least one, not-catheterized (free) flowmetry with post-void residual determination.^{1–3} Pressure flow analysis is the element of urodynamic testing to diagnose voiding dysfunction. Although voiding is, plausibly, negatively influenced by the shift of the autonomic system to sympathetic dominance in the situation of mental stress, there is not very much evidence, that voiding in laboratory circumstances is unacceptably unrepresentative.^{eo} Some indirect evidence exists that differences between office and home are not large in (elderly) male,^{4,5} as long as the bladder is not uncomfortably full.⁶ Perceivably, it is patient friendly to ensure adequate draping, normal seating (or standing, if preferred by the –male patient) and maximum possible privacy during voiding as well as quiet, relaxing circumstances with as little number as possible persons involved during urodynamic testing.^{eo}

Infection prophylaxis necessitates sterile catheterization but for this short time catheterization in the noncompromised

patient prophylactic antibiotics is unnecessary.^{7,eo} Laxatives are also unnecessary and might cause unwanted bowel (over) activity and fecal urgency during the test, but is advantageous to ask the patient to arrive with an empty bowel if possible.^{eo} If high incidences of urinary tract infections after urodynamic testing are observed in a given practice, the first step should be that the procedures are changed so that strict antisepsis is followed.^{eo} Thin (6–8F) double lumen or micro tip with lumen catheters for intravesical filling and pressure recording are advised² with adequate fixation alongside the meatus over the penis or a labium.

PATHOPHYSIOLOGY

Voiding is an autonomic reflex that is, in the normal situation, initiated through voluntary and conscious pelvic floor relaxation. The detrusor dome, when parasympathetically activated delivers the energy to void. The bladder outlet or bladderneck (or autonomic sphincter) relaxes as a result of inhibition of sympathetic input and allows emptying. The normal outlet controls the flow by passive distension and through its visco-elasticity. The outlet collapses when the intravesical pressure is too low to overcome the forces that close the outlet.⁸ Typically, reduced patency of the bladder outlet through an enlarged prostate or a urethral stricture, is limiting the (maximum) flowrate and driving the detrusor muscle to higher power contraction, thus higher intravesical pressures, during voiding.

Christopher Chapple led the peer-review process as the Associate Editor responsible for the paper.

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Clinical nomograms to quantify pressure flow analysis results in a standard manner are available for symptomatic elderly male with an enlarged prostate.⁹⁻¹¹ All of those methods give very consistent results.^{12,13} Women (and young men) voiding dynamics differs from elderly men because there is no prostate to act as a stable nozzle and pressure flow nomograms are more difficult to construct. Time based pressure and flow graphs allow judgement of the voiding; post processing with pressure and flow on an X-Y graph is possible on all contemporary urodynamic equipment, and allows precise appreciation of bladder outlet obstruction (BOO) and outlet dynamics throughout voiding. Nevertheless, good quality and plausibility control as well as an evaluation of clinical representativity are necessary.²

TECHNIQUE AND INTERPRETATION

Technique

Pressure flow starts after permission to void and hesitancy can be recognized if that permission is precisely marked. More important, permission to void indicates the end of storage phase and differentiates between detrusor overactivity (DO) and detrusor voiding contraction; DO to be diagnosed only in the storage phase.

Pressure flow analysis relies on the simultaneous recording of pressures and flow. Pressures in the storage phase are interpreted as pattern; DO or reduced compliance, and there is no evidence that the absolute pressures play a role. In pressure flow analysis however, the absolute pressures, referred to atmospheric pressure, are relevant for the clinical interpretation with the nomograms (v.i.).

There is no specific evidence for the preferred position during pressure flow testing. Plausibly women shall perform best while comfortably sitting, however, many women never really sit on the toilet, or are used to squat.^{14,15} Sitting uncomfortably and voiding in a manner that does not adequately represent the usual way of voiding may likely occur on a videourodynamic equipment, because of the restrictions of the equipment. More in general: in the semi recumbent, supine, or gynecological position, voiding can hardly be as usual, however, direct comparative evidence is lacking.⁶⁰ As in adults, position is of influence for storage phase results, but the relevance of voiding position seems not studied in children and is not mentioned in the standard.^{16,17} Free flow in men is, in group-wise comparisons, influenced by position, however, individuals might have a preferred position and the possibility to allow the patient preferred position seems relevant.¹⁸⁻²⁰ To include the lag-time from meatus to flow recording is necessary in any way,²¹ but a very short meatus to flowmeter distance is beneficial.⁶⁰

If the patient's position is changed during the test, external pressure transducers (if used) must be adjusted to the height of the symphysis pubis again.

Interpretation

Analysis of bladder outlet obstruction is done on the second, passive phase of micturition, usually from the moment maximum of flow when detrusor and outlet act in a steady state and are in balance.^{9,10} Before maximum flow, pelvic floor relaxation and outlet distension dynamics are predominant, but after maximum flow, the true passive outlet resistance is obtained. Pressure at maximum flow in combination with corresponding maximum flow gives a clinically relevant grading of bladder outlet obstruction when used in a formula.¹¹

This grading number is presented, and subsequently adopted, as the ICS-obstruction number.^{22,23}

Likewise, maximum of detrusor contraction (or contractility) can be calculated with the ICS contraction number.²² Detrusor contraction power during voiding can also be calculated throughout the entire voiding²⁴ and relates to bladder outlet obstruction and affectivity of voiding.²⁵ Both analysis methods give similar results.²⁶

Analysis of female micturition is less standardized but follows the principles as mentioned here above. There is usually more flowrate and pressure variation during the time of one female voiding. Most women however, empty with high peak flowrates and because high flowrate rules out static outlet obstruction, outlet dynamics is the cause of variation here. Relatively high detrusor pressure during voiding is also in women regarded as a sign of (static) bladder outlet obstruction.²⁷ This is captured in a nomogram that integrates maximum of (not catheterized) free flowrate with a minimum cut-off pressure, to be observed during voiding cystometry or with observations during radiography.^{28,29} Although frequently used, in variations of application, this nomogram has never been ICS-standard. Pressure at maximum flow is at present accepted as the most relevant parameter.³⁰

Pressure flow voiding can occur in a manner that does not represent the patients' usual behaviour. Comparison with free flowmetry and asking the patients' opinion in this regard are valuable.⁶⁰

Artefacts arise when the (intravesical pressure recording) catheter is slipping out during voiding. This can be suspected already from the pressure recording during voiding and also from the pressures response on cough testing after voiding.² All artefacts that are known from uroflowmetry are to be expected, and should be controlled for, also in pressure flow cystometry.^{2,31}

Very low pressure-voiding, inability to void, or to inability to initiate a full voiding reflex as usual, limits the applicability of pressure flow analysis. Especially in shy voiders, it can become a problem to objectively diagnose the bladder outlet properties, or the real ability of the detrusor muscle to generate sufficient pressure. However, if (little) fluid leaves the bladder during a weak or incomplete voiding reflex, serious bladder outlet obstruction is relatively unlikely when this happens with low pressure, although the level of uncertainty of this diagnosis is high.

CONCLUSIONS

Pressure flow analysis is the golden standard for the analysis of voiding. For male patients, precise and clinically relevant limits for bladder outlet obstruction are available. For female and children, the limits are less precisely defined however, on the basis of what can be expected from normal lower urinary tract physiology, closely linked to the methods and nomograms that are calibrated for male patients. Strict adherence to antisepsis and a patient-centred approach before, during and after testing limits unwanted effects and enhances representativity. Adherence to good urodynamic practice standards, with adequate reference to atmospheric pressure ensures optimal quality of analysis and diagnosis. This ICS educational module provides the background for the basic education of the analysis of voiding in patient with lower urinary tract symptoms.

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Best Practices: Basic Care in Indwelling Urinary Catheter Management

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International Continence Society
Teaching Module

Objectives

- Our purpose is to educate continence nurses to improve patient care and health outcomes globally.

At the conclusion of this presentation, readers should be able to:

- 1. Describe best practices for basic care of people using indwelling urinary catheters.
- 2. Understand the differences and similarities in shorter-term care in acute settings as compared with long-term care in the community.

Prevalence of catheter use

Prevalence in the USA:

- Acute care, 15-25%; 5% nursing homes (Gould et al. HICPAC, 2009)
- Long term catheter users overall estimate is 153,818.
 - 9% home care ;33% hospice (National Home and Hospice Study, 2007.cdc.gov/pub/Health Statistics/NCHS/Datasets/NHHCS/2007)
 - 34% in home care were long-term users (Wilde et al, 2010.)
 - Spinal cord injury– 23% of those discharged from rehabilitation, but some use an intermittent catheter later. (Cameron et al., 2010)

Prevalence in England:

- England & Wales, 19 hospitals 1997 cited by Scottish Nurses Association, 26.3% in acute care, range 12-40% depending on specialty (Glynn et al. 1997)
- England, survey in acute care, 18%, varied by specialty, more in ICU. HPA survey on HCAI and antimicrobial use across acute hospitals in England (2011)
- England, 0.07% community study of 827,595 over two years (0.05% \geq 75 yrs old) (Kohler Ochmore & Feneley 1996)

Indications for short-term catheter use

- Urinary retention or bladder outlet obstruction
- Improving comfort for end-of-life care if needed
- Critically-ill and need for accurate measurements of I&O (e.g., hourly monitoring)
- Selected surgical procedures (GU surgery/colorectal surgery)
- Assist in healing open sacral or perineal wound in the incontinent patient
- Intraoperative monitoring of urinary output during surgery or large volumes of fluid or diuretics anticipated
- Prolonged immobilization (e.g., potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures)

<http://nursingworld.org/CAUTI-Tool> (based on USA CDC guidelines, Gould et al. 2009)

Indications for long-term catheter use

- Intractable **urinary retention** for those who cannot manage an intermittent catheter (and no caregiver to do it)
- **Bladder outlet obstruction**, not surgically treated
- Improving comfort for **end-of-life care** if needed
- **Alternatives to consider**: toileting schedule (when no retention), intermittent catheter, condom/sheath catheter (for cooperative males without obstructed urine or persistent retention)

(USA CDC guidelines, Gould et al. 2009)

Short & long-term catheter use defined:

- **Short term**- less than 1 months' expected use
 - Can be longer, failing trial without catheter
- **Long term**- over 1 months use but often extends over many years.
 - "Indefinite use" would be more accurate term, but no agreement on terminology.
- Both "catheter types" and "catheter use" for expected time of catheterization are called short and long-term, causing confusion. (Cottenden et al. 2013)

Short term catheter types

- Short term use—less than 14 days' expected use
 - **Latex or plastic**, but caution related to latex allergy.
 - **Coated catheters** (silver alloy, nitrofurazone or minocycline/rifampicin) for up to two weeks
 - Can decrease bacteriuria but do not prevent symptomatic UTI & evidence is weak.
 - Can be uncomfortable and are more expensive. (Lam et al., 2014)
 - **Long term catheter types** also can be used. (Cottenden et al., 2013).

Long term catheter types

- Can be used for 28 days and up to 12 weeks, dependent on local policy.
 - Latex coated poly-tetrafluoro-ethylene (**PTFE** or Teflon)
 - **Silicone** elastomer-coated latex or 100% silicone (harder surface but wider lumen). Balloon water can evaporate quicker in pure silicone catheters. Take care to prevent traction as erosion of penis has occurred with silicone.
 - **Hydrogel** polymer-coated latex (softer which can be of benefit) Hydrogel less likely to form suprapubic catheter “deflation cuff”. (Parkin, 2002;Jahn et al. 2012; Cottenden et al. 2013)

Catheter sizes

Catheter sizes (Fr= French which is the same as Charrière or Ch) **Use the smallest size** that permits flow and to prevent potential trauma to urethra and sphincter.

- 12-16 Fr for men and 12-14 Fr for women.
- Children: 5-6 Fr for newborns ; 5-10 Fr toddlers to children to age 12

Balloons 5-10 mL. (30mL only for postoperative bleeding), 2.5-5mL for children

(WOCN, Indwelling Urinary Catheters, Best Practices for Clinicians, 2009; Cottenden et al. 2013)

Catheter insertion

- Long term catheters often changed every 4 weeks. People with frequent blockage can need it every 2-3 weeks or more often. Can extend to 6-8 weeks if no problems.
 - Observe several changes for “catheter life pattern.” (Getliffe, 1994)
 - Good lighting, and help of another if spasticity in legs.
 - Use sterile gloves.
 - Lubricate catheter well, especially for males.
- **For Males:**
 - Insert all the way to Y (bifurcation) to prevent catheter being inflated within the urethra.
 - If resistance is felt, encourage deep breaths and distraction.
 - **For females:** Urethra can be short, especially in older women.
 - Insert 1” further than point of urine flow.
 - Fill balloon all the way to 10mL.

(ANA CAUTI prevention, 2015 <http://nursingworld.org/ANA-CAUTI-Prevention-Tool>; Wilde & Feng, 2013)

Catheter securement

- Nurses often recommend but not use it:
 - Of 82 nurses (8 continence specialists), 98% recommended but only 4% used it. (Siegel, 2006);
 - 18% secured in acute care in one day point-prevalence study (N= 8 of 44) (Appah et al. 2015)
- Securement could **prevent dislodgement and urethral/bladder neck trauma**
 - **Adhesive**—good for those likely to dislodge but irritating to skin
 - **Non-adhesive**—prevent constricting circulation (Wilde & Feng, 2013)

Securement examples

• Non-adhering



Adhering



Holster



General catheter care

- **Hand hygiene** before and after catheter care. In home, teach family.
- If **breaks in the closed system** (e.g., disconnection, cracked tubing), **replace** the catheter and tubing.
- Perform **perineal hygiene** at a minimum daily, per facility protocol/procedure and as needed. Soap and water is all that is needed most often.
- Use **fecal containment device** when appropriate for **fecal incontinence**.

ANA CAUTI prevention, 2015 http://nursingworld.org/ANA_CAUTI_Prevention_Tool

Drainage bags

- **Closed drainage essential in acute care, short term use.**
 - It is the only proven method of decreasing UTI. (Kunin & McCormack, 1966)
- **Types:**
 - Overnight (2000-4000mL)
 - Leg bags (270-1000 mL.)
 - Belly bag (with normal bladder pressure) (WOCN, 2009)
- **Prevent kinks/twists in tubing:** Blocked urine flow can contribute to damage to the kidneys (Feneley et al. 2015)
- **Keep bag at least 12" below the level of the bladder** and off the floor to prevent suction of the catheter eyes on the bladder **MUCOSA**. (Glahn et al. 1988)

Care for drainage bags

- Empty the drainage bag regularly using a separate, clean collecting container for each patient; avoid splashing, and prevent contact of the drainage spout. <http://nursingworld.org/ANA-CAUTI-Prevention-Tool>
- Empty when 1/3 to ½ full.
- For long-term catheter users, replace drainage bags weekly.
- No evidence that connecting a catheter to a leg bag continuously & then hooking up an overnight bag is beneficial. (Cottenden et al. 2013)

Cleaning & reuse of drainage bags

- Systematic review revealed need for research in this area.
 - Conflicting guidelines and research virtually lacking since 1990s. (Wilde, Fader et al. 2013)
- In a U.S. study of 202 long-term catheter users, most switched between leg and night bag
 - 54% cleaned leg bags & 59% night bags. (Wilde, McDonald, et al. 2013)
 - Rehabilitation nurses have used mild bleach (1 part household bleach to 10 parts water). (Dille & Kirchhoff, 1993; Dille et al. 1993)
- In home care in the past: vinegar was recommended (1 part vinegar to 4 parts water) (Wilde, 1986)

Irrigation (also called flushing or washouts)

- Irrigation not recommended. Sometimes used in hospitals to remove blood clots post operatively.
- In one U.S. study of 202 long term catheter users , 42% irrigated and 18% once or more a day.
 - Solutions were saline (76%) and sterile water (23%).
 - Surprising, 9% used plain tap water, which could have bacteria or other impurities in it.
 - 4% used Renacidin --not readily available in the US and made fresh in a pharmacy. (Wilde, McDonald et al. 2013)

Irrigation sachets

- Irrigation sachets (Suby G and Suby R, called catheter maintenance solutions) are available in the United Kingdom, and in some other countries, *to dissolve encrustations if change is not appropriate*. These solutions are not available in every country.
 - Saline or sterile water is not effective in breaking up encrustations.
 - Research in Canada testing saline, no irrigation and Suby G showed no difference in decreasing time to change but underpowered. (Moore et al., 2009)
 - There is a desperate need for irrigation solutions which are *effective, easily obtained and used, inexpensive, and safe*.

Symptoms CAUTI- short term catheter users

- In acute care diagnosis of CAUTI, **catheter in place > 2 days:**
- 1. At least **one symptom below with no other recognized cause:**
 - fever (>38.0°C) • suprapubic tenderness • costovertebral angle pain or tenderness • urinary urgency • urinary frequency • dysuria
- 2. **AND urine culture with no more than two microorganism $\geq 10^5$ CFU/m**
 - <http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf>
- **Differential diagnosis not simple** to identify source of infection
 - Fever-- without other possible source, comorbidities confound
 - Bacteriuria (Lo et al., 2014)

Symptoms CAUTI--long term catheters

• Urine Changes:

- Color – Discolored, cloudy, dark, blood stained
- Odor – Foul smelling, change in smell from usual
- Sediment (grit) – Increased amount

Temperature – Fever, chills

Pain and/or pressure in bladder area or back (Burning possible, not common)

Early, mild symptoms of autonomic dysreflexia (e.g., goosebumps, headaches, sweats) mainly in people with spinal cord injury

General Symptoms Blahs!, feeling sick

- Functioning or mental changes – weakness, spasticity, change in the level of alertness (Wilde, McDonald et al., 2013)

CAUTI prevention


- Do not insert indwelling catheter if bladder management is possible any other way, e.g., condom catheter (sheath, external) or intermittent catheter (including caregiver performing or assisting).
- Remove catheter as soon as possible.
- Track CAUTI rate systematically:

$$\frac{\text{Events of symptomatic UTI}}{\text{Catheter days' use (number of persons X days catheter used)}} \times 1000$$
- Encourage staff and celebrate when CAUTI rate & usage of catheters decreases.
- In acute care, a daily order for catheter continued use is recommended.
- In community, assess regularly whether indwelling is still needed.
- Checkout this important document from the USA, American Nurses' Association: ANA CAUTI prevention, 2015 <http://nursingworld.org/ANA-CAUTI-Prevention-Tool>


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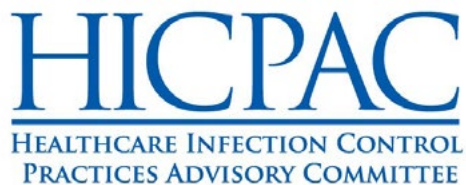
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GUIDELINE FOR PREVENTION OF CATHETER-ASSOCIATED URINARY TRACT INFECTIONS 2009

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Abbreviations

ADL	Activities of daily living
APACHE II	Acute Physiology and Chronic Health Evaluation II
ASA	American Society of Anesthesiologists
ASB	Asymptomatic bacteriuria
BUN	Blood urea nitrogen
CAUTI	Catheter-associated urinary tract infection
CDC	Centers for Disease Control and Prevention
CFU	Colony-forming units
CI	Confidence interval
CIC	Clean intermittent catheterization
CICU	Coronary intensive care unit
COPD	Chronic obstructive pulmonary disease
ED	Emergency department
F/U	Follow-up
GRADE	Grading of Recommendations Assessment, Development, and Evaluation system
Hb	Hemoglobin concentration
HICPAC	Healthcare Infection Control Practices Advisory Committee
H/O	History of
HPF	High power field
HR	Hazard ratio
ICU	Intensive care unit
IDR	Incidence-density ratio
LOS	Length of stay
MDR	Multi-drug resistant
MICU	Medical intensive care unit
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NS	Not significant
OBS	Observational controlled study
OR	Odds ratio
P	P value
PACU	Post-anesthesia care unit
PVC	Polyvinyl chloride

RCT	Randomized controlled trial
RD	Risk difference
RH	Relative hazard
RR	Relative risk
SAPS II	Simplified Acute Physiology Score II
SICU	Surgical intensive care unit
SR	Systematic review
SUTI	Symptomatic urinary tract infection
TMP/SMX	Trimethoprim/sulfamethoxazole
TURP	Transurethral resection of prostate
UTI	Urinary tract infection
VAS	Visual analog scale
WMD	Weighted mean difference

I. Executive Summary

This guideline updates and expands the original Centers for Disease Control and Prevention (CDC) Guideline for Prevention of Catheter-associated Urinary Tract Infections (CAUTI) published in 1981. Several developments necessitated revision of the 1981 guideline, including new research and technological advancements for preventing CAUTI, increasing need to address patients in non-acute care settings and patients requiring long-term urinary catheterization, and greater emphasis on prevention initiatives as well as better defined goals and metrics for outcomes and process measures. In addition to updating the previous guideline, this revised guideline reviews the available evidence on CAUTI prevention for patients requiring chronic indwelling catheters and individuals who can be managed with alternative methods of urinary drainage (e.g., intermittent catheterization). The revised guideline also includes specific recommendations for implementation, performance measurement, and surveillance. Although the general principles of CAUTI prevention have not changed from the previous version, the revised guideline provides clarification and more specific guidance based on a defined, systematic review of the literature through July 2007. For areas where knowledge gaps exist, recommendations for further research are listed. Finally, the revised guideline outlines high-priority recommendations for CAUTI prevention in order to offer guidance for implementation.

This document is intended for use by infection prevention staff, healthcare epidemiologists, healthcare administrators, nurses, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection prevention and control programs for healthcare settings across the continuum of care. The guideline can also be used as a resource for societies or organizations that wish to develop more detailed implementation guidance for prevention of CAUTI.

Our goal was to develop a guideline based on a targeted systematic review of the best available evidence, with explicit links between the evidence and recommendations. To accomplish this, we used an adapted GRADE system approach for evaluating quality of evidence and determining strength of recommendations. The methodology, structure, and components of this guideline are approved by HICPAC and will be used for subsequent guidelines issued by HICPAC. A more detailed description of our approach is available in the [Methods](#) section.

To evaluate the evidence on preventing CAUTI, we examined data addressing three key questions and related subquestions:

1. Who should receive urinary catheters?
 - A. When is urinary catheterization necessary?
 - B. What are the risk factors for CAUTI?
 - C. What populations are at highest risk of mortality related to urinary catheters?
2. For those who may require urinary catheters, what are the best practices?

Specifically, what are the risks and benefits associated with:

 - A. Different approaches to catheterization?
 - B. Different catheters or collecting systems?
 - C. Different catheter management techniques?
 - D. Different systems interventions (i.e., quality improvement programs)?
3. What are the best practices for preventing CAUTI associated with obstructed urinary catheters?

Evidence addressing the key questions was used to formulate recommendations, and explicit links between the evidence and recommendations are available in the [Evidence Review](#) in the body of the guideline, and [Evidence Tables](#) and [GRADE Tables](#) in the [Appendices](#). **It is important to note that Category I recommendations are all considered strong recommendations and should be equally implemented**; it is only the *quality* of the evidence underlying the recommendation that distinguishes between levels A and B. Category IC recommendations are required by state or federal regulation and may have any level of supporting evidence.

The categorization scheme used in this guideline is presented in Table 1 in the [Summary of Recommendations](#) and described further in the [Methods section](#).

The [Summary of Recommendations](#) is organized as follows: 1) recommendations for who should receive indwelling urinary catheters (or, for certain populations, alternatives to indwelling catheters); 2) recommendations for catheter insertion; 3) recommendations for catheter maintenance; 4) quality improvement programs to achieve appropriate placement, care, and removal of catheters; 5) administrative infrastructure required; and 6) surveillance strategies.

The [Implementation and Audit](#) section includes a prioritization of recommendations (i.e., high-priority recommendations that are essential for every healthcare facility), organized by modules, in order to provide facilities more guidance on implementation of these guidelines. A list of recommended performance measures that can potentially be used for internal reporting purposes is also included.

Areas in need of further research identified during the evidence review are outlined in the [Recommendations for Further Research](#). This section includes guidance for specific methodological approaches that should be used in future studies.

Readers who wish to examine the primary evidence underlying the recommendations are referred to the [Evidence Review](#) in the body of the guideline, and the [Evidence Tables](#) and [GRADE Tables](#) in the [Appendices](#). The [Evidence Review](#) includes narrative summaries of the data presented in the [Evidence Tables](#) and [GRADE Tables](#). The [Evidence Tables](#) include all study-level data used in the guideline, and the [GRADE Tables](#) assess the overall quality of evidence for each question. The [Appendices](#) also contain a clearly delineated search strategy that will be used for periodic updates to ensure that the guideline remains a timely resource as new information becomes available.

II. Summary of Recommendations

Category IA	A strong recommendation supported by high to moderate quality† evidence suggesting net clinical benefits or harms
Category IB	A strong recommendation supported by low quality evidence suggesting net clinical benefits or harms or an accepted practice (e.g., aseptic technique) supported by low to very low quality evidence
Category IC	A strong recommendation required by state or federal regulation.
Category II	A weak recommendation supported by any quality evidence suggesting a trade off between clinical benefits and harms
No recommendation/ unresolved issue	Unresolved issue for which there is low to very low quality evidence with uncertain trade offs between benefits and harms

* Please refer to Methods (p.32) for implications of Category designations

†Please refer to Methods (p. 29-30) for process used to grade quality of evidence

I. Appropriate Urinary Catheter Use

- A. Insert catheters only for appropriate indications (see Table 2 for guidance), and leave in place only as long as needed. **(Category IB)** (Key Questions 1B and 2C)
 1. Minimize urinary catheter use and duration of use in all patients, particularly those at higher risk for CAUTI or mortality from catheterization such as women, the elderly, and patients with impaired immunity. **(Category IB)** (Key Questions 1B and 1C)
 2. Avoid use of urinary catheters in patients and nursing home residents for management of incontinence. **(Category IB)** (Key Question 1A)
 - a. Further research is needed on periodic (e.g., nighttime) use of external catheters (e.g., condom catheters) in incontinent patients or residents and the use of catheters to prevent skin breakdown. **(No recommendation/unresolved issue)** (Key Question 1A)
 3. Use urinary catheters in operative patients only as necessary, rather than routinely. **(Category IB)** (Key Question 1A)
 4. For operative patients who have an indication for an indwelling catheter, remove the catheter as soon as possible postoperatively, preferably within 24 hours, unless there are appropriate indications for continued use. **(Category IB)** (Key Questions 2A and 2C)

Table 2.
A. Examples of Appropriate Indications for Indwelling Urethral Catheter Use ¹⁻⁴
Patient has acute urinary retention or bladder outlet obstruction
Need for accurate measurements of urinary output in critically ill patients
Perioperative use for selected surgical procedures: <ul style="list-style-type: none"> • Patients undergoing urologic surgery or other surgery on contiguous structures of the genitourinary tract • Anticipated prolonged duration of surgery (catheters inserted for this reason should be removed in PACU) • Patients anticipated to receive large-volume infusions or diuretics during surgery • Need for intraoperative monitoring of urinary output
To assist in healing of open sacral or perineal wounds in incontinent patients
Patient requires prolonged immobilization (e.g., potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures)
To improve comfort for end of life care if needed
B. Examples of Inappropriate Uses of Indwelling Catheters
As a substitute for nursing care of the patient or resident with incontinence
As a means of obtaining urine for culture or other diagnostic tests when the patient can voluntarily void
For prolonged postoperative duration without appropriate indications (e.g., structural repair of urethra or contiguous structures, prolonged effect of epidural anaesthesia, etc.)

Note: These indications are based primarily on expert consensus.

- B. Consider using alternatives to indwelling urethral catheterization in selected patients when appropriate.
1. Consider using external catheters as an alternative to indwelling urethral catheters in cooperative male patients without urinary retention or bladder outlet obstruction. **(Category II)** (Key Question 2A)
 2. Consider alternatives to chronic indwelling catheters, such as intermittent catheterization, in spinal cord injury patients. **(Category II)** (Key Question 1A)
 3. Intermittent catheterization is preferable to indwelling urethral or suprapubic catheters in patients with bladder emptying dysfunction. **(Category II)** (Key Question 2A)
 4. Consider intermittent catheterization in children with myelomeningocele and neurogenic bladder to reduce the risk of urinary tract deterioration. **(Category II)** (Key Question 1A)
 5. Further research is needed on the benefit of using a urethral stent as an alternative to an indwelling catheter in selected patients with bladder outlet obstruction. **(No recommendation/unresolved issue)** (Key Question 1A)
 6. Further research is needed on the risks and benefits of suprapubic catheters as an alternative to indwelling urethral catheters in selected patients requiring short- or long-term catheterization, particularly with respect to complications related to catheter insertion or the catheter site. **(No recommendation/unresolved issue)** (Key Question 2A)

II. Proper Techniques for Urinary Catheter Insertion

- A. Perform hand hygiene immediately before and after insertion or any manipulation of the catheter device or site. **(Category IB)** (Key Question 2D)
- B. Ensure that only properly trained persons (e.g., hospital personnel, family members, or patients themselves) who know the correct technique of aseptic catheter insertion and maintenance are given this responsibility. **(Category IB)** (Key Question 1B)
- C. In the acute care hospital setting, insert urinary catheters using aseptic technique and sterile equipment. **(Category IB)**
 - 1. Use sterile gloves, drape, sponges, an appropriate antiseptic or sterile solution for periurethral cleaning, and a single-use packet of lubricant jelly for insertion. **(Category IB)**
 - 2. Routine use of antiseptic lubricants is not necessary. **(Category II)** (Key Question 2C)
 - 3. Further research is needed on the use of antiseptic solutions vs. sterile water or saline for periurethral cleaning prior to catheter insertion. **(No recommendation/unresolved issue)** (Key Question 2C)
- D. In the non-acute care setting, clean (i.e., non-sterile) technique for intermittent catheterization is an acceptable and more practical alternative to sterile technique for patients requiring chronic intermittent catheterization. **(Category IA)** (Key Question 2A)
 - 1. Further research is needed on optimal cleaning and storage methods for catheters used for clean intermittent catheterization. **(No recommendation/unresolved issue)** (Key Question 2C)
- E. Properly secure indwelling catheters after insertion to prevent movement and urethral traction. **(Category IB)**
- F. Unless otherwise clinically indicated, consider using the smallest bore catheter possible, consistent with good drainage, to minimize bladder neck and urethral trauma. **(Category II)**
- G. If intermittent catheterization is used, perform it at regular intervals to prevent bladder overdistension. **(Category IB)** (Key Question 2A)
- H. Consider using a portable ultrasound device to assess urine volume in patients undergoing intermittent catheterization to assess urine volume and reduce unnecessary catheter insertions. **(Category II)** (Key Question 2C)
 - 1. If ultrasound bladder scanners are used, ensure that indications for use are clearly stated, nursing staff are trained in their use, and equipment is adequately cleaned and disinfected in between patients. **(Category IB)**

III. Proper Techniques for Urinary Catheter Maintenance

- A. Following aseptic insertion of the urinary catheter, maintain a closed drainage system **(Category IB)** (Key Question 1B and 2B)
 - 1. If breaks in aseptic technique, disconnection, or leakage occur, replace the catheter and collecting system using aseptic technique and sterile equipment. **(Category IB)**
 - 2. Consider using urinary catheter systems with preconnected, sealed catheter-tubing junctions. **(Category II)** (Key Question 2B)
- B. Maintain unobstructed urine flow. **(Category IB)** (Key Questions 1B and 2D)
 - 1. Keep the catheter and collecting tube free from kinking. **(Category IB)**
 - 2. Keep the collecting bag below the level of the bladder at all times. Do not rest the bag on the floor. **(Category IB)**
 - 3. Empty the collecting bag regularly using a separate, clean collecting container for each patient; avoid splashing, and prevent contact of the drainage spigot with the nonsterile collecting container. **(Category IB)**
- C. Use Standard Precautions, including the use of gloves and gown as appropriate, during any manipulation of the catheter or collecting system. **(Category IB)**
- D. Complex urinary drainage systems (utilizing mechanisms for reducing bacterial entry such as antiseptic-release cartridges in the drain port) are not necessary for routine use. **(Category II)** (Key Question 2B)
- E. Changing indwelling catheters or drainage bags at routine, fixed intervals is not recommended. Rather, it is suggested to change catheters and drainage bags based on clinical indications such as infection, obstruction, or when the closed system is compromised. **(Category II)** (Key Question 2C)
- F. Unless clinical indications exist (e.g., in patients with bacteriuria upon catheter removal post urologic surgery), do not use systemic antimicrobials routinely to prevent CAUTI in patients requiring either short or long-term catheterization. **(Category IB)** (Key Question 2C)
 - 1. Further research is needed on the use of urinary antiseptics (e.g., methenamine) to prevent UTI in patients requiring short-term catheterization. **(No recommendation/unresolved issue)** (Key Question 2C)
- G. Do not clean the periurethral area with antiseptics to prevent CAUTI while the catheter is in place. Routine hygiene (e.g., cleansing of the meatal surface during daily bathing or showering) is appropriate. **(Category IB)** (Key Question 2C)
- H. Unless obstruction is anticipated (e.g., as might occur with bleeding after prostatic or bladder surgery) bladder irrigation is not recommended. **(Category II)** (Key Question 2C)

1. If obstruction is anticipated, closed continuous irrigation is suggested to prevent obstruction. **(Category II)**
- I. Routine irrigation of the bladder with antimicrobials is not recommended. **(Category II)** (Key Question 2C)
- J. Routine instillation of antiseptic or antimicrobial solutions into urinary drainage bags is not recommended. **(Category II)** (Key Question 2C)
- K. Clamping indwelling catheters prior to removal is not necessary. **(Category II)** (Key Question 2C)
- L. Further research is needed on the use of bacterial interference (i.e., bladder inoculation with a nonpathogenic bacterial strain) to prevent UTI in patients requiring chronic urinary catheterization. **(No recommendation/unresolved issue)** (Key Question 2C)

Catheter Materials

- M. If the CAUTI rate is not decreasing after implementing a comprehensive strategy to reduce rates of CAUTI, consider using antimicrobial/antiseptic-impregnated catheters. The comprehensive strategy should include, at a minimum, the high priority recommendations for urinary catheter use, aseptic insertion, and maintenance (see Section III. Implementation and Audit). **(Category IB)** (Key Question 2B)
 1. Further research is needed on the effect of antimicrobial/antiseptic-impregnated catheters in reducing the risk of symptomatic UTI, their inclusion among the primary interventions, and the patient populations most likely to benefit from these catheters. **(No recommendation/unresolved issue)** (Key Question 2B)
- N. Hydrophilic catheters might be preferable to standard catheters for patients requiring intermittent catheterization. **(Category II)** (Key Question 2B)
- O. Silicone might be preferable to other catheter materials to reduce the risk of encrustation in long-term catheterized patients who have frequent obstruction. **(Category II)** (Key Question 3)
- P. Further research is needed to clarify the benefit of catheter valves in reducing the risk of CAUTI and other urinary complications. **(No recommendation/unresolved issue)** (Key Question 2B)

Management of Obstruction

- Q. If obstruction occurs and it is likely that the catheter material is contributing to obstruction, change the catheter. **(Category IB)**
- R. Further research is needed on the benefit of irrigating the catheter with acidifying solutions or use of oral urease inhibitors in long-term catheterized patients who have frequent catheter obstruction. **(No recommendation/unresolved issue)** (Key Question 3)

- S. Further research is needed on the use of a portable ultrasound device to evaluate for obstruction in patients with indwelling catheters and low urine output. **(No recommendation/unresolved issue)** (Key Question 2C)
- T. Further research is needed on the use of methenamine to prevent encrustation in patients requiring chronic indwelling catheters who are at high risk for obstruction. **(No recommendation/unresolved issue)** (Key Question 2C)

Specimen Collection

- U. Obtain urine samples aseptically. **(Category IB)**
 - 1. If a small volume of fresh urine is needed for examination (i.e., urinalysis or culture), aspirate the urine from the needleless sampling port with a sterile syringe/cannula adapter after cleansing the port with a disinfectant. **(Category IB)**
 - 2. Obtain large volumes of urine for special analyses (not culture) aseptically from the drainage bag. **(Category IB)**

Spatial Separation of Catheterized Patients

- V. Further research is needed on the benefit of spatial separation of patients with urinary catheters to prevent transmission of pathogens colonizing urinary drainage systems. **(No recommendation/unresolved issue)** (Key Question 2D)

IV. Quality Improvement Programs

- A. Implement quality improvement (QI) programs or strategies to enhance appropriate use of indwelling catheters and to reduce the risk of CAUTI based on a facility risk assessment. **(Category IB)** (Key Question 2D)

The purposes of QI programs should be: 1) to assure appropriate utilization of catheters 2) to identify and remove catheters that are no longer needed (e.g., daily review of their continued need) and 3) to ensure adherence to hand hygiene and proper care of catheters. Examples of programs that have been demonstrated to be effective include:

- 1. A system of alerts or reminders to identify all patients with urinary catheters and assess the need for continued catheterization
- 2. Guidelines and protocols for nurse-directed removal of unnecessary urinary catheters
- 3. Education and performance feedback regarding appropriate use, hand hygiene, and catheter care
- 4. Guidelines and algorithms for appropriate peri-operative catheter management, such as:

- a. Procedure-specific guidelines for catheter placement and postoperative catheter removal
- b. Protocols for management of postoperative urinary retention, such as nurse-directed use of intermittent catheterization and use of bladder ultrasound scanners

V. Administrative Infrastructure

A. Provision of guidelines

- 1. Provide and implement evidence-based guidelines that address catheter use, insertion, and maintenance. **(Category IB)**
 - a. Consider monitoring adherence to facility-based criteria for acceptable indications for indwelling urinary catheter use. **(Category II)**

B. Education and Training

- 1. Ensure that healthcare personnel and others who take care of catheters are given periodic in-service training regarding techniques and procedures for urinary catheter insertion, maintenance, and removal. Provide education about CAUTI, other complications of urinary catheterization, and alternatives to indwelling catheters. **(Category IB)**
- 2. When feasible, consider providing performance feedback to these personnel on what proportion of catheters they have placed meet facility-based criteria and other aspects related to catheter care and maintenance. **(Category II)**

C. Supplies

- 1. Ensure that supplies necessary for aseptic technique for catheter insertion are readily available. **(Category IB)**

D. System of documentation

- 1. Consider implementing a system for documenting the following in the patient record: indications for catheter insertion, date and time of catheter insertion, individual who inserted catheter, and date and time of catheter removal. **(Category II)**
 - a. Ensuring that documentation is accessible in the patient record and recorded in a standard format for data collection and quality improvement purposes is suggested. Electronic documentation that is searchable is preferable. **(Category II)**

E. Surveillance resources

- 1. If surveillance for CAUTI is performed, ensure that there are sufficient trained personnel and technology resources to support surveillance for urinary catheter use and outcomes. **(Category IB)**

VI. Surveillance

- A. Consider surveillance for CAUTI when indicated by facility-based risk assessment. **(Category II)**
 1. Identify the patient groups or units on which to conduct surveillance based on frequency of catheter use and potential risk of CAUTI.
- B. Use standardized methodology for performing CAUTI surveillance. **(Category IB)**
 1. Examples of metrics that should be used for CAUTI surveillance include:
 - a. Number of CAUTI per 1000 catheter-days
 - b. Number of bloodstream infections secondary to CAUTI per 1000 catheter-days
 - c. Catheter utilization ratio: (urinary catheter days/patient days) x 100
 2. Use CDC/NHSN criteria for identifying patients who have symptomatic UTI (SUTI) (numerator data) (see NHSN Patient Safety Manual: <http://www.cdc.gov/nhsn/library.html>).
 3. For more information on metrics, please see the U.S. Department of Health & Human Services (HHS) Action Plan to Prevent Healthcare-Associated Infections: <http://www.hhs.gov/ophs/initiatives/hai/infection.html>.
- C. Routine screening of catheterized patients for asymptomatic bacteriuria (ASB) is not recommended. **(Category II)** (Key Question 2D)
- D. When performing surveillance for CAUTI, consider providing regular (e.g., quarterly) feedback of unit-specific CAUTI rates to nursing staff and other appropriate clinical care staff. **(Category II)** (Key Question 2D)

III. Implementation and Audit

Prioritization of Recommendations

In this section, the recommendations considered essential for *all* healthcare facilities caring for patients requiring urinary catheterization are organized into modules in order to provide more guidance to facilities on implementation of these guidelines. The high-priority recommendations were chosen by a consensus of experts based on strength of recommendation as well as on the likely impact of the strategy in preventing CAUTI. The administrative functions and infrastructure listed above in the summary of recommendations are necessary to accomplish the high priority recommendations and are therefore critical to the success of a prevention program. In addition, quality improvement programs should be implemented as an active approach to accomplishing these recommendations and when process and outcome measure goals are not being met based on internal reporting.

Priority Recommendations for Appropriate Urinary Catheter Use (Module 1)

- Insert catheters only for appropriate indications (see Table 2), and leave in place only as long as needed. **(Category IB)**
 - Avoid use of urinary catheters in patients and nursing home residents for management of incontinence. **(Category IB)**
 - For operative patients who have an indication for an indwelling catheter, remove the catheter as soon as possible postoperatively, preferably within 24 hours, unless there are appropriate indications for continued use. **(Category IB)**

Priority Recommendations for Aseptic Insertion of Urinary Catheters (Module 2)

- Ensure that only properly trained persons (e.g., hospital personnel, family members, or patients themselves) who know the correct technique of aseptic catheter insertion and maintenance are given this responsibility. **(Category IB)**
- In the acute care hospital setting, insert catheters using aseptic technique and sterile equipment. **(Category IB)**

Priority Recommendations for Proper Urinary Catheter Maintenance (Module 3)

- Following aseptic insertion of the urinary catheter, maintain a closed drainage system **(Category IB)**
- Maintain unobstructed urine flow. **(Category IB)**

Performance Measures

- A. Internal Reporting. Consider reporting both process and outcome measures to senior administrative, medical, and nursing leadership and clinicians who care for patients at risk for CAUTI. **(Category II)**
 1. Examples of process measures:
 - a) Compliance with educational program: Calculate percent of personnel who have proper training:
 - Numerator: number of personnel who insert urinary catheters and who have proper training
 - Denominator: number of personnel who insert urinary catheters
 - Standardization factor: 100 (i.e., multiply by 100 so that measure is expressed as a percentage)

- b) Compliance with documentation of catheter insertion and removal dates: Conduct random audits of selected units and calculate compliance rate:
 - Numerator: number of patients on unit with catheters with proper documentation of insertion and removal dates
 - Denominator: number of patients on the unit with a catheter in place at some point during admission
 - Standardization factor: 100 (i.e., multiply by 100 so that measure is expressed as a percentage)
 - c) Compliance with documentation of indication for catheter placement: Conduct random audits of selected units and calculate compliance rate
 - Numerator: number of patients on unit with catheters with proper documentation of indication
 - Denominator: number of patients on the unit with catheter in place
 - Standardization factor: 100 (i.e., multiply by 100 so that measure is expressed as a percentage)
2. Recommended outcome measures:
- a) Rates of CAUTI: Use NHSN definitions (see <http://www.cdc.gov/nhsn/library.html>). Measurement of rates allows an individual facility to gauge the longitudinal impact of implementation of prevention strategies:
 - Numerator: number of CAUTIs in each location monitored
 - Denominator: total number of urinary catheter-days for all patients that have an indwelling urinary catheter in each location monitored
 - Standardization factor: Multiply by 1000 so that the measure is expressed as cases per 1000 catheter-days
 - b) Rate of bloodstream infections secondary to CAUTI: Use NHSN definitions for laboratory-confirmed bloodstream infection, available at <http://www.cdc.gov/nhsn/library.html>.
 - Numerator: number of episodes of bloodstream infections secondary to CAUTI
 - Denominator: total number of urinary catheter-days for all patients that have an indwelling urinary catheter in each location monitored
 - Standardization factor: Multiply by 1000 so that the measure is expressed as cases per 1000 catheter-days
- B. External Reporting. Current NHSN definitions for CAUTI were developed for monitoring of rates within a facility; however, reporting of CAUTI rates for facility-to-facility comparison might be requested by state requirements and external quality initiatives.

IV. Recommendations for Further Research

Our literature review revealed that many of the studies addressing strategies to prevent CAUTI were not of sufficient quality to allow firm conclusions regarding the benefit of certain interventions. Future studies of CAUTI prevention should:

- 1) Be primary analytic research (i.e. systematic reviews, meta-analyses, interventional studies, and observational studies [cohort, case-control, analytic cross-sectional studies])
- 2) Evaluate clinically relevant outcomes (e.g., SUTI, bloodstream infections secondary to CAUTI)
- 3) Adjust for confounders as needed using multivariable analyses
- 4) Stratify outcomes by patient populations at risk for CAUTI
- 5) Ensure adequate statistical power to detect differences

The following is a compilation of recommendations for further research:

1. Catheter materials
 - a. Antimicrobial and antiseptic-impregnated catheters
 - i. Effect of catheters on reducing the risk of SUTI and other clinically significant outcomes
 - ii. Patient populations most likely to benefit
 - iii. Incidence of antimicrobial resistance in urinary pathogens
 - iv. Role of bacterial biofilms in the pathogenesis of CAUTI
 - b. Standard catheters
 - i. Optimal materials for reducing the risk of CAUTI and other urethral complications
2. Appropriate urinary catheter use
 - a. Incontinent patients
 - i. Risks and benefits of periodic (e.g., nighttime) use of external catheters
 - ii. Risk of local complications (e.g., skin maceration, phimosis) with the use of external catheters
 - iii. Appropriate use of urinary catheters to manage sacral or perineal wounds
 - b. Appropriate indications for continued use in postoperative patients and associated risks
3. Antiseptics
 - a. Use of antiseptic vs. sterile solutions for periurethral cleaning prior to catheter insertion
 - b. Use of antiseptics (e.g., methenamine) to prevent CAUTI
4. Alternatives to indwelling urethral catheters and bag drainage
 - a. Risks and benefits of suprapubic catheters as an alternative to chronic indwelling urethral catheters
 - b. Use of a urethral stent as an alternative to an indwelling catheter in selected patients with bladder outlet obstruction
 - c. Use of catheter valves in reducing the risk of CAUTI and other urinary complications
 - d. Other alternative methods of urinary drainage

5. Optimal methods for preventing encrustation in long-term catheterized patients who have frequent obstruction
 - a. Optimal catheter materials
 - b. Irrigation with acidifying solutions or oral urease inhibitors
 - c. Use of methenamine
6. Other prevention measures
 - a. Use of portable ultrasound in patients with low-urine output to reduce unnecessary catheter insertions or irrigations (in catheterized patients)
 - b. Use of new prevention strategies such as bacterial interference in patients requiring chronic catheterization
 - c. Optimal cleaning and storage procedures (e.g., wet vs. dry storage) for catheters used for clean intermittent catheterization
7. Prevention of transmission
 - a. Spatial separation of patients with urinary catheters (in the absence of epidemic spread or frequent cross-infection) to prevent transmission of pathogens colonizing urinary drainage systems

V. Background

Urinary tract infections are the most common type of healthcare-associated infection, accounting for more than 30% of infections reported by acute care hospitals.¹⁹ Virtually all healthcare-associated UTIs are caused by instrumentation of the urinary tract. Catheter-associated urinary tract infection (CAUTI) has been associated with increased morbidity, mortality, hospital cost, and length of stay.⁶⁻⁹ In addition, bacteriuria commonly leads to unnecessary antimicrobial use, and urinary drainage systems are often reservoirs for multidrug-resistant bacteria and a source of transmission to other patients.^{10,11}

Definitions

An indwelling urinary catheter is a drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a closed collection system. Alternative methods of urinary drainage may be employed in some patients. Intermittent (“in-and-out”) catheterization involves brief insertion of a catheter into the bladder through the urethra to drain urine at intervals. An external catheter is a urine containment device that fits over or adheres to the genitalia and is attached to a urinary drainage bag. The most commonly used external catheter is a soft flexible sheath that fits over the penis (“condom” catheter). A suprapubic catheter is surgically inserted into the bladder through an incision above the pubis.

Although UTIs associated with alternative urinary drainage systems are considered device-associated, CAUTI rates reported to the National Healthcare Safety Network (NHSN) only refer to those associated with indwelling urinary catheters. NHSN has recently revised the UTI surveillance definition criteria. Among the changes are removal of the asymptomatic bacteriuria (ASB) criterion and refinement of the criteria for defining symptomatic UTI (SUTI). The time period for follow-up surveillance after catheter removal also has been shortened from 7 days to 48 hours to align with other device-associated infections. The new UTI criteria, which took effect in January 2009, can be found in the NHSN Patient Safety Manual (<http://www.cdc.gov/nhsn/library.html>).

The limitations and heterogeneity of definitions of CAUTI used in various studies present major challenges in appraising the quality of evidence in the CAUTI literature. Study investigators have used numerous different definitions for CAUTI outcomes, ranging from simple bacteriuria at a range of concentrations to, less commonly, symptomatic infection defined by combinations of bacteriuria and various signs and symptoms. Furthermore, most studies that used CDC/NHSN definitions for CAUTI did not distinguish between SUTI and ASB in their analyses.³⁰ The heterogeneity of definitions used for CAUTI may reduce the quality of evidence for a given intervention and often precludes meta-analyses.

The clinical significance of ASB in catheterized patients is undefined. Approximately 75% to 90% of patients with ASB do not develop a systemic inflammatory response or other signs or symptoms to suggest infection.^{6,31} Monitoring and treatment of ASB is also not an effective prevention measure for SUTI, as most cases of SUTI are not preceded by bacteriuria for more than a day.²⁵ Treatment of ASB has not been shown to be clinically beneficial and is associated with the selection of antimicrobial-resistant organisms.

Epidemiology

Between 15% and 25% of hospitalized patients may receive short-term indwelling urinary catheters.^{12,13} In many cases, catheters are placed for inappropriate indications, and healthcare providers are often unaware that their patients have catheters, leading to prolonged, unnecessary use.¹⁴⁻¹⁶ In acute care hospitals reporting to NHSN in 2006, pooled mean urinary catheter utilization ratios in ICU and non-ICU areas ranged from 0.23-0.91 urinary catheter-days/patient-days.¹⁷ While the numbers of units reporting were small, the highest ratios were in trauma ICUs and the lowest in inpatient medical/surgical wards. The overall prevalence of long-term indwelling urethral catheterization use is unknown. The prevalence of urinary catheter use in residents in long-term care facilities in the United States is on the order of 5%, representing approximately 50,000 residents with catheters at any given time.¹⁸ This number appears to be declining over time, likely because of federally mandated nursing home quality measures. However, the high prevalence of urinary catheters in patients transferred to skilled nursing facilities suggests that acute care hospitals should focus more efforts on removing unnecessary catheters prior to transfer.¹⁸

Reported rates of UTI among patients with urinary catheters vary substantially. National data from NHSN acute care hospitals in 2006 showed a range of pooled mean CAUTI rates of 3.1-7.5 infections per 1000 catheter-days.¹⁷ The highest rates were in burn ICUs, followed by inpatient medical wards and neurosurgical ICUs, although these sites also had the fewest numbers of locations reporting. The lowest rates were in medical/surgical ICUs.

Although morbidity and mortality from CAUTI is considered to be relatively low compared to other HAIs, the high prevalence of urinary catheter use leads to a large cumulative burden of infections with resulting infectious complications and deaths. An estimate of annual incidence of HAIs and mortality in 2002, based on a broad survey of US hospitals, found that urinary tract infections made up the highest number of infections (> 560,000) compared to other HAIs, and attributable deaths from UTI were estimated to be over 13,000 (mortality rate 2.3%).¹⁹ And while fewer than 5% of bacteriuric cases develop bacteremia,⁶ CAUTI is the leading cause of secondary nosocomial bloodstream infections; about 17% of hospital-acquired bacteremias are from a urinary source, with an associated mortality of approximately 10%.²⁰ In the nursing home setting, bacteremias are most commonly caused by UTIs, the majority of which are catheter-related.²¹

An estimated 17% to 69% of CAUTI may be preventable with recommended infection control measures, which means that up to 380,000 infections and 9000 deaths related to CAUTI per year could be prevented.²²

Pathogenesis and Microbiology

The source of microorganisms causing CAUTI can be endogenous, typically via meatal, rectal, or vaginal colonization, or exogenous, such as via contaminated hands of healthcare personnel or equipment. Microbial pathogens can enter the urinary tract either by the extraluminal route, via migration along the outside of the catheter in the periurethral mucous sheath, or by the intraluminal route, via movement along the internal lumen of the catheter from a contaminated collection bag or catheter-drainage tube junction. The relative contribution of each route in the pathogenesis of CAUTI is not well known. The marked reduction in risk of bacteriuria with the introduction of the sterile, closed urinary drainage system in the 1960's²³ suggests the importance of the intraluminal route. However, even with the closed drainage system,

bacteriuria inevitably occurs over time either via breaks in the sterile system or via the extraluminal route.²⁴ The daily risk of bacteriuria with catheterization is 3% to 10%,^{25,26} approaching 100% after 30 days, which is considered the delineation between short and long-term catheterization.²⁷

Formation of biofilms by urinary pathogens on the surface of the catheter and drainage system occurs universally with prolonged duration of catheterization.²⁸ Over time, the urinary catheter becomes colonized with microorganisms living in a sessile state within the biofilm, rendering them resistant to antimicrobials and host defenses and virtually impossible to eradicate without removing the catheter. The role of bacteria within biofilms in the pathogenesis of CAUTI is unknown and is an area requiring further research.

The most frequent pathogens associated with CAUTI (combining both ASB and SUTI) in hospitals reporting to NHSN between 2006-2007 were *Escherichia coli* (21.4%) and *Candida* spp (21.0%), followed by *Enterococcus* spp (14.9%), *Pseudomonas aeruginosa* (10.0%), *Klebsiella pneumoniae* (7.7%), and *Enterobacter* spp (4.1%). A smaller proportion was caused by other gram-negative bacteria and *Staphylococcus* spp⁵.

Antimicrobial resistance among urinary pathogens is an ever increasing problem. About a quarter of *E. coli* isolates and one third of *P. aeruginosa* isolates from CAUTI cases were fluoroquinolone-resistant. Resistance of gram-negative pathogens to other agents, including third-generation cephalosporins and carbapenems, was also substantial⁵. The proportion of organisms that were multidrug-resistant, defined by non-susceptibility to all agents in 4 classes, was 4% of *P. aeruginosa*, 9% of *K. pneumoniae*, and 21% of *Acinetobacter baumannii*.²⁹

VI. Scope and Purpose

This guideline updates and expands the original CDC Guideline for Prevention of CAUTI published in 1981. The revised guideline addresses the prevention of CAUTI for patients in need of either short- or long-term (i.e., > 30 days) urinary catheterization in any type of healthcare facility and evaluates evidence for alternative methods of urinary drainage, including intermittent catheterization, external catheters, and suprapubic catheters. The guideline also includes specific recommendations for implementation, performance measurement, and surveillance. Recommendations for further research are also provided to address the knowledge gaps in CAUTI prevention identified during the literature review.

To evaluate the evidence on preventing CAUTI, we examined data addressing three key questions and related subquestions:

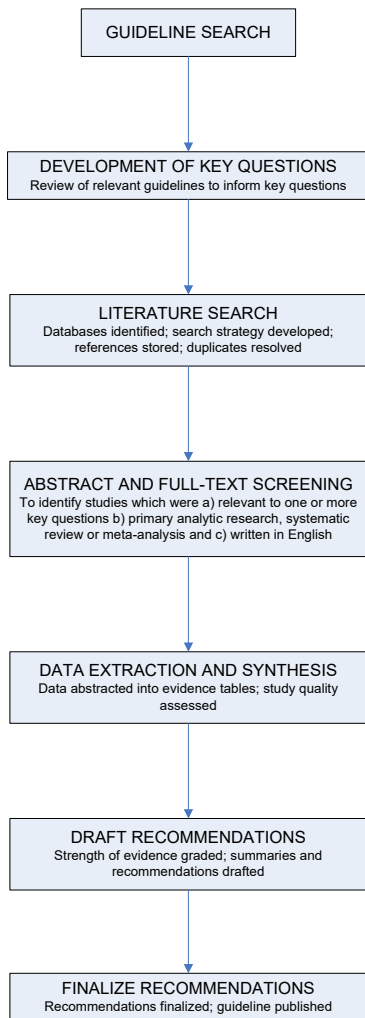
1. Who should receive urinary catheters?
 - A. When is urinary catheterization necessary?
 - B. What are the risk factors for CAUTI?
 - C. What populations are at highest risk of mortality from catheters?
2. For those who may require urinary catheters, what are the best practices? Specifically, what are the risks and benefits associated with:
 - A. Different approaches to catheterization?
 - B. Different catheters or collecting systems?
 - C. Different catheter management techniques?
 - D. Different systems interventions (i.e., quality improvement programs)?
3. What are the best practices for preventing UTI associated with obstructed urinary catheters?

This document is intended for use by infection prevention staff, healthcare epidemiologists, healthcare administrators, nurses, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection prevention and control programs for healthcare settings across the continuum of care. The guideline can also be used as a resource for societies or organizations that wish to develop more detailed implementation guidance for prevention of CAUTI.

VII. Methods

This guideline was based on a targeted systematic review of the best available evidence on CAUTI prevention. We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach³²⁻³⁴ to provide explicit links between the available evidence and the resulting recommendations. Our guideline development process is outlined in *Figure 1*.

Figure 1. The Guideline Development Process



Development of Key Questions

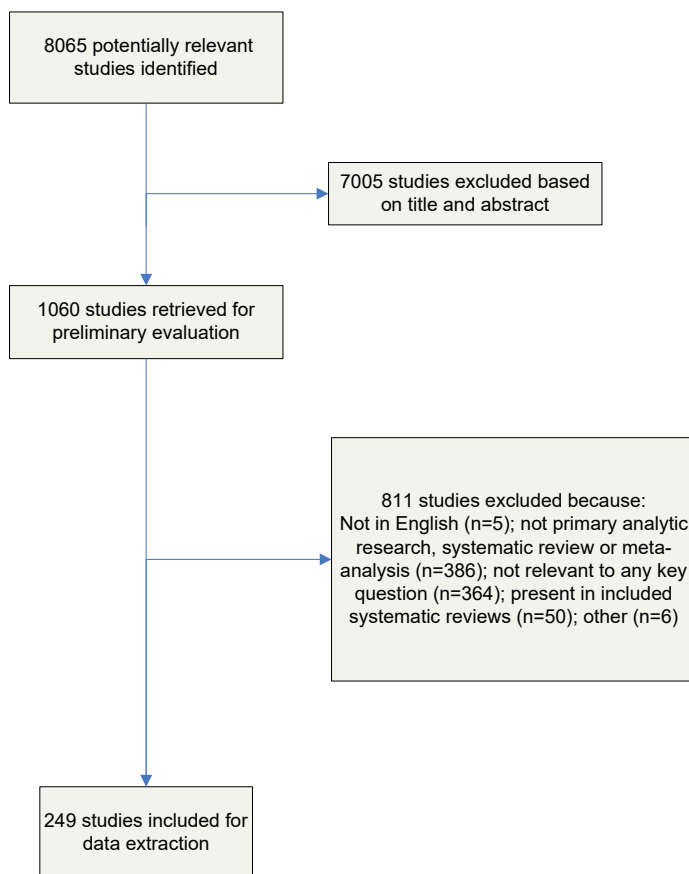
We first conducted an electronic search of the National Guideline Clearinghouse® (Agency for Healthcare Research and Quality), Medline® (National Library of Medicine) using the Ovid® Platform (Ovid Technologies, Wolters Kluwer, New York, NY), the Cochrane® Health Technology Assessment Database (Cochrane Collaboration, Oxford, UK), the NIH Consensus Development Program, and the United States Preventive Services Task Force database for existing national and international guidelines relevant to CAUTI. The strategy used for the guideline search and the search results can be found in [Appendix 1A](#). A preliminary list of key questions was developed from a review of the relevant guidelines identified in the search.^{1,35,36} Key questions were finalized after vetting them with a panel of content experts and HICPAC members.

Literature Search

Following the development of the key questions, search terms were developed for identifying literature relevant to the key questions. For the purposes of quality assurance, we compared these terms to those used in relevant seminal studies and guidelines. These search terms were then incorporated into search strategies for the relevant electronic databases. Searches were performed in Medline® (National Library of Medicine) using the Ovid® Platform (Ovid Technologies, Wolters Kluwer, New York, NY), EMBASE® (Elsevier BV, Amsterdam, Netherlands), CINAHL® (Ebsco Publishing, Ipswich, MA) and Cochrane® (Cochrane Collaboration, Oxford, UK) (all databases were searched in July 2007), and the resulting references were imported into a reference manager, where duplicates were resolved. For Cochrane reviews ultimately included in our guideline, we checked for updates in July 2008. The detailed search strategy used for identifying primary literature and the results of the search can be found in [Appendix 1B](#).

Study Selection

Titles and abstracts from references were screened by a single author (C.V.G, R.K.A., or D.A.P.) and the full text articles were retrieved if they were 1) relevant to one or more key questions, 2) primary analytic research, systematic reviews or meta-analyses, and 3) written in English. Likewise, the full-text articles were screened by a single author (C.V.G. or D.A.P.) using the same criteria, and included studies underwent a second review for inclusion by another author (R.K.A.). Disagreements were resolved by the remaining authors. The results of this process are depicted in *Figure 2*.

Figure 2: Results of the Study Selection Process

Data Extraction and Synthesis

Data on the study author, year, design, objective, population, setting, sample size, power, follow-up, and definitions and results of clinically relevant outcomes were extracted into evidence tables ([Appendix 2](#)). Three evidence tables were developed, each of which represented one of our key questions. Studies were extracted into the most relevant evidence table. Then, studies were organized by the common themes that emerged within each evidence table. Data were extracted by one author (R.K.A.) and cross-checked by another (C.V.G.). Disagreements were resolved by the remaining authors. Data and analyses were extracted as originally presented in the included studies. Meta-analyses were performed only where their use was deemed critical to a recommendation, and only in circumstances where multiple studies with sufficiently homogenous populations, interventions, and outcomes could be analyzed. Systematic reviews were included in our review. To avoid duplication of data, we excluded primary studies if they were also included in a systematic review captured by our search. The only exception to this was if the primary study also addressed a relevant question that was outside the scope of the included systematic review. Before exclusion, data from the primary studies that we originally captured were abstracted into the evidence tables and reviewed. We also excluded systematic reviews that analyzed primary studies that were fully captured in a more recent systematic review. The only exception to this was if the older systematic review also addressed a relevant question that was outside the scope of the newer systematic review. To ensure that all relevant studies were captured in the search, the bibliography was vetted by a panel of clinical experts.

Grading of Evidence

First, the quality of each study was assessed using scales adapted from existing methodology checklists, and scores were recorded in the evidence tables. [Appendix 3](#) includes the sets of questions we used to assess the quality of each of the major study designs. Next, the quality of the evidence base was assessed using methods adapted from the GRADE Working Group.³² Briefly, GRADE tables were developed for each of the interventions or questions addressed within the evidence tables. Included in the GRADE tables were the intervention of interest, any outcomes listed in the evidence tables that were judged to be clinically important, the quantity and type of evidence for each outcome, the relevant findings, and the GRADE of evidence for each outcome, as well as an overall GRADE of the evidence base for the given intervention or question. The initial GRADE of evidence for each outcome was deemed high if the evidence base included a randomized controlled trial (RCT) or a systematic review of RCTs, low if the evidence base included only observational studies, or very low if the evidence base consisted only of uncontrolled studies. The initial GRADE could then be modified by eight criteria.³⁴ Criteria which could decrease the GRADE of an evidence base included quality, consistency, directness, precision, and publication bias. Criteria that could increase the GRADE included a large magnitude of effect, a dose-response gradient, or inclusion of unmeasured confounders that would increase the magnitude of effect ([Table 3](#)). GRADE definitions are as follows:

1. High - further research is very unlikely to change confidence in the estimate of effect
2. Moderate - further research is likely to affect confidence in the estimate of effect and may change the estimate
3. Low - further research is very likely to affect confidence in the estimate of effect and is likely to change the estimate
4. Very low - any estimate of effect is very uncertain

After determining the GRADE of the evidence base for each outcome of a given intervention or question, we calculated the overall GRADE of the evidence base for that intervention or question. The overall GRADE was based on the lowest GRADE for the outcomes deemed critical to making a recommendation.

Type of Evidence	Initial Grade	Criteria to Decrease Grade	Criteria to Increase Grade	Overall Quality Grade
RCT	High	<u>Quality</u> Serious (-1 grade) or very serious (-2 grades) limitation to study quality	<u>Strong association</u> Strong (+1 grade) or very strong evidence of association (+2 grades)	High Moderate
Observational study	Low	<u>Consistency</u> Important inconsistency (-1 grade)	<u>Dose-response</u> Evidence of a dose-response gradient (+1 grade)	Low
Any other evidence (e.g., expert opinion)	Very low	<u>Directness</u> Some (-1 grade) or major (-2 grades) uncertainty about directness <u>Precision</u> Imprecise or sparse data (-1 grade) <u>Publication bias</u> High risk of bias (-1 grade)	<u>Unmeasured Confounders</u> Inclusion of unmeasured confounders increases the magnitude of effect (+1 grade)	Very low

Formulating Recommendations

Narrative evidence summaries were then drafted by the working group using the evidence and GRADE tables. One summary was written for each theme that emerged under each key question. The working group then used the narrative evidence summaries to develop guideline recommendations. Factors determining the strength of a recommendation included 1) the values and preferences used to determine which outcomes were "critical," 2) the harms and benefits that result from weighing the "critical" outcomes, and 3) the overall GRADE of the evidence base for the given intervention or question (Table 4).³³ If weighing the "critical outcomes" for a given intervention or question resulted in a "net benefit" or a "net harm," then a "Category I Recommendation" was formulated to strongly recommend for or against the given intervention respectively. If weighing the "critical outcomes" for a given intervention or question resulted in a "trade off" between benefits and harms, then a "Category II Recommendation" was formulated to recommend that providers or institutions consider the intervention when deemed appropriate. If weighing the "critical outcomes" for a given intervention or question resulted in

an "uncertain trade off" between benefits and harms, then a "No Recommendation" was formulated to reflect this uncertainty.

HICPAC Recommendation	Weighing Benefits and Harms for Critical Outcomes	Quality of Evidence
STRONG (I)	Interventions with net benefits or net harms	IA – High to Moderate IB – Low or Very Low (Accepted Practice) IC – High to Very Low (Regulatory)
WEAK (II)	Interventions with trade offs between benefits and harms	High to Very Low
No recommendation/ unresolved issue	Uncertain trade offs between benefits and harms	Low to Very Low

For Category I recommendations, levels A and B represent the quality of the evidence underlying the recommendation, with A representing high to moderate quality evidence and B representing low quality evidence or, in the case of an established standard (e.g., aseptic technique, education and training), very low quality to no evidence based on our literature review. For IB recommendations, although there may be low to very low quality or even no available evidence directly supporting the benefits of the intervention, the theoretical benefits are clear, and the theoretical risks are marginal. Level C represents practices required by state or federal regulation, regardless of the quality of evidence. It is important to note that the strength of a Category IA recommendation is equivalent to that of a Category IB or IC recommendation; it is only the quality of the evidence underlying the IA recommendation that makes it different from a IB.

In some instances, multiple recommendations emerged from a single narrative evidence summary. The new HICPAC categorization scheme for recommendations is provided in [Table 1](#), which is reproduced below.

Category IA	A strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms
Category IB	A strong recommendation supported by low quality evidence suggesting net clinical benefits or harms or an accepted practice (e.g., aseptic technique) supported by low to very low quality evidence
Category IC	A strong recommendation required by state or federal regulation.
Category II	A weak recommendation supported by any quality evidence suggesting a trade off between clinical benefits and harms
No recommendation/ unresolved issue	Unresolved issue for which there is low to very low quality evidence with uncertain trade offs between benefits and harms

Category I recommendations are defined as strong recommendations with the following implications:

1. For patients: Most people in the patient's situation would want the recommended course of action and only a small proportion would not; request discussion if the intervention is not offered.
2. For clinicians: Most patients should receive the recommended course of action.
3. For policymakers: The recommendation may be adopted as a policy.

Category II recommendations are defined as weak recommendations with the following implications:

1. For patients: Most people in the patient's situation would want the recommended course of action, but many would not.
2. For clinicians: Different choices will be appropriate for different patients, and clinicians must help each patient to arrive at a management decision consistent with her or his values and preferences.
3. For policymakers: Policy making will require substantial debate and involvement of many stakeholders.

It should be noted that Category II recommendations are discretionary for the individual institution and are not intended to be enforced.

The wording of each recommendation was carefully selected to reflect the recommendation's strength. In most cases, we used the active voice when writing Category I recommendations - the strong recommendations. Phrases like "do" or "do not" and verbs without auxiliaries or conditionals were used to convey certainty. We used a more passive voice when writing Category II recommendations - the weak recommendations. Words like "consider" and phrases like "is preferable," "is suggested," "is not suggested," or "is not recommended" were chosen to reflect the lesser certainty of the Category II recommendations. Rather than a simple statement of fact, each recommendation is actionable, describing precisely a proposed action to take.

The category "No recommendation/unresolved issue" was most commonly applied to situations where either 1) the overall quality of the evidence base for a given intervention was low to very low and there was no consensus on the benefit of the intervention or 2) there was no published evidence on outcomes deemed critical to weighing the risks and benefits of a given intervention. If the latter was the case, those critical outcomes will be noted at the end of the relevant evidence summary.

Our evidence-based recommendations were cross-checked with those from guidelines identified in our original systematic search. Recommendations from previous guidelines for topics not directly addressed by our systematic review of the evidence were included in our "Summary of Recommendations" if they were deemed critical to the target users of this guideline. Unlike recommendations informed by our literature search, these recommendations are not linked to a key question. These recommendations were agreed upon by expert consensus and are designated either IB if they represent a strong recommendation based on accepted practices (e.g., aseptic technique) or II if they are a suggestion based on a probable net benefit despite limited evidence.

All recommendations were approved by HICPAC. Recommendations focused only on efficacy, effectiveness, and safety. The optimal use of these guidelines should include a consideration of the costs relevant to the local setting of guideline users.

Reviewing and Finalizing the Guideline

After a draft of the tables, narrative summaries, and recommendations was completed, the working group shared the draft with the expert panel for in-depth review. While the expert panel was reviewing this draft, the working group completed the remaining sections of the guideline, including the executive summary, background, scope and purpose, methods, summary of recommendations, and recommendations for guideline implementation, audit, and further research. The working group then made revisions to the draft based on feedback from members of the expert panel and presented the entire draft guideline to HICPAC for review. The guideline was then posted on the Federal Register for public comment. After a period of public comment, the guideline was revised accordingly, and the changes were reviewed and voted on by HICPAC. The final guideline was cleared internally by CDC and published and posted on the HICPAC website.

Updating the Guideline

Future revisions to this guideline will be dictated by new research and technological advancements for preventing CAUTI and will occur at the request of HICPAC.

VIII. Evidence Review

Q1. Who should receive urinary catheters?

To answer this question, we focused on three subquestions: A) When is urinary catheterization necessary? B) What are the risk factors for CAUTI? and C) What populations are at highest risk of mortality from urinary catheters?

Q1A. When is urinary catheterization necessary?

The available data examined five main populations. In all populations, we considered CAUTI outcomes as well as other outcomes we deemed critical to weighing the risks and benefits of catheterization. The evidence for this question consists of 1 systematic review,³⁷ 9 RCTs,³⁸⁻⁴⁶ and 12 observational studies.⁴⁷⁻⁵⁸ The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 1A.

For *operative patients*, low-quality evidence suggested a benefit of avoiding urinary catheterization.^{37-44,47-49} This was based on a decreased risk of bacteriuria/unspecified UTI, no effect on bladder injury, and increased risk of urinary retention in patients without catheters. Urinary retention in patients without catheters was specifically seen following urogenital surgeries. The most common surgeries studied were urogenital, gynecological, laparoscopic, and orthopedic surgeries. Our search did not reveal data on the impact of catheterization on peri-operative hemodynamic management.

For *incontinent patients*, low-quality evidence suggested a benefit of avoiding urinary catheterization.^{45,50-52} This was based on a decreased risk of both SUTI and bacteriuria/unspecified UTI in male nursing home residents without urinary catheters compared to those with continuous condom catheters. We found no difference in the risk of UTI between having a condom catheter only at night and having no catheter. Our search did not reveal data on the impact of catheterization on skin breakdown.

For *patients with bladder outlet obstruction*, very low-quality evidence suggested a benefit of a urethral stent over an indwelling catheter.⁵³ This was based on a reduced risk of bacteriuria in those receiving a urethral stent. Our search did not reveal data on the impact of catheterization versus stent placement on urinary complications.

For *patients with spinal cord injury*, very low-quality evidence suggested a benefit of avoiding indwelling urinary catheters.^{54,56} This was based on a decreased risk of SUTI and bacteriuria in those without indwelling catheters (including patients managed with spontaneous voiding, clean intermittent catheterization [CIC], and external striated sphincterotomy with condom catheter drainage), as well as a lower risk of urinary complications, including hematuria, stones, and urethral injury (fistula, erosion, stricture).

For *children with myelomeningocele and neurogenic bladder*, very low-quality evidence suggested a benefit of CIC compared to urinary diversion or self voiding.^{46,57,58} This was based on a decreased risk of bacteriuria/unspecified UTI in patients receiving CIC compared to urinary diversion, and a lower risk of urinary tract deterioration (defined by febrile urinary tract infection, vesicoureteral reflux, hydronephrosis, or increases in BUN or serum creatinine) compared to self-voiding and in those receiving CIC early (< 1 year of age) versus late (> 3 years of age).

Evidence Review Table 1A. When is urinary catheterization necessary?

1A.1. Use urinary catheters in operative patients only as necessary, rather than routinely. **(Category IB)**

1A.2. Avoid use of urinary catheters in patients and nursing home residents for management of incontinence. **(Category IB)**

1A.2.a. Further research is needed on periodic (e.g., nighttime) use of external catheters in incontinent patients or residents and the use of catheters to prevent skin breakdown. **(No recommendation/unresolved issue)**

1A.3. Further research is needed on the benefit of using a urethral stent as an alternative to an indwelling catheter in selected patients with bladder outlet obstruction. **(No recommendation/unresolved issue)**

1A.4. Consider alternatives to chronic indwelling catheters, such as intermittent catheterization, in spinal cord injury patients. **(Category II)**

1A.5. Consider intermittent catheterization in children with myelomeningocele and neurogenic bladder to reduce the risk of urinary tract deterioration. **(Category II)**

Q1B. What are the risk factors for CAUTI?

To answer this question, we reviewed the quality of evidence for those risk factors examined in more than one study. We considered the critical outcomes for decision-making to be SUTI and bacteriuria. The evidence for this question consists of 11 RCTs⁵⁹⁻⁶⁹ and 37 observational studies.^{9,50,54,70-103} The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 1B.

For *SUTI*,^{50,54,61,62,74,75,79,83,102,103} low-quality evidence suggested that female sex, older age, prolonged catheterization, impaired immunity, and lack of antimicrobial exposure are risk factors. Very low quality evidence suggested that catheter blockage and low albumin level are also risk factors. For *bacteriuria*,^{9,59-61,63-68,72,73,76-78,82,84-86,89-94,96-100} multiple risk factors were identified; there was high quality evidence for prolonged catheterization and moderate quality evidence for female sex, positive meatal cultures, and lack of antimicrobial exposure. Low-quality evidence also implicated the following risk factors for bacteriuria: older age, disconnection of the drainage system, diabetes, renal dysfunction, higher severity of illness, impaired immunity, placement of the catheter outside of the operating room, lower professional training of the person inserting the catheter, incontinence, and being on an orthopaedic or neurology service. Our search did not reveal data on adverse events and antimicrobial resistance associated with antimicrobial use, although one observational study found that the protective effect of antimicrobials lasted only for the first four days of catheterization, and that antimicrobial exposure led to changes in the epidemiology of bacterial flora in the urine.

Evidence Review Table 1B. What are the risk factors for CAUTI?

1B.1. Following aseptic insertion of the urinary catheter, maintain a closed drainage system. **(Category IB)^a**

1B.2. Insert catheters only for appropriate indications, and leave in place only as long as needed. **(Category IB)^b**

1B.3. Minimize urinary catheter use and duration of use in all patients, particularly those at higher risk for CAUTI such as women, the elderly, and patients with impaired immunity. **(Category IB)**

1B.4. Ensure that only properly trained persons (e.g., hospital personnel, family members, or patients themselves) who know the correct technique of aseptic catheter insertion and maintenance are given this responsibility. **(Category IB)**

1B.5. Maintain unobstructed urine flow. **(Category IB)^c**

^a More data are available under Question 2B.

^b More data are available under Question 2C.

^c More data are available under Question 2D.

Q1C. What populations are at highest risk of mortality from urinary catheters?

To answer this question, we reviewed the quality of evidence for those risk factors examined in more than one study. The evidence for this question consists of 2 observational studies.^{7,74} The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 1C.

Low-quality evidence suggested that older age, higher severity of illness, and being on an internal medicine service compared to a surgical service were independent risk factors for mortality in patients with indwelling urinary catheters. Both studies evaluating these risk factors found the highest risk of mortality in patients over 70 years of age. Low-quality evidence also suggested that CAUTI was a risk factor for mortality in patients with catheters.

Evidence Review Table 1C. What populations are at highest risk of mortality from catheters?

1C.1. Minimize urinary catheter use and duration in all patients, particularly those who may be at higher risk for mortality due to catheterization, such as the elderly and patients with severe illness. **(Category IB)**

Q2. For those who may require urinary catheters, what are the best practices?

To answer this question, we focused on four subquestions: A) What are the risks and benefits associated with different approaches to catheterization?, B) What are the risks and benefits associated with different types of catheters or collecting systems?, C) What are the risks and benefits associated with different catheter management techniques, and D) What are the risks and benefits associated with different systems interventions?

Q2A. What are the risks and benefits associated with different approaches to catheterization?

The available data examined the following comparisons of different catheterization approaches:

- 1) External versus indwelling urethral
- 2) Intermittent versus indwelling urethral
- 3) Intermittent versus suprapubic
- 4) Suprapubic versus indwelling urethral
- 5) Clean intermittent versus sterile intermittent

For all comparisons, we considered SUTI, bacteriuria/unspecified UTI, or combinations of these outcomes depending on availability, as well as other outcomes critical to weighing the risks and benefits of different catheterization approaches. The evidence for this question consists of 6 systematic reviews,^{37,104-108} 16 RCTs,^{62,63,109-122} and 18 observational studies.^{54,73,81,84,123-136} The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 2A

Q2A.1. External versus indwelling urethral

Low-quality evidence suggested a benefit of using external catheters over indwelling urethral catheters in male patients who require a urinary collection device but do not have an indication for an indwelling catheter such as urinary retention or bladder outlet obstruction.^{81,109,123} This was based on a decreased risk of a composite outcome of SUTI, bacteriuria, or death as well as increased patient satisfaction with condom catheters. Differences were most pronounced in men without dementia. Statistically significant differences were not found or reported for the individual CAUTI outcomes or death. Our search did not reveal data on differences in local complications such as skin maceration or phimosis.

Q2A.2. Intermittent versus indwelling urethral

Low-quality evidence suggested a benefit of using intermittent catheterization over indwelling urethral catheters in selected populations.^{84,104-106,110-114,124-126,135,136} This was based on a decreased risk of SUTI and bacteriuria/unspecified UTI but an increased risk of urinary retention in postoperative patients with intermittent catheterization. In one study, urinary retention and bladder distension were avoided by performing catheterization at regular intervals (every 6-8 hrs) until return of voiding. Studies of patients with neurogenic bladder most consistently found a decreased risk of CAUTI with intermittent catheterization. Studies in operative patients whose catheters were removed within 24 hrs of surgery found no differences in bacteriuria with intermittent vs. indwelling catheterization, while studies where catheters were left in for longer durations had mixed results. Our search did not reveal data on differences in patient satisfaction.

Q2A.3. Intermittent versus suprapubic

Very low-quality evidence suggested a benefit of intermittent over suprapubic catheterization in selected populations^{115,116,134-136} based on increased patient acceptability and decreased risk of urinary complications (bladder calculi, vesicoureteral reflux, and upper tract abnormalities). Although we found a decreased risk of bacteriuria/unspecified UTI with suprapubic catheterization, there were no differences in SUTI. The populations studied included women undergoing gynecologic surgery and spinal cord injury patients.

Q2A.4. *Suprapubic versus indwelling urethral*

Low-quality evidence suggested a benefit of suprapubic catheters over indwelling urethral catheters in selected populations.^{37,62,104,107,108,128-133,135,136} This was based on a decreased risk of bacteriuria/unspecified UTI, recatheterization, and urethral stricture, and increased patient comfort and satisfaction. However, there were no differences in SUTI and an increased risk of longer duration of catheterization with suprapubic catheters. Studies involved primarily postoperative and spinal cord injury patients. Our search did not reveal data on differences in complications related to catheter insertion or the catheter site.

Q2A.5. *Clean intermittent versus sterile intermittent*

Moderate-quality evidence suggested no benefit of using sterile over clean technique for intermittent catheterization.^{63,73,105,117-122} No differences were found in the risk of SUTI or bacteriuria/unspecified UTI. Study populations included nursing home residents and adults and children with neurogenic bladder/spinal cord injury.

Evidence Review Table 2A. What are the risks and benefits associated with different approaches to catheterization?

2A.1. Consider using external catheters as an alternative to indwelling urethral catheters in cooperative male patients without urinary retention or bladder outlet obstruction. **(Category II)**

2A.2. Intermittent catheterization is preferable to indwelling urethral or suprapubic catheters in patients with bladder emptying dysfunction. **(Category II)**

2A.3. If intermittent catheterization is used, perform it at regular intervals to prevent bladder overdistension. **(Category IB)**

2A.4. For operative patients who have an indication for an indwelling catheter, remove the catheter as soon as possible postoperatively, preferably within 24 hours, unless there are appropriate indications for continued use. **(Category IB)***

2A.5. Further research is needed on the risks and benefits of suprapubic catheters as an alternative to indwelling urethral catheters in selected patients requiring short- or long-term catheterization, particularly with respect to complications related to catheter insertion or the catheter site. **(No recommendation/unresolved issue)**

2A.6. In the non-acute care setting, clean (i.e., non-sterile) technique for intermittent catheterization is an acceptable and more practical alternative to sterile technique for patients requiring chronic intermittent catheterization. **(Category IA)**

* More data are available under Question 2C

Q2B. What are the risks and benefits associated with different catheters or collecting systems?

The available data examined the following comparisons between different types of catheters and drainage systems:

1. Antimicrobial/antiseptic catheters vs. standard catheters
 - a. Silver-coated catheters vs. standard catheters
 - b. Nitrofurazone-impregnated catheters vs. standard catheters
2. Hydrophilic catheters vs. standard catheters
3. Closed vs. open drainage systems
4. Complex vs. simple drainage systems
5. Preconnected/sealed junction catheters vs. standard catheters
6. Catheter valves vs. catheter bags

For all comparisons, we considered CAUTI outcomes as well as other outcomes critical to weighing the risks and benefits of different types of catheters or collecting systems. The evidence for this question consists of 5 systematic reviews,^{37,137-140} 17 RCTs,^{64,143-158} 23 observational studies,^{82,86,89,97,159-163, 165-178} and 3 economic analyses.^{179,180,181} The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 2B.

Q2B.1.a. Silver-coated catheters vs. standard catheters

Low-quality evidence suggested a benefit of silver-coated catheters over standard latex catheters.^{37,82,86,137-139,143,159-163, 165,166} This was based on a decreased risk of bacteriuria/unspecified UTI with silver-coated catheters and no evidence of increased urethral irritation or antimicrobial resistance in studies that reported data on microbiological outcomes. Differences were significant for silver alloy-coated catheters but not silver oxide-coated catheters. In a meta-analysis of randomized controlled trials (see [Appendix](#)), silver alloy-coated catheters reduced the risk of asymptomatic bacteriuria compared to standard latex catheters (control latex catheters were either uncoated or coated with hydrogel, Teflon®, or silicone), whereas there were no differences when compared to standard, all silicone catheters. The effect of silver alloy catheters compared to latex catheters was more pronounced when used in patients catheterized <1 week. The results were robust to inclusion or exclusion of non peer-reviewed studies. Only one observational study found a decrease in SUTI with silver alloy-coated catheters.¹⁶⁶ The setting was a burn referral center, where the control catheters were latex, and patients in the intervention group had new catheters placed on admission, whereas the control group did not. Recent observational studies in hospitalized patients found mixed results for bacteriuria/unspecified UTI.

Q2B.1.b. Nitrofurazone-impregnated catheters vs. standard catheters

Low-quality evidence suggested a benefit of nitrofurazone-impregnated catheters in patients catheterized for short periods of time.^{137,138} This was based on a decreased risk of bacteriuria and no evidence of increased antimicrobial resistance in studies that reported microbiological outcomes. Differences were significant in a meta-analysis of three studies examining nitrofurazone-impregnated catheters (only one individual study significant) when duration of catheterization was <1 week. No differences were seen when duration of catheterization was >1 week, although the meta-analysis was borderline significant.

Q2B.2. Hydrophilic catheters vs. standard catheters

Very low-quality evidence suggested a benefit of hydrophilic catheters over standard non-hydrophilic catheters in specific populations undergoing clean intermittent catheterization.^{137,144-148,169} This was based on a decreased risk of SUTI, bacteriuria, hematuria, and pain during insertion, and increased patient satisfaction. Differences in CAUTI outcomes were limited to one study of spinal cord injury patients and one study of patients receiving intravesical immunochromophylaxis for bladder cancer, while multiple other studies found no significant differences.

Q2B.3. Closed vs. open drainage systems

Very low-quality evidence suggested a benefit of using a closed rather than open urinary drainage system.^{89,171} This was based on a decreased risk of bacteriuria with a closed drainage system. One study also found a suggestion of a decreased risk of SUTI, bacteremia, and UTI-related mortality associated with closed drainage systems, but differences were not statistically significant. Sterile, continuously closed drainage systems became the standard of care based on an uncontrolled study published in 1966 demonstrating a dramatic reduction in the risk of infection in short-term catheterized patients with the use of a closed system.²³ Recent data also include the finding that disconnection of the drainage system is a risk factor for bacteriuria (Q1B).

Q2B.4. Complex vs. simple drainage systems

Low-quality evidence suggested no benefit of complex closed urinary drainage systems over simple closed urinary drainage systems.^{150-152,154,172,176,177} Although there was a decreased risk of bacteriuria with the complex systems, differences were found only in studies published before 1990, and not in more recent studies. The complex drainage systems studied included various mechanisms for reducing bacterial entry, such as antiseptic-releasing cartridges at the drain port of the urine collection bag; see evidence table for systems evaluated.

Q2B.5. Preconnected/sealed junction catheters vs. standard catheters

Low-quality evidence suggested a benefit of using preconnected catheters with junction seals over catheters with unsealed junctions to reduce the risk of disconnections.^{64,153,156,175} This was based on a decreased risk of SUTI and bacteriuria with preconnected sealed catheters. Studies that found differences had higher rates of CAUTI in the control group than studies that did not find an effect.

Q2B.6. Catheter valves vs. drainage bags

Moderate-quality evidence suggested a benefit of catheter valves over drainage bags in selected patients with indwelling urinary catheters.¹⁴⁰ Catheter valves led to greater patient satisfaction but no differences in bacteriuria/unspecified UTI or pain/bladder spasms. Details regarding the setting for recruitment and follow-up of the patients in the studies were unclear, and the majority of subjects were men. Our search did not reveal data on the effect of catheter valves on bladder function, bladder/urethral trauma, or catheter blockage.

Evidence Review Table 2B. What are the risks and benefits associated with different catheters or collecting systems?

2B.1. If the CAUTI rate is not decreasing after implementing a comprehensive strategy to reduce rates of CAUTI, consider using antimicrobial/antiseptic-impregnated catheters. The comprehensive strategy should include, at a minimum, the high priority recommendations for urinary catheter use, aseptic insertion, and maintenance (see Section III. Implementation and Audit). **(Category IB)**

2B.1.a. Further research is needed on the effect of antimicrobial/antiseptic-impregnated catheters in reducing the risk of symptomatic UTI, their inclusion among the primary interventions, and the patient populations most likely to benefit from these catheters. **(No recommendation/unresolved issue)**

2B.2. Hydrophilic catheters might be preferable to standard catheters for patients requiring intermittent catheterization. **(Category II)**

2B.3. Following aseptic insertion of the urinary catheter, maintain a closed drainage system. **(Category IB)**

2B.4. Complex urinary drainage systems (utilizing mechanisms for reducing bacterial entry such as antiseptic-release cartridges in the drain port) are not necessary for routine use. **(Category II)**

2B.5. Urinary catheter systems with preconnected, sealed catheter-tubing junctions are suggested for use. **(Category II)**

2B.6. Further research is needed to clarify the benefit of catheter valves in reducing the risk of CAUTI and other urinary complications. **(No recommendation/unresolved issue)**

Q2C. What are the risks and benefits associated with different catheter management techniques?

The available data examined the following catheter management techniques:

1. Antimicrobial prophylaxis
2. Urinary antiseptics (i.e., methanamine)
3. Bladder irrigation
4. Antiseptic instillation in the drainage bag
5. Periurethral care
6. Routine catheter or bag change
7. Catheter lubricants
8. Securing devices
9. Bacterial interference
10. Catheter cleansing
11. Catheter removal strategies (clamping vs. free drainage prior to removal, postoperative duration of catheterization)
12. Assessment of urine volumes

For all comparisons, we considered CAUTI outcomes as well as other outcomes critical to weighing the risks and benefits of different catheter management techniques. The evidence for this question consists of 6 systematic reviews,^{37,105,106,182-184} 56 RCTs,^{60,61,65-69,143,158,158,185-231} 34 observational studies,^{83,85,88,90,96,102,133,167,178,232-258} and 1 economic analysis.¹⁸⁰ The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 2C.

Q2C.1. Antimicrobial prophylaxis

Low-quality evidence suggested no benefit of antimicrobial prophylaxis in patients undergoing short-term catheterization.^{37,60,61,83,85,133,158,178,182,185,186,189-191,232-234} This was based on heterogeneous results for SUTI and bacteriuria/unspecified UTI and no adverse events related to antimicrobials. Lack of consistency in specific factors, such as patient population, antimicrobial agents, timing of administration, and duration of follow-up, did not allow for a summary of evidence of the effect of antimicrobial prophylaxis on CAUTI in patients undergoing short term catheterization. Only two studies evaluated adverse events related to antimicrobials. Our search did not reveal data on antimicrobial resistance or *Clostridium difficile* infection.

Low-quality evidence suggested no benefit of antimicrobial prophylaxis in patients undergoing long-term catheterization (indwelling and clean intermittent catheterization).^{106,183,192,194,235,238} This was based on a decreased risk of bacteriuria, heterogeneous results for SUTI, and no differences reported for catheter encrustation or adverse events, although data were sparse. One systematic review suggested an increase in antimicrobial resistance with antimicrobial use.

Q2C.2. Urinary antiseptics

Low-quality evidence suggested a benefit of methenamine for short-term catheterized patients.^{196,197} This was based on a reduced risk of SUTI and bacteriuria and no differences in adverse events. Evidence was limited to two studies of patients following gynecological surgery in Norway and Sweden.

Very low-quality evidence suggested a benefit of methanamine for long-term catheterized patients.^{106,236-239} This was based on a reduced risk of encrustation but no differences in risk of SUTI or bacteriuria. Data on encrustation was limited to one study. Studies involved primarily elderly and spinal cord injury patients with chronic indwelling catheters

Q2C.3. Bladder irrigation

Low-quality evidence suggested no benefit of bladder irrigation in patients with indwelling or intermittent catheters.^{66,69,199-206,240-242} This was based on no differences in SUTI and heterogeneous findings for bacteriuria.

Q2C.4. Antiseptic instillation in the drainage bag

Low-quality evidence suggested no benefit of antiseptic instillation in urinary drainage bags.^{90,207-211,243-245} This was based on no differences in SUTI and heterogeneous results for bacteriuria.

Q2C.5. Periurethral care

Low-quality evidence suggested no benefit of antiseptic meatal cleaning regimens before or during catheterization to prevent CAUTI.^{65,67,68,88,158,212-216,246,247} This was based on no difference in the risk of bacteriuria in patients receiving periurethral care regimens compared to those not receiving them. One study found a higher risk of bacteriuria with cleaning of the urethral meatus-catheter junction (either twice daily application of povidine-iodine or once daily cleaning with a non-antiseptic solution of green soap and water) in a subgroup of women with positive meatal cultures and in patients not receiving antimicrobials. Periurethral cleaning with chlorhexidine before catheter insertion did not have an effect in two studies.

Q2C.6. Routine catheter or bag change

Low-quality evidence suggested no benefit of routine catheter or drainage bag changes to prevent CAUTI.^{102,217-219,248,249} This was based on no difference or an increased risk of SUTI and no difference in bacteriuria with routine compared to as-needed changes or with more frequent changing intervals. One study in nursing home residents found no differences in SUTI with routine monthly catheter changes compared to changing only for obstruction or infection, but the study was underpowered to detect a difference. Another study in home care patients found an increased risk of SUTI when catheters were changed more frequently than monthly.

Q2C.7. Catheter lubricants

Very low-quality evidence suggested a benefit of using lubricants for catheter insertion.^{167,220-223,250-254} This was based on a decreased risk of SUTI and bacteriuria with the use of a pre-lubricated catheter compared to a catheter lubricated by the patient and a decreased risk of bacteriuria with use of a lubricant versus no lubricant. Studies were heterogeneous both in the interventions and outcomes studied. Several studies comparing antiseptic lubricants to non-antiseptic lubricants found no significant differences.

Q2C.8. Securing devices

Low-quality evidence suggested no benefit of using catheter securing devices to prevent CAUTI.²²⁴ This was based on no significant difference in the risk of SUTI or meatal erosion. The only study in this category looked at one particular product.

Q2C.9. Bacterial interference

Moderate-quality evidence suggested a benefit of using bacterial interference in catheterized patients.²²⁵ In the one study evaluating this intervention, urinary colonization with a non-pathogenic *Escherichia coli* was associated with a decreased risk of SUTI in adults with spinal cord injury and a history of frequent CAUTI.

Q2C.10. Catheter cleansing

Very low-quality evidence suggested a benefit of wet versus dry storage procedures for catheters used in clean intermittent catheterization.²⁵⁵ This was based on a decreased risk of SUTI with a wet storage procedure in one study of spinal cord injury patients undergoing clean intermittent catheterization compared to a dry storage procedure where the catheter was left to air dry after washing. In the wet procedure, the catheter was stored in a dilute povidone-iodine solution after washing with soap and water.

Q2C.11. Catheter removal strategies

a. Clamping vs. free drainage prior to removal

Low-quality evidence suggested no benefit of clamping versus free drainage before catheter removal.^{37,184} This was based on no difference in risk of bacteriuria, urinary retention, or recatheterization between the two strategies. One study comparing a clamp and release strategy to free drainage over 72 hours found a greater risk of bacteriuria in the clamping group.

b. Postoperative duration of catheterization

Moderate-quality evidence suggested a benefit of shorter versus longer postoperative durations of catheterization.^{37,184,227,228} This was based on a decreased risk of bacteriuria/unspecified UTI, decreased time to ambulation and length of stay, no differences in urinary retention and SUTI, and increased risk of recatheterization. Significant decreases in bacteriuria/unspecified UTI were found specifically for comparisons of 1 day versus 3 or 5 days of postoperative catheterization. Recatheterization risk was greater in only one study comparing immediate removal to removal 6 or 12 hours after hysterectomy.

Q2C.12. Assessment of urine volumes

Low-quality evidence suggested a benefit of using portable ultrasound to assess urine volume in patients undergoing intermittent catheterization.^{229,230} This was based on fewer catheterizations but no reported differences in risk of unspecified UTI. Patients studied were adults with neurogenic bladder in inpatient rehabilitation centers. Our search did not reveal data on the use of ultrasound in catheterized patients in other settings.

Evidence Review Table 2C. What are the risks and benefits associated with different catheter management techniques?

2C.1. Unless clinical indications exist (e.g., in patients with bacteriuria upon catheter removal post urologic surgery), do not use systemic antimicrobials routinely as prophylaxis for UTI in patients requiring either short or long-term catheterization. **(Category IB)**

2C.2.a. Further research is needed on the use of urinary antiseptics (e.g., methanamine) to prevent UTI in patients requiring short-term catheterization. **(No recommendation/unresolved issue)**

2C.2.b. Further research is needed on the use of methanamine to prevent encrustation in patients requiring chronic indwelling catheters who are at high risk for obstruction. **(No recommendation/unresolved issue)**

2C.3.a. Unless obstruction is anticipated (e.g., as might occur with bleeding after prostatic or bladder surgery), bladder irrigation is not recommended. **(Category II)**

2C.3.b. Routine irrigation of the bladder with antimicrobials is not recommended. **(Category II)**

2C.4. Routine instillation of antiseptic or antimicrobial solutions into urinary drainage bags is not recommended. **(Category II)**

2C.5.a. Do not clean the periurethral area with antiseptics to prevent CAUTI while the catheter is in place. Routine hygiene (e.g., cleansing of the meatal surface during daily bathing) is

appropriate. **(Category IB)**
 2C.5.b. Further research is needed on the use of antiseptic solutions vs. sterile water or saline for periurethral cleaning prior to catheter insertion. **(No recommendation/unresolved issue)**

2C.6. Changing indwelling catheters or drainage bags at routine, fixed intervals is not recommended. Rather, catheters and drainage bags should be changed based on clinical indications such as infection, obstruction, or when the closed system is compromised. **(Category II)**

2C.7.a. Use a sterile, single-use packet of lubricant jelly for catheter insertion. **(Category IB)**
 2C.7.b. Routine use of antiseptic lubricants is not necessary. **(Category II)**

2C.8. Further research is needed on the use of bacterial interference to prevent UTI in patients requiring chronic urinary catheterization. **(No recommendation/unresolved issue)**

2C.9. Further research is needed on optimal cleaning and storage methods for catheters used for clean intermittent catheterization. **(No recommendation/unresolved issue)**

2C.10.a. Clamping indwelling catheters prior to removal is not necessary. **(Category II)**
 2C.10.b. Insert catheters only for appropriate indications, and leave in place only as long as needed. **(Category IB)**
 2C.10.c. For operative patients who have an indication for an indwelling catheter, remove the catheter as soon as possible postoperatively, preferably within 24 hours, unless there are appropriate indications for continued use. **(Category IB)**

2C.11.a. Consider using a portable ultrasound device to assess urine volume in patients undergoing intermittent catheterization to assess urine volume and reduce unnecessary catheter insertions. **(Category II)**
 2C.11.b. Further research is needed on the use of a portable ultrasound device to evaluate for obstruction in patients with indwelling catheters and low urine output. **(No recommendation/unresolved issue)**

Q2D. What are the risks and benefits associated with different systems interventions?

The available data examined the following systems interventions:

1. Infection control/quality improvement programs (multifaceted)
2. Catheter reminders
3. Bacteriologic monitoring
4. Hand hygiene
5. Patient placement
6. Catheter team versus self-catheterization
7. Feedback
8. Nurse-directed catheter removal

We considered CAUTI outcomes, duration of catheterization, recatheterization, and transmission of pathogens when weighing the risks and benefits of different systems interventions. The evidence for this question consists of 1 RCT²⁵⁹ and 19 observational

studies.^{3,25,260-276} The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 2D.

Q2D.1. Multifaceted infection control/quality improvement programs

Low-quality evidence suggested a benefit of multifaceted infection control/quality improvement programs to reduce the risk of CAUTI.^{3,260-267} This was based on a decreased risk of SUTI, bacteriuria/unspecified UTI, and duration of catheter use with implementation of such programs. Studies evaluated various multifaceted interventions. The studies with significant findings included: 1) education and performance feedback regarding compliance with catheter care, emphasizing hand hygiene, and maintaining unobstructed urine flow; 2) computerized alerts to physicians, nurse-driven protocols to remove catheters, and use of handheld bladder scanners to assess for urinary retention; 3) guidelines and education focusing on perioperative catheter management; and 4) a multifaceted infection control program including guidelines for catheter insertion and maintenance. A program using a checklist and algorithm for appropriate catheter use also suggested a decrease in unspecified UTI and catheter duration, but statistical differences were not reported.

Q2D.2. Reminders

Very low-quality evidence suggested a benefit of using urinary catheter reminders to prevent CAUTI.²⁶⁸⁻²⁷⁰ This was based on a decreased risk of bacteriuria and duration of catheterization and no differences in recatheterization or SUTI when reminders were used. Reminders to physicians included both computerized and non-computerized alerts about the presence of urinary catheters and the need to remove unnecessary catheters.

Q2D.3. Bacteriologic monitoring

Very low-quality evidence suggested no benefit of bacteriologic monitoring to prevent CAUTI.^{25,271} Although one study found a decreased risk of bacteriuria during a period of bacteriologic monitoring and feedback, only 2% of SUTI episodes were considered potentially preventable with the use of bacteriologic monitoring.

Q2D.4. Hand hygiene

Very low-quality evidence suggested a benefit of using alcohol hand sanitizer in reducing CAUTI. This was based on one study in a rehabilitation facility that found a decrease in unspecified UTI, although no statistical differences were reported.²⁷² A separate multifaceted study that included education and performance feedback on compliance with catheter care and hand hygiene showed a decrease in risk of SUTI.²⁶⁵

Q2D.5. Patient placement

Very low-quality evidence suggested a benefit of spatially separating patients to prevent transmission of urinary pathogens.²⁷³ This was based on a decreased risk of transmission of urinary bacterial pathogens in nursing home residents in separate rooms compared to residents in the same rooms.

Q2D.6. Catheter team versus self-catheterization

Very low-quality evidence suggested no benefit of a catheter team to prevent CAUTI among patients requiring intermittent catheterization.²⁷⁴ This was based on one study showing no difference in unspecified UTI between use of a catheter care team and self-catheterization for intermittent catheterization in paraplegic patients.

Q2D.7. Feedback

Very low-quality evidence suggested a benefit of using nursing feedback to prevent CAUTI.²⁷⁵ This was based on a decreased risk of unspecified UTI during an intervention where nursing staff were provided with regular reports of unit-specific rates of CAUTI.

Q2D.8. Nurse-directed catheter removal

Very low-quality evidence suggested a benefit of a nurse-directed catheter removal program to prevent CAUTI.²⁷⁶ This was based on a decreased risk of unspecified UTI during an intervention where criteria were developed that allowed a registered nurse to remove a catheter without a physician's order when no longer medically necessary. Of the three intensive care units where the intervention was implemented, differences were significant only in the coronary intensive care unit.

Evidence Review Table 2D. What are the risks and benefits associated with different systems interventions?

2D.1.a. Ensure that healthcare personnel and others who take care of catheters are given periodic in-service training stressing the correct techniques and procedures for urinary catheter insertion, maintenance, and removal. **(Category IB)**

2D.1.b. Implement quality improvement (QI) programs or strategies to enhance appropriate use of indwelling catheters and to reduce the risk of CAUTI based on a facility risk assessment. **(Category IB)**

Examples of programs that have been demonstrated to be effective include:

1. A system of alerts or reminders to identify all patients with urinary catheters and assess the need for continued catheterization
2. Guidelines and protocols for nurse-directed removal of unnecessary urinary catheters
3. Education and performance feedback regarding appropriate use, hand hygiene, and catheter care
4. Guidelines and algorithms for appropriate peri-operative catheter management, such as:
 - a. Procedure-specific guidelines for catheter placement and postoperative catheter removal
 - b. Protocols for management of postoperative urinary retention, such as nurse-directed use of intermittent catheterization and use of ultrasound bladder scanners

2D.2. Routine screening of catheterized patients for asymptomatic bacteriuria is not recommended. **(Category II)**

2D.3. Perform hand hygiene immediately before and after insertion or any manipulation of the catheter site or device. **(Category IB)**

2D.5. Maintain unobstructed urine flow. **(Category IB)**

2D.6. Further research is needed on the benefit of spatial separation of patients with urinary catheters to prevent transmission of pathogens colonizing urinary drainage systems. **(No recommendation/unresolved issue)**

2D.7. When performing surveillance for CAUTI, consider providing regular (e.g., quarterly) feedback of unit-specific CAUTI rates to nursing staff and other appropriate clinical care staff. **(Category II)**

Q3: What are the best practices for preventing UTI associated with obstructed urinary catheters?

The available data examined the following practices:

1. Methods to prevent/reduce encrustations or blockage
2. Catheter materials preventing blockage

For this question, available relevant outcomes included blockage/encrustation. We did not find data on the outcomes of CAUTI. The evidence for this question consists of 1 systematic review,²⁷⁷ 2 RCTs,^{278,279} and 2 observational studies.^{280,281} The findings of the evidence review and the grades for all important outcomes are shown in Evidence Review Table 3.

Q3.1. Methods to prevent/reduce encrustations or blockage

Low-quality evidence suggested a benefit of acidifying solutions or oral acetohydroxamic acid in preventing or reducing catheter encrustations and blockage in long-term catheterized patients.^{277,278,280,281} No differences were seen with daily catheter irrigation with normal saline.

Q3.2. Catheter materials preventing blockage

Low-quality evidence suggested a benefit of silicone over latex or Teflon-coated catheters in prevention or reducing catheter encrustations in long-term catheterized patients who were prone to blockage. No differences were seen with different materials in patients considered “non-blockers.”²⁷⁹

Evidence Review Table 3. What are the best practices for preventing UTI associated with obstructed urinary catheters?

3.1.a. Further research is needed on the benefit of irrigating the catheter with acidifying solutions or use of oral urease inhibitors in long-term catheterized patients who have frequent catheter obstruction. **(No recommendation/unresolved issue)**

3.2.a. Silicone might be preferable to other materials to reduce the risk of encrustation in long-term catheterized patients who have frequent obstruction. **(Category II)**

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ICS teaching module: Clinical stress test for urinary incontinence

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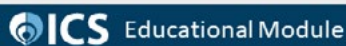


Clinical Testing For SUI – Cough Stress Test (CST)

International Consultation Incontinence

[ICS Standard Terminology 2002]:

- 'The stress test involves observation for urine loss with coughing or Valsalva manoeuvre ...
- Can be used to help make the diagnosis of SUI (objective test done in clinic) especially prior to surgical management
- Can be used as objective outcome measure when reporting treatment effects.



Endorsed By Many Societies

- **French College of Gynaecologists and Obstetricians (CNGOF)**

- Fritel X et al. French College of Gynaecologists and Obstetricians. Diagnosis and management of adult female stress urinary incontinence: guidelines for clinical practice from the French College of Gynaecologists and Obstetricians. *Eur J Obstet Gynecol Reprod Biol.* 2010 Jul;151(1):14-9

- **International Federation of Gynecology and Obstetrics (FIGO)**


- Medina CA et al. Evaluation and surgery for stress urinary incontinence: A FIGO working group report. *Neurourol Urodyn.* 2017 Feb;36(2):518-528

- **International Urogynecological Association (IUGA)**

- Ghoniem G, Stanford E, Kenton K et al. Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice. *Int Urogynecol J Pelvic Floor Dysfunct* 2008; 19:5-33

- **American College of Obstetricians and Gynecologists (ACOG)**

- Evaluation of uncomplicated stress urinary incontinence in women before surgical treatment. Committee Opinion No. 603. The American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2014; 123:1403-7

 **ICS** Educational Module

Reliability of CST (UDS as gold standard)

- **CST combined with the symptom of SUI:**

- PPV **78-97%**

Harvey MA, Versi E. Predictive value of clinical evaluation of stress urinary incontinence: A summary of the published literature. *Int Urogynecol J* 2001; 12:31-7

- **CST with simple bladder filling:**

- Sensitivity **88%**
- Specificity **77%**
- PPV **82%**
- NPV **84%**

Wall LL, Wiskind AK, Taylor PA. Simple bladder filling with a cough stress test compared with subtracted cystometry for the diagnosis of urinary incontinence. *Am J Obstet Gynecol.* 1994 Dec;171(6):1472-7


- **Agreement between CST and UDS:**

- **89% ($k=0.51$)**

Price DM, Noblett K. Comparison of the cough stress test and 24-h pad test in the assessment of stress urinary incontinence. *Int Urogynecol J.* 2012 Apr;23(4):429-33

- **Agreement between CST and 24 hr pad test:**

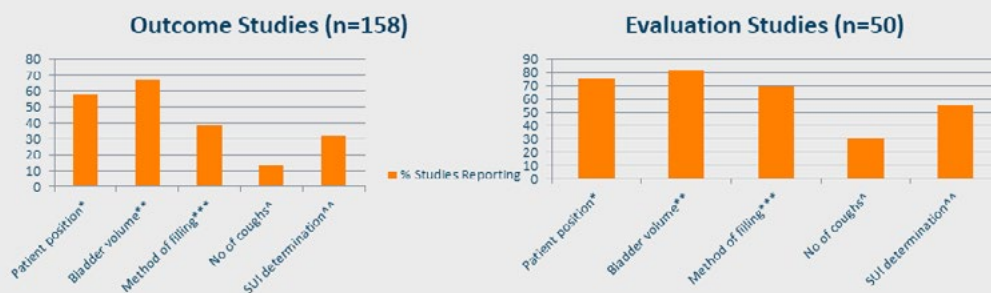
- **67% ($k=0.26$)**

 **ICS** Educational Module

No Standardization of Performance/Reporting of CST

- Variables to consider:
 - Patient position (supine/lithotomy/seated/standing)
 - Bladder volume and method of determination
 - Number of coughs
 - Method of SUI detection

Many Reports Fail to Describe How The CST Was Done



- positioning included: supine/lithotomy, semi lithotomy, seated, standing
- ** bladder volumes included “empty”, “comfortably/symptomatically full”, “full”, 100-700mL
- *** natural fill or retrograde fill via catheter (often done during UDS)
- ^ number of coughs ranged from 1-10 or reported as “a series of coughs”
- ^^ direct visualization of incontinence or pad testing

ICS Uniform Cough Stress Test (ICS-UCST)

Provisional (consensus)

- To standardize performance/reporting of CST to allow for easier, more consistent interpretation
- Recommendations of ICS working group based on review of more than 200 articles that have some mention of stress test
- To be done during uro-gynecological examination

Inform patient:

- ... there are diverse causes of urinary incontinence
- ... physical effort as one of the causes will be tested
- ... through a forceful cough during the clinical examination
 - vaginal inspection
- ... not pleasant, nor elegant, but helps select the best management

ICS-UCST Variables

(Evidence base in accompanying manuscript)

- Patient Position:
 - Supine/lithotomy

- Bladder volume:
 - 200-400mL

- Method of bladder filling:
 - Natural:
 - Patient advised to present with comfortably full bladder
 - Use ultrasound or voided volume + PVR after ICS-UCST to determine

 - Retrograde:
 - Specific volume instilled by examiner

ICS-UCST Variables:

- Number of coughs (up to 4):
 - Patient coughs forcefully x 1
 - If no SUI, patient then coughs 3 more times
 - if SUI noted after 1 cough, additional coughs not needed

- Method of SUI detection:
 - Examiner spreads labia and directly visualizes leakage of urine per urethral meatus

Interpretation ICS-UCST:

- ICS-UCST is **positive** when urine (fluid) is observed, leaving the meatus *coincident/simultaneous* to one or more of the coughs
- ICS-UCST is **negative** when there is no urine (fluid) lost or leakage of urine (fluid) lasts longer than the cough/delayed from the cough (cough induced detrusor overactivity)
 - Report: ‘... incontinence is not demonstrated during ICS-UCST.’

Other Tests (Accessory Stress Tests):

- ‘Stress tests -variants’
 - In other positions or with alternative provocation
 - *Standing / seated*
 - Generally recommended that upright CST be done if supine CST is negative in patient with complaint of SUI
 - *Strain / Valsalva*
 - Other bladder volumes:
 - *Empty (Supine Empty Stress Test, SEST)* – may help identify potential intrinsic sphincter deficiency
 - “full bladder” (>300mL)
- Cystometry (e.g. LPP testing):
 - Confirming or refuting (U)SUI

Scientific Reporting

- Report proportion (%) of patients (recruited or included) with:
 - Positive ICS-UCST
 - Positive accessory tests (specify)
 - Cystometry

Conclusion:

- ICS-Uniform Cough Stress Test is presented
 - ICS-UCST:
 - Supine/lithotomy position
 - Bladder volume 200-400mL
 - 1-4 forceful coughs
 - Incontinence seen coincident/simultaneous to the cough(s)
 - Accessory stress tests may be used when ICS-UCST negative to further clarify diagnosis
 - Not standardized

Future

- Validity of ICS-UCST should be determined/quantified:
 - Specificity
 - Sensitivity (compare with accessory tests, UDS)
 - Predictive value towards outcome of management

Thank you!

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ICS Educational Module: Cough stress test in the evaluation of female urinary incontinence: Introducing the ICS-Uniform Cough Stress Test

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Introduction: A cough stress test (CST) is recommended in the evaluation of the uncomplicated female patient with the complaint of stress urinary incontinence (SUI) to identify the sign of SUI, and is often used as an outcome measure following SUI treatment. However, there has been no standardization of the performance or reporting of CST. A working group of the International Continence Society (ICS) has developed an educational module, comprising a Powerpoint™ presentation and evidence base manuscript, to instruct on the performance, interpretation, and reporting of the CST in a standardized manner: the ICS-Uniform Cough Stress Test (ICS-UCST).

Methods: The working group performed a PUBMED literature search of articles (observational/experimental and reviews) published prior to 2017 that mentioned a CST. The evidence base examined various variables in performing a CST as well as sensitivity/specificity and positive/negative predictive values of CST.

Results: The variables involved in performing/interpreting an ICS-UCST include: patient positioning, degree of bladder filling, number, and forcefulness of coughs, and method of SUI detection. For the ICS-UCST it is recommended that the patient be in a supine/lithotomy position with 200-400 mL of fluid in the bladder. She coughs forcefully 1-4 times and the examiner directly visualizes the urethral meatus for the presence of leakage. Leakage of fluid from the urethral meatus coincident with/simultaneous to the cough(s) is considered a positive test.

Conclusion: This module provides instructions to educate a uniform CST (the ICS-UCST), with the aim of improving the clinical practice of cough stress testing in female patients with urinary incontinence.

KEYWORDS

cough stress test, stress urinary incontinence

1 | INTRODUCTION

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

The cough stress test (CST) is a clinical test used in the evaluation of urinary incontinence (UI). The patient coughs

and the visualization of urine loss synchronous with the cough confirms the presence of stress urinary incontinence (SUI).¹ CST is used to objectively make the diagnosis of SUI² and assess the outcome of treatment for SUI.^{3,4} Its use in the evaluation of UI (when symptoms of SUI are expressed; the SUI syndrome: SUI-S⁵) has been endorsed by several societies including the French College of Gynecologists and Obstetricians; International Federation of Gynecology and Obstetrics (FIGO); International Urogynecological Association (IUGA), and American College of Obstetricians and Gynecologists.^{2,6-8} Although the European Association of Urology guideline is brief about this test, the recent American Urological Association guideline considers it a sine-qua-non for the diagnosis of SUI.^{9,10} Based on their review, the FIGO working group recommended all patients being evaluated for SUI-S should have a CST (Grade A)⁸ and in a research context, CST has been the most commonly used measure for evaluating the outcome of SUI surgery.^{3,4} Despite the support for the CST, standardization of how to perform a CST does not exist. The ICS Urodynamics Committee presents the teaching module “Cough stress test in the evaluation of female urinary incontinence” to serve as a standard for educating a CST for the evaluation of female UI and/or SUI-S.

A new ICS term for the CST is introduced: ICS Uniform Cough Stress Test (ICS-UCST) because the secondary aim of this module is to uniformize, by teaching, CST for clinical routine and research. This manuscript provides the evidence base for the ICS educational PowerPoint™ presentation that accompanies this module as well as the arguments for the uniformization. The aim of this module is to educate the utilization and interpretation of the CST which will hopefully improve and facilitate the clinical diagnosis of SUI and the assessment/reporting of SUI treatment outcomes.

2 | METHODS

The working group for this module did an extensive literature review of more than 200 articles published prior to 2017 that mention a cough stress test, via a PUBMED online search using the terms “cough and stress test and incontinence.” These included observational/experimental studies as well as review articles. References used specifically for this manuscript are provided at the end and a full references list in an accessory file on the publisher’s website.

2.1 | The evidence base for standardization of CST

There is general consensus that the CST in combination with the SUI-S is reliable in confirming that the pathophysiology of the UI is SUI.¹¹⁻¹⁸ In a review of the

literature to determine the predictive value of the clinical evaluation of SUI (history, physical exam with CST) using multichannel UDS as the comparator, it was found that for the diagnosis of genuine SUI, the CST alone had sensitivity (sens:) 57%, specificity (spec:) 71%, positive predictive value (PPV) of 55% and negative predictive value (NPV) of 73%.¹⁵ However, when other UDS diagnoses (eg, mixed incontinence) were included, the PPV was 91%, indicating that CST had been demonstrating UI but not “uncomplicated SUI” in all patients. When combined with the symptoms of SUI-S, the CST had a PPV of 78-97%.¹⁵ A randomized trial of UDS prior to SUI surgery observed that an office evaluation including a CST correctly identified 97% of women found to have SUI on UDS and the demonstration of SUI during UDS subsequent to a positive CST did not improve the treatment success of SUI surgery.¹² In a prospective study, when CST was compared to multichannel UDS and 24 h pad testing the agreement between UDS and CST was 89% ($k=0.51$), whereas agreement between UDS and 24 h pad test was only 60% ($k=0.08$) and agreement between the CST and 24 h pad test was only 67% ($k=0.26$).¹⁶ Using UDS as the reference, the sens, spec, PPV and NPV of the CST were 90%, 80%, 98%, and 44% respectively. CST during single channel cystometry was compared to CST during multichannel UDS in another prospective study¹³ that alternated the gold standard for diagnosing SUI (a cough UPP during multichannel UDS versus CST and simple CMG). No significant difference between the two methods was seen with both having sens, spec, PPV, and NPV between 80% and 87%. In a similar study, when CST with simple bladder filling was compared to CST during multichannel UDS (using CST during UDS as the gold standard),¹⁴ for the diagnosis of SUI the CST with simple bladder filling had a sens 88%, spec 77%; PPV 82% and NPV 84%. It was concluded that CST with simple bladder filling is a reliable method of diagnosing SUI and can replace complex UDS which is in keeping with an assessment of AHCPR criteria for predicting SUI clinically (using UDS as the gold standard) that found that the most helpful criterion was the CST which had sens 93%; spec 56%; PPV 68% and NPV 89%.¹⁷

Despite the evidence supporting the use of CST there has not been any standardization of the performance or reporting of CST. In fact, in reviewing 208 studies that make mention of a CST (outcome assessment studies, test evaluation studies) we found that only 62% specified the patient positioning, 71% the bladder volume, 45% the method of filling, 17% the number of coughs and 38% the method of SUI determination (Figures 1 and 2). The lack of standardization makes every statement about the predictive value of (history and) clinical examination (and CST) on the outcome of management for UI difficult to evaluate and/or impossible to extrapolate.

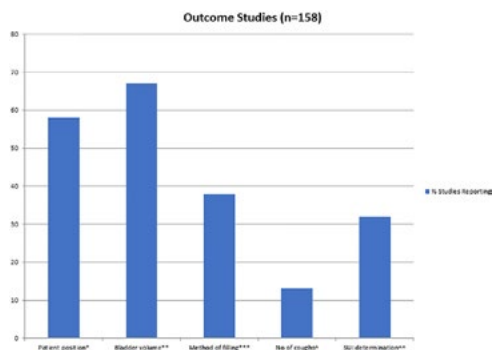


FIGURE 1 Studies assessing the outcome of a treatment intervention that mentioned using a CST (references online). *Positioning included: supine/lithotomy, semi-lithotomy, seated, standing. **Bladder volumes included “empty,” “comfortably/symptomatically full,” “full,” 100-700 mL. ***Natural fill or retrograde fill via catheter (often done during UDS). ^Number of coughs ranged from 1 to 10 or reported as “a series of coughs.” ^^Direct visualization of incontinence or pad testing

2.2 | Educating the ICS-UCST

From the available evidence we have selected the elements of CST: (1) preparation for the test; (2) performing the test: (a) patient positioning; (b) bladder volume; (c) number of coughs; (d) leakage detection; and (3) interpretation and reporting of the test. On the basis of our review of the evidence, we propose, to educate the elements of the CST to be performed in a standard manner, the ICS-UCST (Figure 3).

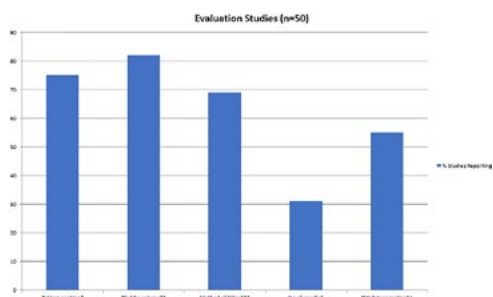


FIGURE 2 Studies looking at the evaluation of incontinence (e.g. studies assessing clinical factors contributing to incontinence, studies evaluating the performance of UDS, that mentioned using a CST (references online). *Positioning included: supine/lithotomy, semi-lithotomy, seated, standing. **Bladder volumes included “empty,” “comfortably/symptomatically full,” “full,” 100-700 mL. ***Natural fill or retrograde fill via catheter (often done during UDS). ^Number of coughs ranged from 1 to 10 or reported as “a series of coughs.” ^^Direct visualization of incontinence or pad testing

The education of the ICS-Uniform Cough Stress Test includes the explanation of the instructions:

The physician should:

- Explain to the patient before or during clinical exam in lithotomy position that the ICS-UCST is one of the tests that is used to unravel the nature/origin of the urinary incontinence
- That the test may be embarrassing, however considered valuable and necessary
- Ask the patient about bladder fullness (see below)
- Be aware of the usual voided volumes (and frequency)

The physician:

- Has instructed the patient to be in supine/lithotomy position and is able to observe the meatus
- Considers likelihood that the present intravesical volume, during the test, is representative for this patient and between 200 and 400mL
- Asks the patient to cough as forceful as possible and if no leakage is observed, asks to cough 3 more times, as forceful as possible

The physician:

- Objectively determines what the intravesical volume is or has been during the CST
- Reports that the ICS-UCST has been ‘positive with ***mL,’ or ‘negative’
- Considers repeating CST (up to 4 coughs) in standing position and reports the standing accessory CST to be positive or negative
- Considers complimentary or accessory evaluation to determine the pathophysiology as the cause of the UI*

** In a patient with UI or more specifically with SUI-S, a negative ICS-UCST and a negative accessory CST, an ICS standard pad test¹⁹ and/or (full) urodynamic testing may be considered to evaluate the complete lower urinary tract function, as per current practice guidelines.*

FIGURE 3 Educating the ICS-UCST

2.2.1 | Preparation

A cough stress test is typically performed during the physical examination of the patient in the outpatient clinic, but can be done at the time of a procedure or during urodynamic testing. The last being a urodynamic stress test and/or leak point pressure (LPP) determination. Practice and validity of (UDS-) LPP testing are not further discussed but are summarized, for example, in the ICI-consultation report.¹⁸

We believe that before the ICS-UCST the patient should be informed about the relevance and rationale for performing the test and also the potential embarrassing nature of the test. Apart from undressing the lower part of the body and some issues mentioned below, the patient does not have to prepare herself specifically for the test.

2.2.2 | Technique

Patient position

A CST can be performed in the supine, semi supine, standing, sitting, or lithotomy positions. In the supine position (using pads to measure the leakage), it was noted that only 49% of women leaked during the cough stress test (when floor and trampoline jumping were used as the comparator).¹⁹ In addition, CST was negative when done in a semi-supine position in 14% of patients who complain of SUI in another study on the effects of a UDS catheter on the diagnosis of SUI.²⁰ Furthermore, it has been noted that during LPP testing (done during CMG with a catheter in place), both Valsalva LPP and CLPP are significantly lower when the patient is standing versus supine.²¹

However, probably the most convenient time to do a CST is when the patient is undergoing a vaginal exam in the supine/lithotomy position (legs either in stirrups or abducted in a “frog-leg” position), when one assesses vaginal anatomy and pelvic floor function. This positioning allows for relatively easy visualization of the urethral meatus for the occurrence of urine leakage.

Because of the observed potential for a false negative in the supine position, reported in some cohort studies, it has been recommended that patients undergo a CST in the upright position, especially if they had a negative test in the supine position.^{7,8} However, having the patient stand for the CST requires more effort on the examiner's part to expose the urethral meatus for visualization of the leakage. As well, not all patients are able to stand on their own, and testing in the standing position may therefore be less relevant and/or representative in these patients. Furthermore, it is currently unknown if the pathophysiology of a patient who has a positive CST in the upright position but negative in the supine/lithotomy position is comparable to a patient who has a positive CST in the supine position.

Conclusion for the purposes of uniformized practice of the ICS-UCST, we recommend that the CST be done in the supine/lithotomy position at the time of vaginal examination (LoE 1b, GoR A). If the test is negative (ie, no leakage detected), then accessory stress testing such as repeating the test in the upright position should be considered. When reporting the results of an ICS-UCST, it can be assumed that the test was done in the supine/lithotomy position. A patient with a negative test in the supine/lithotomy position and a positive accessory stress test in the upright position should be reported as: “ICS-UCST negative, accessory (upright CST) positive.”

Bladder volume

A spectrum of CST bladder volumes has been used in the literature from empty to 700 mL, including a “comfortably full” or a “symptomatically full” bladder. No consensus exists regarding the bladder volume for CST and to our knowledge no one has evaluated CST at differing bladder volumes in the same patient. The effect of differing bladder volumes has been evaluated in the context of LPP testing during UDS: Valsalva LPP was lower when bladder volumes were larger and the detection of SUI on LPP testing increased with increased bladder volumes.^{22–25} During (cystometry-) LPP testing in women with SUI-S, leakage was not detected in any patient with a bladder volume <100 mL while leakage was detected in 19% of patients with a volume of 150 mL, 58% with a volume of 200 mL and 95% with a volume of 250 mL.²⁶ It seems reasonable to extrapolate this to the CST done in the clinic: a larger bladder volume may be more likely to elicit a positive test. On the other hand, one wants to avoid overfilling the bladder and elicit results that are not

representative. Some patients may not routinely store more than 250–300 mL and it may be unrealistic for them to be filled to a larger volume. The use of a “comfortably full bladder might remedy this because one presumes that the patient's bladder volume will be close to their functional capacity but this reported sensation may be affected by anxiety level. Basing the CST volume on a percentage of the patient's bladder (maximum) capacity seems logical and this concept was used in the context of pad weight testing using a bladder filled to a volume of 50% of cystometric capacity.²⁷ It was concluded that this type of standardization reduced test retest variation in the quantifying of UI volume. However, determining cystometric capacity requires the patient undergo UDS first. Another option is to base the CST volume on a percentage of the capacity/maximum voided volume on a frequency-volume chart, or use the “usual/average voided volume” avoiding the need for urethral instrumentation/UDS. To our knowledge this has not been studied in the context of a CST and therefore requires additional evaluation. For the purposes of standardization for the ICS-UCST, we recommend that the patient has a bladder volume in the range of 200–400 mL, and to ensure that this volume is not exceptional (far too low or far too high) for this patient (LoE 2, GoR B).

How one achieves/determines the bladder volume is also up for debate. Natural bladder filling or retrograde filling with a catheter can be used. Retrograde bladder filling allows for filling to a preset amount independent of patient activity. This requires catheterization which carries a small risk for infection and a potential to irritate/injure the urethral mucosa which could affect the results.²⁸ Natural bladder filling avoids urethral instrumentation albeit with lesser control over the actual bladder volume. One may determine the patient's bladder volume at the time of CST via an ultrasound bladder scan prior to or immediately after a CST or one could do a CST then have the patient void and add the voided volume to the postvoid residual volume (via bladder scanner or catheterization) to calculate the bladder volume retroactively.

For the ICS-UCST we recommend the patient be asked about their sense of bladder fullness and the time since the last micturition to get an idea of the degree of fullness with natural filling. We propose the test be performed in a target range of bladder volumes between 200 and 400 mL with the frequency volume chart serving as a guide for usual normal desire to void. We recommend furthermore that a more precise determination of the bladder volume during the test, using one of the aforementioned methods, be reported (in mL) when reporting the results of the ICS-UCST. (eg, “ICS-UCST 380 mL positive”)

Number/Forcefulness of coughs

The goal of a CST is to reproduce the patient's UI or at least to determine the likelihood that SUI is a cause of the UI. The CST, therefore, should ideally reproduce the kinds of

provocative maneuvers that are experienced by the patient on a day to day basis. In addition, the test must be easy to perform and interpret (ie, it should be of minimal burden to the patient and provide clear, easy to interpret results). While it has been demonstrated that with greater exertional effort (eg, jumping), SUI will be more likely to be elicited,^{19,29} many women do not routinely subject themselves to such exertion and furthermore, it may be unrealistic, or too risky, to expect women to do such strenuous maneuvers in the clinic. Hence, on the basis of the available evidence as well as practicality, we propose that coughing be the provocative maneuver within the ICS-UCST.

In many reports that used a CST there was no mention of the number of times the patient was asked to cough (Figures 1 and 2). There is some evidence that, during UDS, multiple coughs are more likely to elicit leakage as was demonstrated during a “1-3-5” cough test.³⁰ The patient initially coughs once and if no SUI is noted then coughs three times and again if no SUI is noted then coughs five times. The “severity” of SUI was graded based on the occurrence of SUI after fewer coughs (more severe) versus many coughs (more mild). When compared with patient-perception questionnaires (eg, ICIQ-FLUTS, King's Health Questionnaire, UDI-6, and UIQ-7), statistically significant associations of higher grades of SUI (based on the 1-3-5 CST) with higher scores of incontinence domains on the questionnaires were noted. Others have speculated that (pelvic) muscular fatigue may have a role in SUI and its diagnosis: by having patients cough repeatedly (up to seven times), a greater than 20% decrease in MUCP was measured in almost a quarter of patients with SUI-S.³¹

While standardization of cough effort/force has been attempted using an audiometer as a gauge (to measure audible cough strength),³² it has been suggested that it is rather difficult to achieve reliable standardization of coughing force/effort³³ and for the purposes of a routine office visit it is impractical. Rather, the recommendation of three coughs “as hard as possible” seems reasonable.³⁴

Taking all of this together, we recommend that for the ICS-UCST: The patient should cough as forceful as possible. If no leakage is seen after the first cough, coughing should be repeated three more times (ie, total of four coughs) before calling the test negative (LoE 2, GoR B). If no leakage is seen after four forceful coughs, accessory stress testing (eg, greater number of coughs; upright testing; alternative provocations; ICS standard pad testing or UDS) can be performed, with no evidence based preference for any of these. We recommend this however to be reported specifically, especially for scientific purposes.

Determination of SUI/Interpretation

Most reports that describe the method of CST use direct visualization of incontinence that occurs simultaneous with a

cough as the definition of a positive CST.^{7,8,34} Incontinence occurring subsequent to a cough (ie, after a brief delay) or incontinence that persists after the cough has subsided is reported to be indicative of a concurrent detrusor contraction and usually referred to as cough induced DO² or cough associated DO.³⁵

While some have used pads to capture the incontinence, avoiding the need for direct visualization of the incontinence,^{29,32} the lack of direct visualization of the moment of the incontinence could call into doubt whether one is dealing with actual SUI versus cough associated DO. For the ICS-UCST therefore, we recommend that a positive test requires direct visualization of the efflux of urine from the urethral meatus synchronous with the cough.

2.2.3 | Accessory stress tests

Upright CST

As previously noted, a negative CST in the supine/lithotomy position does not necessarily rule out the presence of SUI. It has therefore been recommended that a patient with the complaint of SUI who has a negative CST in the supine/lithotomy position undergo a repeat test in the upright position.⁷ This can be done in the same fashion as the standard ICS-UCST (bladder volume of 200-400 mL), up to four forceful coughs. If the upright CST is positive and the ICS-UCST (supine/lithotomy) is negative, the patient should be reported as having ICS-UCST negative, accessory (upright CST) positive.

Supine empty stress test (SEST)

A positive CST performed in the supine position with an “empty” bladder (volume <100 mL) has been suggested to indicate the presence of intrinsic sphincter deficiency (ISD). In a prospective series it was noted that a positive SEST was associated with a lower MUCP (mean, 20 vs 36 cm H₂O) and SEST had sens: 65-70% and spec: 67-76% for predicting ISD using low MUCP to diagnose ISD.³⁶ A positive SEST was also associated with a low LPP (40% of women with a positive SEST had a LPP of 60 cm H₂O or less versus 10% with negative SEST) with sens: 93.5%, spec: 90%, PPV 96.7% and NPV 81.8% for detecting ISD using ALPP to define ISD.³⁷ The IUGA suggests that SEST could be used as a simple test to be reasonably assured that ISD is not present (without resorting to multichannel UDS)² If a SEST is done as an accessory to (or preceding) an ICS-UCST, the results of each should be specified and reported.

In a patient with UI or more specifically with SUI-S, a negative ICS-UCST and a negative accessory CST, an ICS standard pad test³⁸ and/or (full) urodynamic testing may be considered to evaluate the complete lower urinary tract function, as per current practice guidelines.

3 | CONCLUSION

This module has introduced and provided the evidence base for the International Continence Society-Uniform Cough Stress Test (ICS-UCST) to standardize the performance and reporting of the cough stress test used in the clinical and outcomes assessment of women with urinary incontinence.

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Detrusor Leak Point Pressures (DLPP) in Patients with Relevant Neurological Abnormalities

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International Continence Society
Educational Module

1

Publication



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ICS Teaching Module: Detrusor Leak Point Pressures in Patients With Relevant Neurological Abnormalities

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ICS Educational Module

2

Background

- McGuire, 1981
 - Observations of videourodynamic studies of children with MMC and UI secondary to impaired bladder compliance
 - DLPP was found to predict the upper urinary tract deterioration (UUTD)*
- Further applied to different etiologies of neurogenic lower urinary tract dysfunction (N-LUTD) in adults

*McGuireMcGuire EJ, WoodsideJR, BordenTA. Upper urinary tract deterioration in patients with myelodysplasia and detrusor hypertonia: a followup study. J Urol 1983;129:823-6.

The ICS definition of DLPP

- The lowest detrusor pressure at which urine leakage occurs in the absence of either a detrusor contraction or increased abdominal pressure*

*Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A; Standardisation Sub-committee of the International Continence Society. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub committee of the International Continence Society. NeuroUrol Urodyn. 2002; 21:167-78.

Controversies

- The exact value of DLPP to predict UUTD is debatable
- Measuring DLPP lacks standardization and carries pitfalls
- A common mistake:
 - Using DLPP in N-LUTD during detrusor contractions (neurogenic detrusor overactivity) instead of reduced bladder compliance

The ICS Urodynamics Committee Teaching Module

- Aim
 - To standardize and improve the method of DLPP measurement in patients with N-LUTD to minimize performer- and patient dependent variations
 - To review the clinical implications
- Methods
 - Literature search, key word: Detrusor Leak Point Pressure

Preparation and Technique: DLPP is a cystometric finding

- Should be in accordance with:
 - ICS reports on Good Urodynamic Practices (GUP) and urodynamic equipment performance*
 - The International Children's Continence Society (ICCS) report on the standardization of terminology of LUT function**

*Schäfer W, Abrams P, Liao L, Mattiasson A, Pesce F, Spangberg A, Sterling AM, Zinner NR, van Kerrebroeck P; International Continence Society. Good urodynamic practices: uroflowmetry, filling cystometry, and pressure-flow studies. *Neurourol Urodyn.* 2002;21:261-74.


**Nevéus T, von Gontard A, Hoebeke P, Hjalms K, Bauer S, Bower W, Jørgensen TM, Rittig S, Walle JV, Yeung CK, Djurhuus JC. The standardization of terminology of lower urinary tract function in children and adolescents: report from the Standardisation Committee of the International Children's Continence Society. *J Urol.* 2006;176(1):314-24

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Technique I

- Standard urodynamic equipment
- Patients in supine position with empty bladder
- ICI recommends sitting position in suitable patients (grade B)*
- No evidence for the influence of specific positioning of patients with N-LUTD on the DLPP

*Rosier P.F.W.M., Kuo H.C, De Gennaro M, Kakizaki H, Hashim H, Van Meel TD, Hobson PT. Urodynamic Testing. In 5th International Consultation on Incontinence, Paris February, 2012 Editors: Paul Abrams, Linda Cardozo, Saad Khoury, Alan Wein. 5th EDITION 2013.

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Technique II: Catheter

- Using progressively larger catheters increase DLPP
 - Small cystometry catheter (≤ 10 F)
 - As thin as possible, 'one-catheter-systems' LoE 4*
 - 5-8 F double lumen cystometry catheters during water cystometry
- Underestimation of DLPP when suprapubical catheter is used**

*Rosier P.F.W.M., Kuo H-C, De Gennaro M, Kakizaki H, Hashim H, Van Meel TD, Hobson PT. Urodynamic Testing. In 5th International Consultation on Incontinence, Paris February, 2012. Editors: Paul Abrams, Linda Cardozo, Saad Khoury, Alan Wein. 5th EDITION 2013.


**Combs AJ, Horowitz M. A new technique for assessing detrusor leak point pressure in patients with spina bifida. J Urol 1996;156:757-60.

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Technique III: Filling rate

- Not standardized in the ICS GUP
- Usually done with a rate dependent on age (from 20ml/min in children to 30-60 ml/min in adults)
 - Detrusor adaptation to volume (compliance) may be challenged in high filling rates
- Classified as physiologic and non-physiologic by ICS rather than slow-medium-rapid*

*Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A; Standardisation Sub-committee of the International Continence Society. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. NeuroUrol Urodyn. 2002; 21:167-78.

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Technique III: Filling rate (cont'd)

- Day-to-day bladder capacity by using voiding or catheterization diary-volumes
- 5-10% of known or predicted capacity may be used in children*
- Slow filling rate needed in adult neurogenic patients with a known hypocompliant bladder (EO)

*Neveus T, von Gontard A, Hoebcke P, Hjälmås K, Bauer S, Bower W, Jørgensen TM, Rittig S, Walle JV, Yeung CK, Djurhuus JC. The standardization of terminology of lower urinary tract function in children and adolescents: report from the Standardisation Committee of the International Children's Continence Society. J Urol. 2006;176(1):314-24

Technique IV: Pump and filling

- Infusion pump devices rather than gravity-type infusion systems
 - Avoid iatrogenic bladder pressure increases
- The influence of fluid temperature on DLPP is never studied
- More accurate representation of bladder activity with natural fill (ambulatory) cystometry in children*

*Neveus T, von Gontard A, Hoebcke P, et al. The standardization of terminology of lower urinary tract function in children and adolescents: Report from the standardisation committee of the International Children's Continence Society. J Urol 2006;176:314-24.

Technique V: Detection of urinary leakage

- One person observing for leakage and another observing the recording and marking pressures
- In video-UDS, fluoroscopic visualization of contrast around the catheter may be more accurate
 - Lane TM, Shah PJ. Leak-point pressures. BJU Int 2000;86:942–9.

Technique VI: When to stop?

- Cystometry may be stopped when*;
 - Pdet exceeds 40 cmH₂O
 - Maximum bladder volume at intermittent catheterization is reached
 - A detrusor contraction occurs

*McGuire EJ, Cespedes RD, O'Connell HE. Leak-point pressures. UrolClin North Am. 1996;23:253-62

Technique VII: Other definitions

- End filling pressure (EFP)
 - When the cystometry is ended without leakage
- Neurogenic Detrusor Overactivity Leak Point Pressure (N-DO LPP)*
 - If leakage occurs with an episode of neurogenic detrusor overactivity (N-DO) any time during filling cystometry
- Detrusor Overactivity Leak Point Pressure (DO LPP)**
 - In non-neurogenic women with urgency

*N-DOLPP has not been defined yet, but suggested by the authors of this module

**Smith AL, Jaffe WI, Wang M, Wein AJ. Detrusor overactivity leak point pressure in women with urgency incontinence. Int Urogynecol J. 2012;23:443-6

Basic Pathophysiology related to DLPP

- DLPP is the pressure which overwhelms the bladder outlet resistance and causes urinary leakage
- Reflection of the resistance of the bladder outlet or external sphincter
- DLPP may estimate how much and how long the urinary tract will be exposed to high pressure in-between bladder emptying periods (with or without CIC)

The treatment of patients with a high DLPP aims:

- Reduction of outlet resistance is proposed to improve safe bladder storage and preserve upper tracts
 - remains unproven and leads to incontinence

- The treatment of patients with a high DLPP who are on CIC should aim:
 - Improving bladder compliance

*McGuireMcGuire E.J, Woodside JR, Borden TA. Upper urinary tract deterioration in patients with myelodysplasia and detrusor hypertonia: a followup study. J Urol 1983;129:823-6.

Which cut off for DLPP?

- The absolute values of DLPP are unreliable
 - No UUT deterioration of several patients with DLPP's of >40 cmH₂O in the long term follow-up*

*Combs AJ, Horowitz M. A new technique for assessing detrusor leak point pressure in patients with spina bifida. J Urol 1996, 156. 757-60.

Is 40 cm H₂O Detrusor Leak Point Pressure Cut-Off Reliable for Upper Urinary Tract Protection in Children With Myelodysplasia?

Tufan Tuzcan,* Cagil Akın Bekeri, Cem Akbal, Ekber Tınay, Yüven Taşkın, Ahmet Şahan, Behaeddin Şahin, Tuncay Top, and Feriuh Şimşek

- Higher sensitivity of 20 cm H₂O DLPP cutoff to predict the risk group for UUT deterioration in children with MMC

DLPP	Percentage of patients with UUT deterioration (%)	P-value
>40 cm H ₂ O	37.8 (37/98)	0.510
20–40 cm H ₂ O	43.5 (27/62)	0.014
<20 cm H ₂ O	18.1 (6/33)	

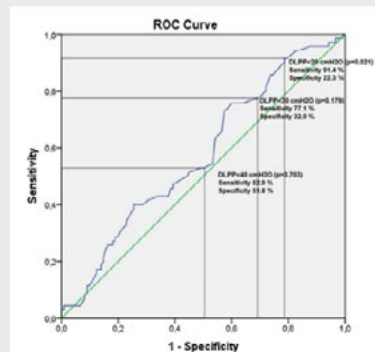


Fig. 1. UUT damage in three different DLPP cut-off values with their sensitivity and specificity is shown in ROC curve analysis.

N- DO is also a risk factor for UUT

- Significant association with hydronephrosis in patients with N-DO >75 cmH₂O*
- The total duration of N-DO contractions**
 - The only statistically significant urodynamic variable for upper tract dilatation or VUR in spinal cord lesion patients

* Ozkan B, Demirkesen O, Durak H, Uygun N, Ismailoglu V, Cetinel B. Which factors predict upper urinary tract deterioration in overactive neurogenic bladder dysfunction? Urology. 2005 Jul;66(1):99-104.

**Linsenmyer TA, Bagaria SP, Gendron B et al. The impact of urodynamic parameters on the upper tracts of spinal cord injured men who void reflexly. J Spinal Cord Med 1998; 21:15-20

Conclusions and recommendations I

- DLPP
 - A part of cystometric evaluation of children and adults with N-LUTD to help predicting (and preventing) UUTD (Grade B/C)
- Recommendations of ICS and ICCS should be followed for cystometric equipment and for the measurement technique

Conclusions and recommendations II

- Discrimination of high risk (for UUTD) patients on the basis of DLPP (Grade B/C)
- Not to be used as the sole parameter to decide on invasive therapies, e.g.
 - Bladder augmentation and sphincterotomy

Conclusions and recommendations III

- Other factors to predict UUTD in N-LUTD
 - Bladder compliance
 - Volume where leakage occurs
 - Duration and amplitude of detrusor contractions
 - Volume which obtained by CIC
- Low sensitivity of traditional cutoff >40 cmH₂O for the prediction of UUTD

Conclusions and recommendations IV

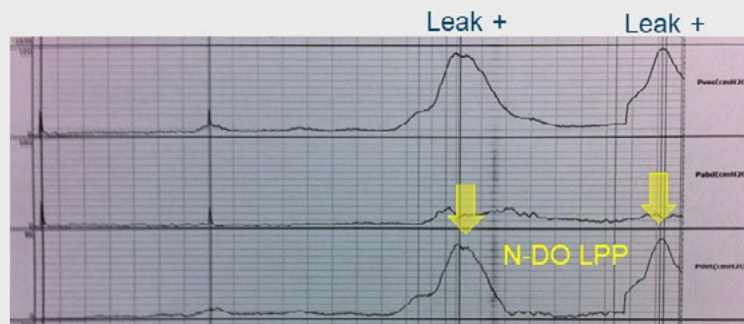
- Future research to standardize the technique and better classify DLPP cutoffs in N-LUTD
- The predictive value of LPP may differ according to underlying etiology of N-LUTD such as MMC, MS or SCI.

Conclusions and recommendations V

- Cystometric readings should be sub-classified and differentiated according to the presence of N-DO

Conclusions and recommendations V (cont'd)

- N-DO LPP: refers to the detrusor pressure that belongs to a spontaneous N-DO leading to leakage during cystometry



Conclusions and recommendations VI

- EFP should be taken into consideration if the leakage does not occur during cystometry however, the clinical relevance of EFP is unclear.

Thank you



ICS Teaching Module: Detrusor Leak Point Pressures in Patients With Relevant Neurological Abnormalities

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Aims: This manuscript serves as a scientific background review; the evidence base, for the presentation made available on ICS website to summarize current knowledge and recommendations for the measurement and use of the DLPP.

Methods: This review has been prepared by a Working Group of The ICS Urodynamics Committee. The methodology used included comprehensive literature review, consensus formation by the members of the Working Group, and review by members of the ICS Urodynamics Committee core panel. **Results:** DLPP has been recommended and utilized in the urodynamic evaluation of N-LUTD for many years, but it lacks standardization and there are numerous pitfalls in its measurement. EFP and LPP associated with N-DO are frequently and mistakenly reported as DLPP. The information that high DLPP predicts UUTD originates from retrospective cohort studies of a low level of evidence (LoE 3). Existing data confirm that patients with lower DLPP do better than patients with higher DLPP in terms of their upper urinary tract. However, there appears to be no reliable 'safe/no safe' cut-off for DLPP since there are other urodynamic factors that influence UUTD such as bladder compliance and more. **Conclusion:** Although higher DLPP is associated with a greater risk of UUTD, there is no reliable cut-off level to undoubtedly discriminate the risky group, including the traditional cut-off level of 40 cm H₂O. Therefore, DLPP should not be used as the sole urodynamic parameter. Future research should be directed to standardization of the technique and better classification of DLPP cut-offs in N-LUTD. *Neurourol. Urodynam.*

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Key words: detrusor leak point pressure; neurogenic bladder; urodynamics

INTRODUCTION

Detrusor leak-point pressure (DLPP) testing originates from observations of videourodynamic studies of children with myelomeningocele (MMC) and urinary incontinence secondary to impaired bladder compliance. McGuire retrospectively evaluated this group of children with the aim of finding predictors for upper urinary tract deterioration (UUTD).^{1–3} This concept has been further applied to different etiologies of neurogenic lower urinary tract dysfunction (N-LUTD) in adults.⁴ The International Continence Society (ICS) defines the DLPP as the lowest detrusor pressure at which urine leakage occurs in the absence of either a detrusor contraction or increased abdominal pressure.⁵ The value of DLPP to predict UUTD is not known very precisely, and the measurement of DLPP lacks standardization and carries pitfalls. For example, although DLPP measurement has been recommended in neurological patients with reduced bladder compliance, some authors measure DLPP during involuntary detrusor contractions.⁵

The ICS Urodynamics Committee presents the teaching module “detrusor leak point pressures in patients with relevant neurological abnormalities” to serve as a standard education of good urodynamic practice for everyone involved in indicating, performing, and analyzing urodynamic testing in general and more specifically, for those caring for patients with N-LUTD. The teaching module consists of a web-casted presentation, in combination with this manuscript, which is available on the ICS website. The presentation explains testing requirements, clinical workup, and analysis. The presentation and this manuscript contain experts' opinion where evidence is

unavailable, especially for the clinical practice aspects, and is marked with: “EO” (expert's opinion).

This module reviews the value of DLPP measurement in predicting UUTD in N-LUTD in light of the existing literature. Our purpose is to standardize and improve the method of DLPP measurement in patients with N-LUTD to minimize performer- and patient-dependent variations.

MATERIALS AND METHODS

All the requirements and instructions for the measurement of DLPP described in this section follow the ICS reports on Good Urodynamic Practices (GUP)⁶ and urodynamic equipment performance.⁷ The International Children's Continence Society (ICCS) report on the standardization of terminology of lower urinary tract function in children and adolescents has been taken into consideration for the measurement of DLPP in children.⁸ DLPP is obtained during a standard cystometry and no specific other equipment or specific patient preparation is needed to determine DLPP. DLPP uses detrusor pressure;

Prof. Christopher Chapple led the peer-review process as the Associate Editor responsible for the paper.

Potential conflicts of interest: Nothing to disclose.

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consequently, it cannot be obtained via a single channel cystometry and, therefore, both vesical and intra-abdominal pressure must be recorded.

Technique

The measurement of DLPP is a part of cystometric evaluation in patients with N-LUTD. Traditionally, the patient is positioned supine and the bladder emptied. A small cystometry catheter (≤ 10 F) is inserted into the urethra and standard urodynamic equipment used to measure vesical pressure via a pressure transducer with a rectal probe to monitor intra-abdominal pressure changes.⁹

In suitable patients, the study can also be performed in the sitting position according to ICI recommendations, because this is reported to have a higher sensitivity for the diagnosis of filling phase abnormalities (recommendation Grade B).¹⁰ No evidence is available on the influence of positioning of patients with N-LUTD on the DLPP. The size of the catheter has an influence on the DLPP and it has been shown that using progressively larger catheters increases DLPP.¹¹ According to the ICI 2013, there is evidence of level 3 that, in general, flow rate during voiding is reduced with a urodynamic catheter in the urethra and that this reduction is partially caused by the size of the catheter. Use of, as thin as possible, "one-catheter systems" (dual lumen if fluid filled) for filling and pressure recording during urodynamic testing is recommended with a level of evidence 4.¹⁰ This recommendation may correspond to 5–8F double lumen cystometry catheters during water cystometry. The consequence of this recommendation is that DLPP is also done with a 5–8F transurethral catheter. Another consequence is that when cystometry is performed via a suprapubic catheter, the DLPP will theoretically be underestimated if compared with published data, as this can also indirectly be deduced from a study where catheters were removed and reinserted during cystometry.¹³

A cystometry filling rate is not standardized in the ICS GUP but is usually done with a rate dependent on age (from 20 ml/min in children to 30–60 ml/min in adults).⁶ There is some evidence that fluid temperature may not be relevant for the outcome of cystometry; however, the influence on DLPP has not been studied.^{14,15}

Detrusor adaptation to volume (compliance) may however, be challenged if relatively high filling rates are used.⁹ The ICS classifies infusion rates as physiologic and non-physiologic and no longer wishes to divide the filling rates as slow if < 10 ml/min, medium if 10–100 ml/min, or rapid if > 100 ml/min, although almost all investigations are performed using medium filling rates within a wide range.⁵ It is advised to learn the day-to-day bladder capacity by using voiding (or catheterization) diary volumes before the study, although particularly large or small capacities might affect the desired filling rates. For this reason, we recommend a slow filling rate in adult neurogenic patients with a known hypocompliant bladder (EO).

According to the ICCS, filling rates (per minute) of 5–10% of known or predicted capacity may be used in children. Infusion pump devices rather than gravity-type infusion systems are recommended to avoid iatrogenic bladder pressure increases during filling and inaccurate interpretation by pressure transducers.^{9–11} The ICCS also reports that the use of natural fill (ambulatory) cystometry provides a true physiological filling rate and offers a more accurate representation of bladder activity than traditional cystometry in children and may be the technique of choice in pediatric urodynamics if time and equipment are available.⁶

According to an expert review, urinary leakage (in the absence of fluoroscopy) is best detected by having one person

observing for leakage and another observing the recording and marking pressures using an event marker. However, the authors also stated that fluoroscopy visualization of contrast around the catheter is more accurate than observing the meatus or observing urine falling onto a sheet.⁹

It is suggested that the cystometry for patients with N-LUTD may be stopped when P_{det} exceeds 40 cm H₂O or the maximum volume recovered at intermittent catheterization is reached or if a detrusor contraction occurs.³ When cystometry ends without leakage, the end filling pressure (EFP) should be noted. If leakage occurs with an episode of neurogenic detrusor overactivity (N-DO) any time during filling cystometry, we suggest that it should be noted as N-DO LPP. A similar definition in non-neurogenic patients has recently been proposed as the "detrusor overactivity leak point pressure" in women with urgency incontinence.¹⁶ The bladder volume at which leak occurs should also be noted, as it may be important for a particular patient to organize their clean intermittent self-catheterization (CIC) regimen.

Basic Pathophysiology and Clinical Implications of DLPP in Patients With N-LUTD

DLPP is the pressure that overwhelms bladder outlet resistance, causing urinary leakage. DLPP is a reflection of the resistance of the bladder outlet or external sphincter.¹ McGuire's pioneering work has stated that patients with MMC and a LPP > 40 cm were at risk of developing UUTD and this cutoff has been traditionally accepted without a high level of evidence.² It was shown in another study that reduction of outlet resistance may improve bladder storage in the long-term and may preserve the upper tracts.¹² Combs et al., however, reported that several of their patients with DLPPs of > 40 cm H₂O (followed over a long period) showed no deterioration in their upper tracts, while by contrast some individuals undergoing successful bladder augmentation required an artificial urinary sphincter, despite apparently good outlet resistance before surgery.¹³ These authors suggested that absolute values of DLPP reported previously were unreliable because the technique lacked standardization. Another retrospective study has challenged the single cutoff level of 40 cm H₂O¹⁷ showing that UUT involvement rates are 18% in children with a DLPP below 20 cm H₂O; 38% between 20 and 40 cm H₂O; and 28% above 40 cm H₂O, respectively. The authors concluded that determining the cut-off value of the DLPP as 20 cm H₂O instead of 40 cm H₂O showed a higher sensitivity to predict the risk group for UUT deterioration (Table I). They also suggested that children with MMC and a DLPP between 20 and 40 cm H₂O should be closely monitored, since 38.4% of children in their study had UUT deterioration at the age of 3.¹⁷

In spite of the ICS definition, DLPP is sometimes referred to as the elevation of the detrusor pressure during contractions leading to leakage. In fact, this is not DLPP but is N-DO LPP. However, the (clinical) significance of N-DO LPP versus DLPP in

TABLE I. UUT Involvement According to Different DLPP Cut-Off Values¹⁷

DLPP	Percentage of patients with upper tract involvement	Sensitivity (ROC analysis)
> 40 cm H ₂ O	18/64 (28.1%)	51.4%
> 30 cm H ₂ O	24/88 (27.3%)	68.6%
> 20 cm H ₂ O	33/102 (32.3%)	91.4%

TABLE II. Recommendations of the ICS Teaching Module for the Measurement, Clinical Utilization, and Future Research on DLPP

(1) Measuring and reporting of DLPP should be a part of cystometric evaluation of children and adults with N-LUTD to help predict (and prevent) UUTD (Grade B/C)
a. The recommendations of the ICS and the ICCS should be followed for cystometric equipment and technique
(2) Discrimination of high-risk (UUTD) patients is, however, not very precisely possible on the basis of DLPP (Grade B/C)
(3) DLPP should not be used as the sole parameter to decide on invasive therapies such as bladder augmentation and sphincterotomy
a. UUTD in N-LUTD does not only depend on DLPP but will also depend on other factors such as bladder compliance; volume where leakage occurs; and detrusor contraction duration and amplitude, with all of these related to CIC obtained volumes. On the other hand, the resistance of the bladder outlet to the involuntary rise in detrusor pressure is another important parameter for deterioration
b. The traditional cut-off for DLPP of 40 cm H ₂ O may have too low a sensitivity for the prediction of UUTD
(4) Future research should be directed to standardization of the technique and better classification of DLPP cut-offs in N-LUTD
a. The predictive value of LPP may differ according to underlying etiology of N-LUTD such as MMC, MS, or SCI
b. Cystometric readings should be sub-classified according to the presence of neurogenic DO (overactive detrusor contractions with or without leakage)
c. EFP should be taken into consideration if the leakage does not occur during cystometry, however, the clinical relevance of EFP is unclear

N-LUTD has not been investigated. Frequent DO episodes with high LPP are plausibly a similar risk for future upper tract changes. The duration of the bladder contraction during an N-DO episode and DLPP >75 mmH₂O is reported to have a significant association with hydronephrosis.^{4,18} In a study with spinal cord lesion patients, the total duration of DO contractions appeared as the only statistically significant urodynamic variable that correlated with upper tract dilatation or with vesicoureteral reflux.¹⁸ Although DLPP is a measure of outlet resistance, treatment of patients with a high DLPP is directed toward reducing the vesical pressures and increasing the bladder capacity. Reducing the number and amplitude of overactive detrusor contractions and improving bladder compliance, for example, with antimuscarinics, botulinum neurotoxin, or bladder augmentation is the mainstay of treatment. The clinical implication of DLPP is to help estimating how much and how long the urinary tract system will be exposed to high pressure in-between bladder emptying periods (with or without CIC) in the patient's daily life.

End Filling Pressure (EFP)

Another problem with the utilization of DLPP is that a significant number of patients with N-LUTD do not leak during studies. It is generally accepted that the filling phase finishes when the detrusor pressure remains over 40 cm H₂O without leakage. In a recent study of 80 children with MMC and a median age of 7 years (range 2–17), the majority of children with MMC did not leak during urodynamics but bladder wall thickness as well as urinary levels of TGF- β 1, NGF, and TIMP-2 were found to be significantly increased when DLPP or EFP was greater than 40 cm H₂O in this cohort.¹⁹ Alternative methods, such as biomarkers, may become available to predict UUTD.

A recent study has challenged the predictive value of EFP in predicting UUTD in a cohort of children who underwent bladder neck surgery (different types of slings) without augmentation for neurogenic incontinence.²⁰ Seventeen children with sustained EFP >40 cm for more than 1 year despite anticholinergics were included in the study. During a mean follow-up of 39 months, new hydronephrosis or VUR developed in six (35%), whereas all new hydronephrosis resolved with medical treatment, as did two out of three new VUR cases. The other patient with VUR had successful suburethric injection.

The authors concluded that despite a sustained EFP >40 cm, upper tract changes developed in only 35% of patients, and resolved with medical management or minimally invasive interventions, and suggested that EFP should not be used as an independent indication for augmentation.

Neurourology and Urodynamics DOI 10.1002/nau

CONCLUSION

Although the causative relationship between the pressure within the urinary tract and UUTD has been acknowledged for a long time, there are still many caveats regarding the standardization of urodynamic measurements and their predictive roles. According to the fifth International Consultation on Incontinence, DLPP in patients with N-LUTD is considered a relevant parameter with the recommendations of grade B/C.¹⁰ It has been stated that DLPP is not consistently defined throughout the literature and that lack of standardization is hindering comparison of studies.

Using a single "safe-unsafe" cut-off at 40 cm H₂O may not reflect clinical reality and as McGuire suggested, a clinical management approach with an "as low as" reasonably achievable detrusor pressure over the entire daily volume range is advisable.²¹

The clinical recommendations on the basis of this review of DLPP are summarized in Table II. Better standardization of DLPP measurements as well as better definition of urodynamic capacity where leakage occurs and of EFP as well as of leak point pressure at overactive detrusor contraction will be helpful. The bladder volume at which leakage occurs is very important in order to adapt patients to CIC. Furthermore, EFP and N-DO LPP should be separated from DLPP in urodynamic investigations, and the definition should include the difference between these terms in order to prevent any confusion. Prospective follow-up studies in patients with N-LUTD to evaluate the predictive value of these parameters for upper tract deterioration are recommended. This manuscript has summarized the practice and interpretation of DLPP from a clinical perspective.

ACKNOWLEDGMENT

We would like to thank the members of the ICS Urodynamics Committee core panel for establishing the teaching module and reviewing the manuscript.

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ICS Educational Module: Electromyography in the assessment and therapy of lower urinary tract dysfunction in adults

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International Continence Society
Educational Module

1

ICS Educational module

- This slide set should be used together with manuscript „ICS educational module: Electromyography in the assessment and therapy of lower urinary tract dysfunction in adults. Neurourol Urodyn. 2018;37: 27-32“, which provides the scientific background and the evidence base for use of EMG in urology as well as references.

Principle of EMG

- Recording of the electrical activity from (striated) muscle with electrodes, to unveil function and innervation.

2 methods:

Needle EMG > Needle electrode(s): Inside muscle – motor unit.

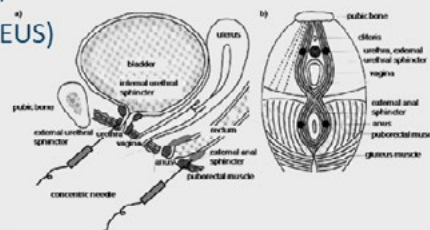
- Positive: - allows assessment of single action potentials
- Negative: - invasive
 - complex expertise in EMG required

Surface EMG > Surface (patch) electrode(s): On muscle – ‘whole’ muscle.

- Positive: - non-invasive, less time- and money-consuming
- Negative: - less specific, less ‘detail’
 - does not allow assessment of single action potentials

EMG tests in adult urology

- Needle EMG of external anal sphincter (EAS)
- Needle EMG of external urethral sphincter (EUS)
 - Monopolar
 - Bipolar (concentric)
 - Wire(s)



- Surface EMG of external anal sphincter (EAS)
- Surface EMG and sacral reflexes conductivity testing
- Surface EMG and biofeedback
- Surface EMG with cystometry and pressure/flow
- *Surface EMG = ‘kinesiological EMG’: with pair (or array) of electrodes over muscle*

Needle EMG of external anal sphincter (EAS)

Principle:

- Recording of electrical activity of EAS
- Elements of muscle activity of the pelvic floor

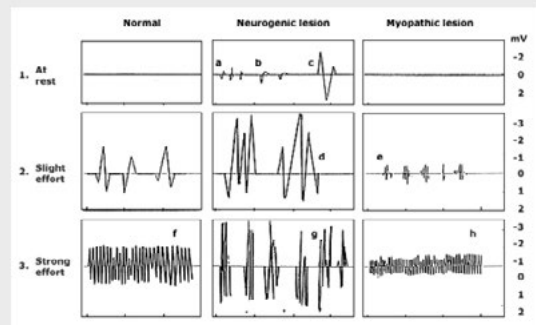
Technique:

- Patient in lateral decubitus or lithotomy position
- EAS: Needle electrodes inserted bilaterally, approximately 0.5 cm lateral to the anus
- Assessment during maximal relaxation, during slight pelvic floor contraction, during maximal voluntary contraction and or during artificial bladder filling

Needle EMG of external anal sphincter (EAS)

Evidence:

- Potentially useful to detect disturbances in neuroregulation of the pelvic floor muscles in patients with
 - lower motor neuron lesion
 - demyelinating diseases
 - with Parkinson disease
 - Multiple System Atrophy



Sakakibara R, et al.: J Neurol Neurosurg Psychiatry 2000; 68:25

Needle EMG of external urethral sphincter (EUS)

Principle:

- Direct recording of electrical activity of EUS

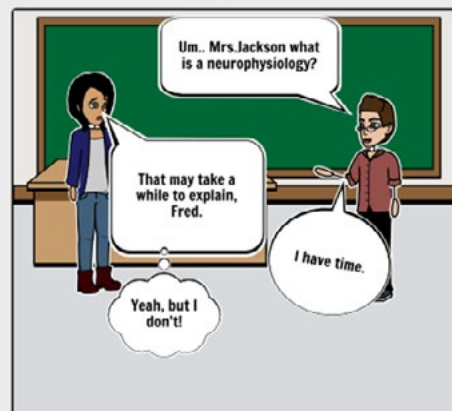
Technique:

- Patient in lateral decubitus or lithotomy position
- Needle electrodes inserted transperineally (♂) or transvaginally (♀) or transurethrally – via catheter
- Assessment during maximal relaxation, during slight pelvic floor contraction, during maximal voluntary contraction and or during artificial bladder filling

Needle EMG of external urethral sphincter (EUS)

Evidence:

- Limited evidence for role in clinical setting for EUS –EMG
- Some role in Fowler's (♀ retention) syndrome
- Potentially useful in direct detection of electrical activity while bladder filling



Surface EMG of external anal sphincter (EAS)

Principle:

- Recording of muscle activity using surface (patch) electrodes or electrodes on cone or plug

Technique:

- Degreasing of the perianal skin
- 2 'active' electrodes adjusted bilaterally to the muco-cutaneous line + ground electrode
- Assessment of activity rest vs. contraction

Evidence:

- Tool to detect pelvic floor muscle activity or relaxation

Surface EMG and Sacral reflexes conductivity testing

Principle:

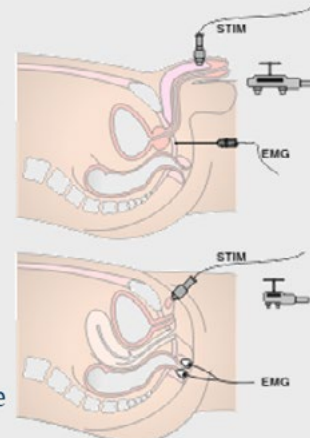
- Stimulation of the pudendal nerve to induce pelvic floor contraction to evaluate of bulbocavernosus (cliterno-anal) reflex

Technique:

- Stimulation using electrode dorsal at the base on the penis (♂) or on clitoris (♀)
- The response recorded with surface or needle electrodes from the region of anal sphincter or bulbocavernous muscle

Evidence:

- Absence or delay in response, suggest lower motor neuron impairment
- No relevant recent study which could support the role of this examination in the daily clinical work-up was found



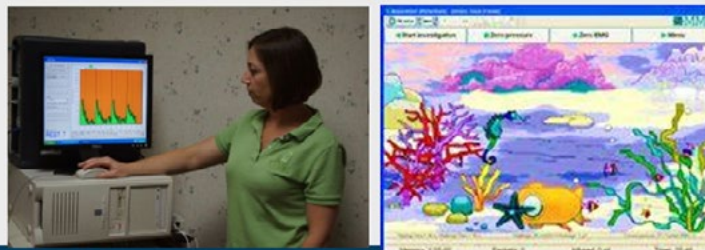
Surface EMG and biofeedback

- **Principle:**

- Detect the pelvic floor muscle activity and transform it into a visual and/or acoustic display in order convey the information to the patient

- **Technique:**

- Surface electrodes are placed close to the anal sphincter or on an anal or intravaginal plug
- Recorded signal transformed into apparent sound or visual clue
- Allows the patient to better understand the functional status of the pelvic floor



Surface EMG and biofeedback

- **Clinical observations:**

- Baseline between contractions – inconsistent and elevating
- Resting baseline – varies widely from session to session, especially when pain exists
- Erratic tracing without artifact or noise
- Patient has symptoms of overactive PFM – obstructed urination, defecation, pain
- Return to baseline after startle or frightening – overactive PFM is slow
- 2/3 of dysfunctional muscles will have normal resting baseline

Surface EMG and biofeedback

- **Evidence:**

- Potentially useful for conservative treatment (PFM training) of stress urinary incontinence and OAB
- Little evidence regarding the use of EMG biofeedback as tool to help relax the pelvic floor muscles during micturition in adults

Dannecker C, et al: Arch Gynecol Obstet. 2005;273(2):93-7; Wang AC, et al: Urology. 2004 Jan;63(1):61-6

Surface EMG with cystometry

Principle:

- Recording of pelvic floor muscle activity during filling of the bladder.

Technique:

- Surface EMG (as on earlier slides)

Evidence:


- Introduced on the basis of expert opinion/ plausibility
- No (comparative) evidence
- Surface EMG may fail to reflect urethral (continence) function

Surface EMG with pressure flow studies

Principle and technique:

- Identical to surface EMG

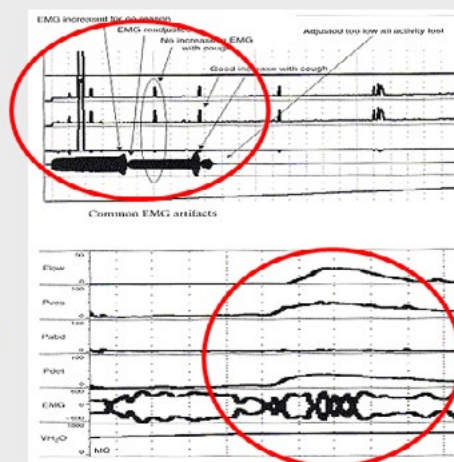
Evidence:

- Introduced on the basis of expert opinion/ plausibility
- No (comparative) evidence
- Expert series demonstrating plausible results
- However: Large (n= 655) prospective cohort  with EMG revised:
 - Many (51%) were not interpretable (but also)...
 - ...surface EMG failed to reflect EUS relaxation.

Kirby AC et al. Neurol Urodyn 2011; 30: 1591-1596

Surface EMG (adult)

- May be not interpretable
 - (technical) artefacts
- May give not plausible results
 - Not reflect relevant (EUS) activity
 - Smooth flow-rate and bizarre EMG



sEMG with urodynamic tests (adult)

Lacking practice standards for:

- Display: envelope; linear envelope; full wave; half wave
- Time scale
- Sampling: ... Hz; Filtering: moving average; root mean square
- Placing of active electrodes (♀ ; ♂)
- Impedance check(s) (cleaning of skin): <5 (or <10) k Ω
- Reference electrode - neutral! (Not on another muscle); trochanter; pelvic rim; sacrum
- Technical and clinical quality checks
- Analysis, interpretation and reporting

sEMG with urodynamic tests (adult)

- Not very invasive
- Not very time and cost consuming
- Without standard
- Without certainty of relevance
- May add confusion if artefacts are not acknowledged
- May be of help in (pelvic) muscle strength and control training and learning to relax


EMG tests in adult urology

- The concept of use of EMG methods in functional urology/urogynaecology and physiotherapy is supported by good theoretical basis
- Current value of EMG in diagnosis is however limited
- Currently EMG practice can only rarely play a decision making role in diagnostics of LUT partially due to lack of standards

A long way ahead.....



ICS Educational Module: Electromyography in the assessment and therapy of lower urinary tract dysfunction in adults

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Aim: To present the teaching module “Electromyography in the assessment and therapy of lower urinary tract dysfunction in adults.” This teaching module embodies a presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base made available on ICS website to summarize current knowledge and recommendations.

Methods: This review has been prepared by a Working Group of The ICS Urodynamics Committee. The methodology used included comprehensive literature review, consensus formation by the members of the Working Group, and review by members of the ICS Urodynamics Committee core panel.

Results: Electromyography (EMG) is a method to record spontaneous or artificially induced electrical activity of the nerve-muscle unit or to test nerve conductivity. EMG of the anal sphincter using surface electrode is most widely used screening technique to detect detrusor-sphincter dyssynergia in urology. It is non-invasive and easy to perform. EMG methods using needle electrodes are reserved for diagnostics in well selected group of mainly neurogenic patients. These methods require expertise in the field of general EMG and are usually performed by neurologist and neuro-physiologist. The evidence in many aspects of use of EMG in urology remains sparse.

Conclusions: Currently EMG methods rarely play a decision making role in selecting proper treatment of lower urinary tract dysfunction. With the current efforts to improve phenotyping of these patients in order to provide individualized treatment, the role of EMG could increase.

KEY WORDS

bio-feedback, diagnostics, electrode, electromyography, ICS teaching module, urinary incontinence

1 | INTRODUCTION

The role of electromyography (EMG) is to record spontaneous or artificially induced electrical activity of the nerve-muscle unit or to test nerve conductivity. It is a component of the comprehensive urodynamic evaluation, however, the current

use of this method is limited. The aim of this communication is to summarize the current evidence regarding the use of EMG in adult urology and provide some suggestions for future research which could lead to further development of this diagnostic and therapeutic method in urology. This paper was prepared by a Working Group of The ICS Urodynamics Committee. The methodology used included comprehensive literature review, consensus formation by the members of the Working Group,

Roman Zachoval led the review process.

and review by members of the ICS Urodynamics Committee core panel. Literature review was performed according to the modified PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) methodology in March 2016.¹ Following Medical Subject Heading (MeSH) were used for electronic search on MEDLINE database: (a) electromyography; (b) neurofeedback; (c) lower urinary tract symptoms; (d) urodynamics; (e) pelvic floor disorders. Terms (a) and (b) were subsequently crossed with (c); (d); and (e). Total 1576 publications were identified. After removing duplications (1576-355 = 1221), all articles published before 1986 (1221-302 = 919) and all articles in other than English language were excluded (919-132 = 787). We identified 81 relevant papers which served as a evidence base for preparation of this manuscript and slide set. The ICS Urodynamics Committee presents this teaching module to serve as a standard education tool for professionals involved in diagnostics and treatment of lower urinary tract dysfunctions. The teaching module consists of a ICS Power Point Presentation, available via <http://www.icsoffice.org/eLearning/> and this paper which serves as a scientific background review. The presentation and this manuscript contain experts' opinion where evidence is, especially for the clinical practice aspects, unavailable and is marked with: "eo" (expert opinion).

1.1 | History

EMG is the oldest and most widely used electrophysiological assessment method. The first records of EMG use involved examination of skeletal muscles and it dates back to 19th century. The first sphincter EMG was described by Beck in 1930.² The EMG of the anal sphincter was first used in clinical setting by Bailey in 1968.³ He used EMG as a part of complex neuro-urological evaluation of 184 incontinent children with neurogenic bladder. He also proposed that EMG could be used in adults with neurogenic bladder. Chantrain was the first to conduct comparative studies of skeletal muscle and anal sphincter EMG.⁴ In 1979, Mayo included EMG of the anal sphincter into the urodynamic assessment.⁵ The future steps in the development of this diagnostic method were marked by neural conductivity studies looking at sacral reflex pathways in 1970s and finally introduction of sensory and motor evoked potentials testing which was first published in 1982.^{6,7}

1.2 | Electrophysiology

An intact and functioning motor unit (MU) is the basic component required for adequate function of any muscle. MU consists of a single α -motoneuron residing in the anterior horn of the spinal cord, axon nerve fiber and corresponding muscle fiber. Neurons conduct electrical impulses—action

potentials. Action potentials are waves of cell membrane depolarization which travels toward the periphery. The transmission of neural action potential to a respective muscle, which leads to its contraction, takes place at the neuromuscular junction. The action potentials are associated with changes in extracellular and intracellular currents, which could be recorded and processed for their quantitative (frequency and amplitude of action potential) and qualitative (pattern of action potential) characteristics. Simultaneous activation of multiple motor units leads to contraction of a single muscle. Voluntary contraction force is modulated by the number of recruited MU and changes in the activation frequency. The number of recruited MU and their mean discharge frequency of excitation determines the electrical activity, which could be recorded using EMG. There is a direct relationship between the EMG and the muscle force.

1.3 | Technical aspects of EMG

Most clinical EMG devices use a differential amplifier to enhance the display of information. This includes two or more active electrodes placed in proximity to the target muscle or muscle fibers and a common electrode placed equidistant from the active electrodes or on a neutral tissue. The differential amplifier compares the information in all electrodes and discards any information that is the same in all electrodes. This represents the background electrical noise of the body. The remaining information (the target muscle) is then amplified to reduce the influence of artifact or environmental noise on the signal.

Technical parameters of the EMG unit play crucial role in validity of the obtained information. The quality of units used in urology differs significantly. A minimal technical requirement for EMG unit for use in urology should include: Bandwidth: 30 Hz-10 kHz; Time scale: 10-100 ms; Sensitivity: 0.1-2.0 mV; 5p DIN connector; 1.5 mm touch-proof connector for common electrode; EMG processing average rectified curve, raw EMG curve, and audio EMG.

1.4 | Electrodes

In general electrodes are used for recording changes in the algebraic sum of motor unit action potentials, or for neural stimulation. The recording unit consists of two or more active electrode and a ground electrode. The size of the electrode determines the specificity of the recording. Larger electrodes are used to record large muscle areas such as the activity of the entire pelvic floor muscle contraction. Smaller electrodes are used to evaluate single motor units. According to their design, technical characteristics and purpose (recording vs stimulation) electrodes are divided in several groups:

Needle electrodes are inserted into the recording muscle and are designed to record single fiber action potentials or action potentials from a small number of units.

1.4.1 | Coaxial needle electrode

Is the most widely used type of needle electrode used in myography performed by neurologists. It consists of the platinum wire (active electrode) which is wrapped in a steel sheet (reference/common electrode). The electrode records the differences in a single action potential between the tip of the platinum wire and the conductive sheet.

1.4.2 | Bipolar needle electrode

Consists of two platinum wires embedded in the sheet and records the difference between action potentials recorded by the two active wires.

1.4.3 | Monopolar needle electrodes

Measure activity recorded by a conically shaped tip of the needle which is embedded in the unconducting sheet. Compared to coaxial needles, it has a larger recording surface, and a wider pick-up field, resulting in higher amplitudes of recorded potentials. This does not allow for recording of action potential from a single muscle fiber and is therefore less specific.

1.4.4 | Surface electrodes

Surface electrodes are placed on the skin overlaying the muscle of interest. This includes both external patch and internal vaginal or rectal probe electrodes. They consist of silver chloride conductive discs or bars. They have a larger reception field, which means that they display a summary of the entire muscle not single action potential. They are however, easy to use and not associated with needle insertion, therefore, despite their low sensitivity they are the most widely used electrodes in urodynamic evaluation.

1.4.5 | Stimulation electrodes

Their principal use is to provoke action potential remotely, which is then picked up by the recording electrode for the purpose of assessing the nerve conductivity and neuromuscular transmission. They could be designed as both needle or surface electrodes of different shapes according to the type of use (clip electrodes, band electrodes).

2 | EMG METHODS USED IN UROLOGY

2.1 | Needle EMG of anal sphincter

2.1.1 | Principle

External anal sphincter is the component of the pelvic floor which is easiest to identify and target using a needle electrode. Due to close anatomical location and shared innervation, its activity could implicate the activity of other anatomical structures of the pelvic floor. It is therefore used as a tool for indirect evaluation of the urethral closing mechanism.

2.1.2 | Technique

With the patient in the lateral decubitus or lithotomy position, under digital rectal control, needle electrodes are inserted bilaterally, approximately 0.5 cm lateral to the anus. The depth of insertion is 3-8 cm, depending on patient's constitution.

First, we assess the EMG during maximal relaxation, then during slight pelvic floor muscle contraction or during slow artificial bladder filling. Subsequently we assess the sphincter activity during maximal voluntary contraction of the anal sphincter. To obtain reproducible results it is necessary to record at least 10-20 single action potentials in every phase of the assessment.⁸ This assessment is challenging for the patient, time consuming, requiring skills, and expertise.

2.1.3 | Evidence

Anal sphincter EMG using needle electrodes allows the physician to detect disturbances in neuroregulation of the pelvic floor muscles, which could be due to spinal cord injury, lower motor neuron lesion, demyelinating diseases, and Parkinson disease. It could indirectly detect detrusor-sphincter dyssynergia (*eo*).

However, no systematic study or meta-analysis has been published during last two decades with the topic of the use of needle EMG of the anal sphincter in urology. Currently, only limited evidence based on single center expert opinion is available (*eo*).

2.2 | Needle EMG of urethral sphincter

2.2.1 | Principle

Direct detection of the activity of the striated external urethral sphincter.

2.2.2 | Technique

In male patients the needles are inserted into the perineum 0.5 cm lateral to the midline at the point of projection of the urethral bulb. The needle tip is directed toward the apex of the prostate and the depth of insertion is controlled by digital rectal examination (DRE) and by acoustic and visual evidence of activity recorded by the EMG equipment. In female patients the electrodes are inserted transvaginal, after the bladder neck is identified with help of a urethral Foley catheter. The recording technique is identical to that of the anal sphincter.

2.2.3 | Evidence

Allows direct recording of the urethral sphincter, however, due to its invasive nature and technical difficulty is used only used in a limited number of carefully selected cases, most often in research studies.⁹ Basic work describing the use of needle EMG of the urethral sphincter can be dated back to 1984.¹⁰ More recently Mahajan confirmed the superiority of needle urethral sphincter electrodes compared to surface electrodes.¹¹ However, only limited evidence based on single center expert opinion is available.

2.3 | EMG of anal sphincter using surface electrodes

2.3.1 | Principle

Non-invasive detection of activity of the entire pelvic floor muscles which is routinely used in urology in course of uroflowmetry or invasive urodynamics.

2.3.2 | Technique

Surface patch electrodes are attached adjacent to the mucocutaneous line of anus bilaterally. The impedance of the skin is reduced using careful degreasing. In some cases a careful epidermis abrasion is required. Excessive hair and adipose tissue around the anal sphincter decrease accuracy of the EMG reading. The electrode wires need to be positioned away from the urine stream. Practitioners are also cautioned not to place the electrodes too lateral in which case the gluteus muscles are being recorded. The common electrode can be placed on the thigh or trochanter. The proper attachment of the electrodes is subsequently tested by recording increased activity during the voluntary pelvic floor contractions.

2.3.3 | Evidence

Evidence for using EMG diagnosis of anal sphincter dysfunction using surface electrodes in adults remains weak. This modality is used for screening purposes to detect detrusor-

sphincter dyssynergia in patients with neurogenic bladder and impaired pelvic floor muscle relaxation in patients with dysfunctional voiding. Recently it has been documented that anal sphincter EMG using surface electrodes did not document pelvic floor muscle relaxation during voiding in the majority of a large cohort of patients, suggesting the low sensitivity of this evaluation.¹² However, in pediatric urology literature evidence has been published in support of the beneficial role of simultaneous uroflowmetry and EMG to detect dysfunctional voiding. The argument is that abnormal voiding pattern, that is, staccato and interrupted/fractionated voiding observed on uroflowmetry alone, can lead to overdiagnosis of dysfunctional voiding or detrusor underactivity and that adding simultaneous EMG could significantly improve the diagnostic accuracy.¹³ In addition, evidence of usefulness of EMG lag time has been reported in children. EMG lag time is a uroflow/EMG measurement of the time interval between the moment that relaxation of the pelvic floor EMG takes place and the moment urine flow begins. When the lag time is short it is supportive of the diagnosis of detrusor overactivity, while prolongation supports the diagnosis of primary bladder neck dysfunction, especially when they appear in combination with certain LUTS and uroflow patterns.¹⁴ These data should stimulate future studies exploring the role of simultaneous uroflow and EMG in adults.

2.4 | Sacral reflex conductivity testing

2.4.1 | Principle

Stimulation of the pudendal nerve to induce pelvic floor muscle contraction. The presence or absence of response of pelvic floor muscles is evaluated together with recording for latency interval between the stimulus and the response. The goal is to assess the peripheral limb of the micturition reflex.

2.4.2 | Technique

Neurostimulation is performed with surface electrodes attached at the dorsal aspect close to the base of the penis in men and to small labia in women. The response could be recorded by both surface or needle electrodes from the region of anal sphincter or bulbocavernous muscle.

2.4.3 | Evidence

This modality is potentially useful for evaluation of bulbocavernosus and anorectal reflexes.

Absence or delay in response, suggest lower motor neuron impairment. No relevant recent study which could support the role of this examination in daily clinical work-up was found.

2.5 | EMG biofeedback

2.5.1 | Principle

Detect the pelvic floor muscle activity and transform it into a visual and/or acoustic display in order to convey the information to the patient. This is subsequently used for biofeedback training.

2.5.2 | Technique

Surface electrodes are placed close to the anal sphincter (as described above) or inside the vaginal or rectal canal. The recording signal is transformed into sound or visual clue and used to guide the patient to better understand the functional status of the pelvic floor muscles.

2.5.3 | Evidence

This technique is widely used in conservative treatment of incontinence. Acoustic or visual clues help patients to improved awareness of their pelvic floor muscles and to improve their ability to selectively contract the appropriate group of muscles. EMG biofeedback seems to be effective in the conservative treatment of stress urinary incontinence as well as overactive bladder.^{15,16} However, there is only limited number of well designed randomized controlled studies to support this observation.

On the other hand, in dysfunctional voiders, EMG biofeedback is used as a tool to help relax the pelvic floor muscles during micturition. While being a well established method in the treatment of voiding dysfunctions in the pediatric population, where combination of acoustic and visual biofeedback plays an important role, evidence in adults is lacking.^{17,18}(*eo*).

2.6 | Patients perspective

Electromyography does not require any specific patient preparation. Patients must be properly instructed that insertion of EMG needles is associated with a certain degree of pain. Surface EMG is non-invasive and painless. However, the patient must be informed that hair removal, skin defatting and, in some cases, epidermis abrasion is required before placing electrodes. In all cases, but especially for EMG used for biofeedback, patients should be physically and mentally capable of following instructions given by the health care professional (eg, contraction or relaxation of the pelvic floor muscles).

2.7 | Standards for reporting EMG data

The “Standards for Reporting EMG Data” endorsed by the International Society of Electrophysiology and Kinesiology have

been written by Dr. Roberto Merletti.¹⁹ This document summarizes technical information that has to be included for each type of electrode, necessary data on detection mode, amplification, rectification of signal and its computer processing. In addition it provides guidelines on EMG amplitude and frequency processing, normalization, EMG processing for estimation of muscle fiber conduction velocity and EMG crosstalk. Every medical professional using EMG, especially in research, should follow these guidelines.

2.8 | Suggestions for future research

There is a clear lack of evidence in many aspects of the use of EMG in urology. High quality trials are required especially in following topics:

1. EMG pattern of the pelvic floor muscle under physiological and pathological conditions.
2. Role of the EMG in the comprehensive urodynamic evaluation.
3. Role of EMG in the phenotypisation of the patients suffering from LUTS.
4. Role of the pelvic floor muscle EMG as a biofeedback tool in LUT dysfunctions.
5. Role of audio monitoring during EMG in adults.
6. Role of simultaneous uroflowmetry and EMG in detection of voiding dysfunctions, detrusor overactivity, and detrusor underactivity in adults.

3 | CONCLUSIONS

The concept of the use of electrophysiological methods in urology is supported by good theoretical basis. However, the evidence supporting the value of EMG techniques in diagnostics is limited. With the current efforts to improve phenotyping of these patients in order to provide individualized treatment, the role of EMG could increase. In contrary evidence in support of EMG biofeedback exists and should be considered an integral part of conservative treatment of incontinence, OAB, and dysfunctional voiding.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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Filling Cystometry

Carlos D'Ancona, Mario João Gomes, Peter F.W.M. Rosier

Cystometry - Definition

- Transurethral or suprapubic continuous fluid filling of the bladder, and measurement of vesical and abdominal pressures
- ...Cystometry ends with 'permission to void' or with incontinence (involuntary loss) of the (total) bladder content.

Cystometry: Aims

- To diagnose lower urinary tract reservoir function and find an explanation for the patients' complaints
- To evaluate lower urinary tract reservoir function for research purposes

Cystometry (clinical relevance)

- Demonstrate the reservoir function of the bladder relevant to the symptoms and signs that the patient perceives

What should be known before starting?

- Patient's perceived (LUT-) symptoms and signs
 - Symptoms questionnaire (preferable)
 - Voiding diary ('usual' volumes voided)
 - 'Predict' -estimated- cystometric capacity
 - Free uroflowmetry
 - Post void residual urine

ICS Standard:

- Fluid filled: saline solution
- External pressure transducers
- Reference = pressure at the level of the symphysis
- Patient in standing position
- Fill until strong desire to void
- Medium fill-rate (e.g. 10% of expected capacity /minute)
- Indicate end of cystometry on trace
 - Stopping of the pump (and /or)
 - 'Permission to void'

Solution infused

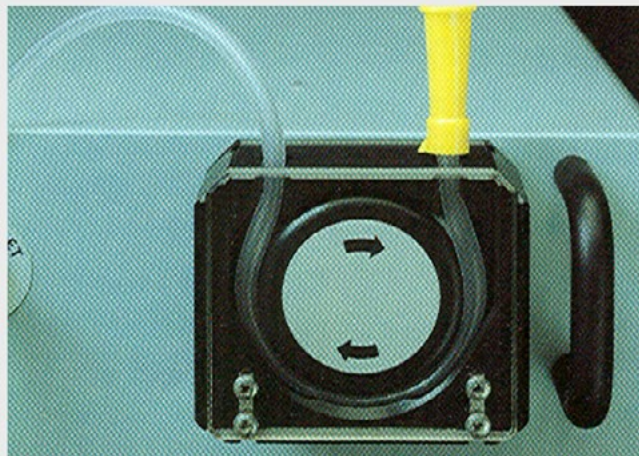
- Saline solution
 - Or contrast
- Temperature
 - Room temperature



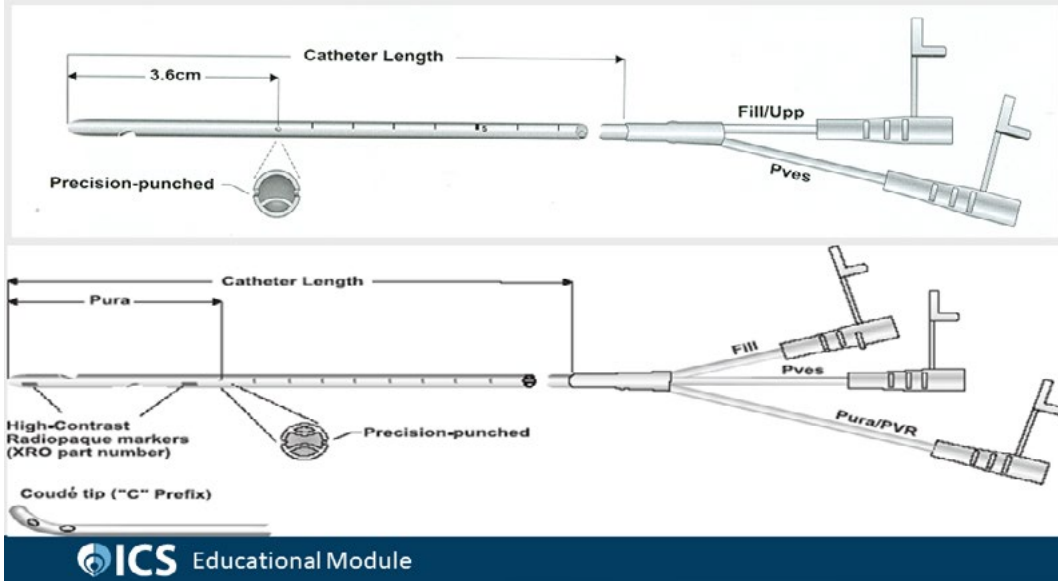
Patient position during cystometry

- Sitting (standing) position is more provocative for abnormal detrusor activity (ex. overactivity) than the supine position. At some point in the test, filling might desirably take place with the patient standing.
- Patients unable to sit or stand → supine position.

Infusion Pump



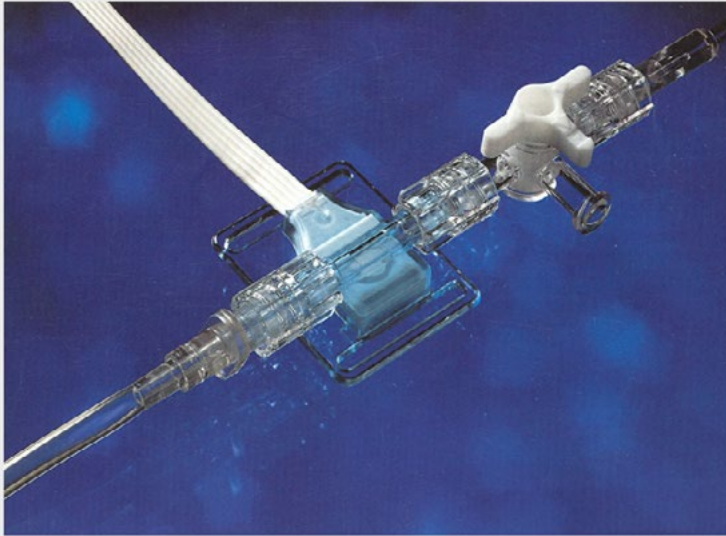
Urethral Catheter



Insert catheters

- Usually lithotomy position
- Sterile catheters
 - Vesical: double lumen (or separate)
 - 6-7F
 - Rectal: catheter with a punctured balloon
- Fix the catheters adjacent to the meatus
- Patient in comfortable position
- Cover the patient - ex. with a towel

Transducer



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Position of the Transducer

- External transducer measured at the level of the symphysis pubis
- Equals: Base of the bladder
- Intra rectal and intravesical pressures are assumed to be measured at identical levels



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Filling cystometry

- Initial resting pressure
 - Supine 5 -20cmH₂O
 - Sitting 15-40cmH₂O
 - Standing 30-50cmH₂O

Hogan S. Neurourol & Urodyn 2012, 31: 1104-117

Bladder sensation - classification

- ***Normal bladder sensation***
 - can be judged by three defined points noted during filling cystometry and evaluated in relation to the bladder volume at that moment and in relation to the patient's symptomatic complaints.
- ***First sensation of bladder filling***
 - is the feeling the patient has, during filling cystometry, when he/she first becomes aware of the bladder filling.
 - To be separated from the sensation that the catheterisation has caused, that means it disappears after a few minutes.
- ***First desire to void***
 - is defined as the feeling, that would lead the patient to pass urine at the next convenient moment, but voiding can be delayed if necessary.
- ***Strong desire to void***
 - is defined, as a persistent desire to void without the fear of leakage.
- ***Urgency***
 - during filling cystometry, is a sudden compelling desire to void.

- **Increased bladder sensation**
 - is defined, as an early first sensation of bladder filling (or an early desire to void) and/or an early strong desire to void, which occurs at low bladder volume and which persists.
- **Reduced bladder sensation**
 - is defined, as diminished sensation through out bladder filling.
- **Absent bladder sensation**
 - means that, during filling cystometry, the individual has no bladder sensation.
- **Non-specific bladder sensations,**
 - during filling cystometry, may make the individual aware of bladder filling, for example, abdominal fullness or vegetative symptoms.
- **Bladder pain,**
 - is a self explanatory term and is an abnormal finding.
 - Pain may increase with volume, or not, which should be reported.

Filling cystometry - information

- Cystometric capacity (mL)
 - Infused weight and pump-speed helpful during the test
 - And include diuresis (capacity: voided volume + PVR) after the test.
 - Measure PVR after pressure flow via the catheter
- Bladder sensations (mL)
 - Electronic buttons during cystometry do not include diuresis; correct after the test if needed

Bladder filling sensation

- Is a subjective parameter
 - *Depending on interaction /communication with the patient*
- Normal bladder sensation (rule of thumb) of cap.

• First sensation	+/- 175-250mL	33%
• First desire to void	+/- 272-450mL	66%
• Strong desire to void	+/- 429-700mL	100%

Bladder capacity

- Cystometric capacity – bladder volume at the end of filling phase
 - Commonly there is no reason to fill more than 800mL e.g. in the absence of sensation and/or contraction
- Maximum cystometric capacity – patient can no longer delay micturition
 - Overfilling hinders subsequent representative voiding
- Maximum anesthetic capacity – volume of bladder without urinary leakage

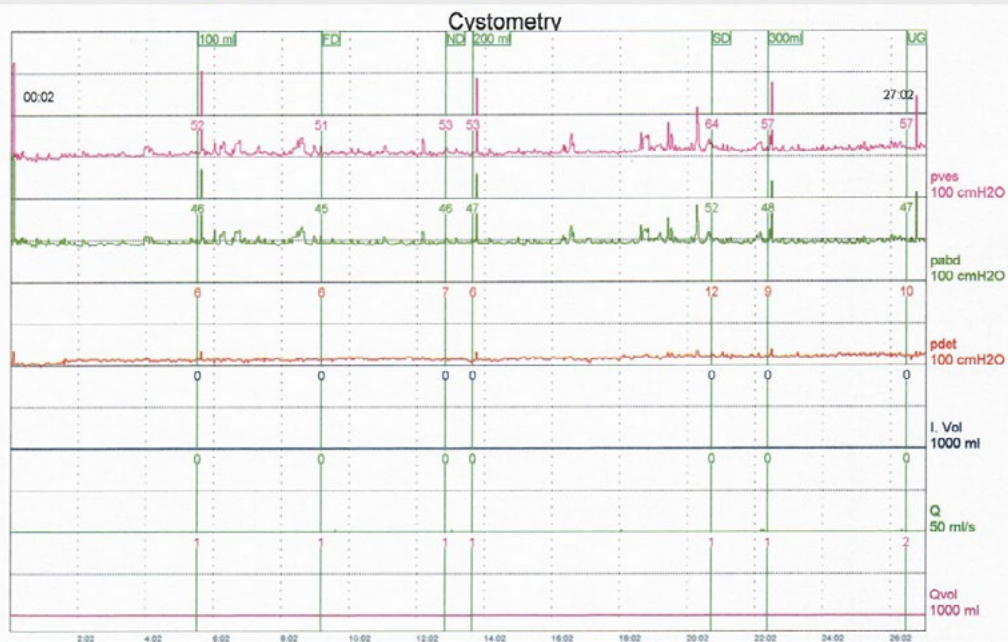
Detrusor Pressure

$$P_{det} = P_{ves} - P_{abd}$$

Schafer W. NeuroUrol & Urodyn. 2002, 21: 261-74

ICS Educational Module

Filling Cystometry



ICS Educational Module

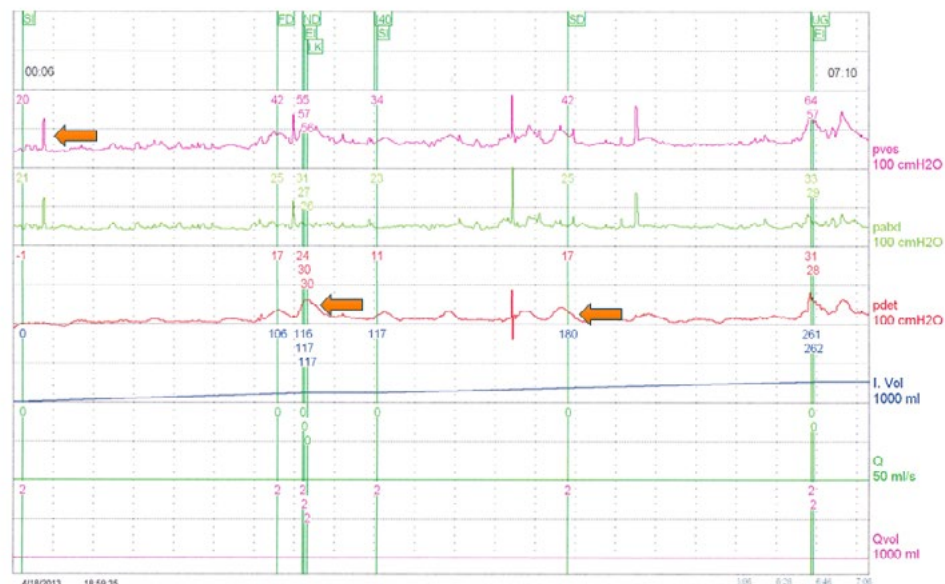
Detrusor function

- Normal detrusor function – little or no changes in pressure
 - Detrusor overactivity – ANY amplitude of detrusor pressure raise before permission to void:
 - Neurogenic; when relevant neurological abnormalities are present
 - Idiopathic
- Cystometry patterns do not discriminate Neurogenicity: History and clinical exam**

Abrams P. Urology. 2003, 61: 37-49

ICS Educational Module

Detrusor overactivity



ICS Educational Module

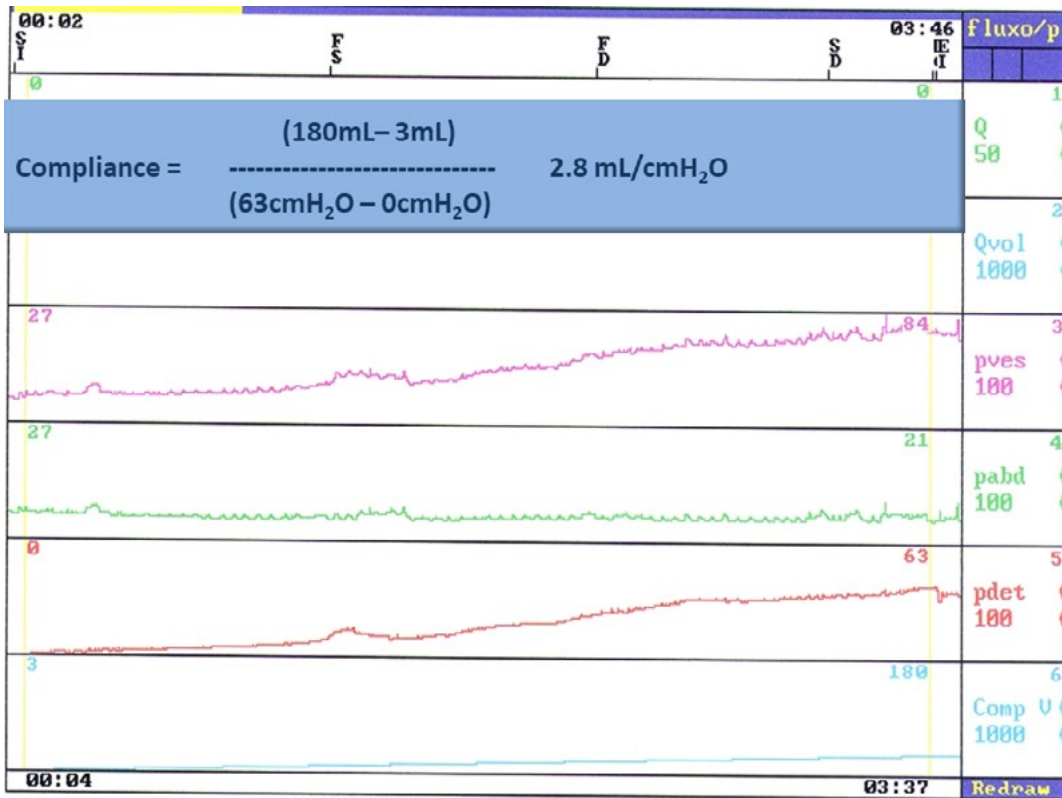
Bladder Compliance

- Good compliance is large volume and low pressure

$$C = \frac{(V1 - V0)}{(P1 - P0)}$$

Abrams P. Urology. 2003, 61: 37-49

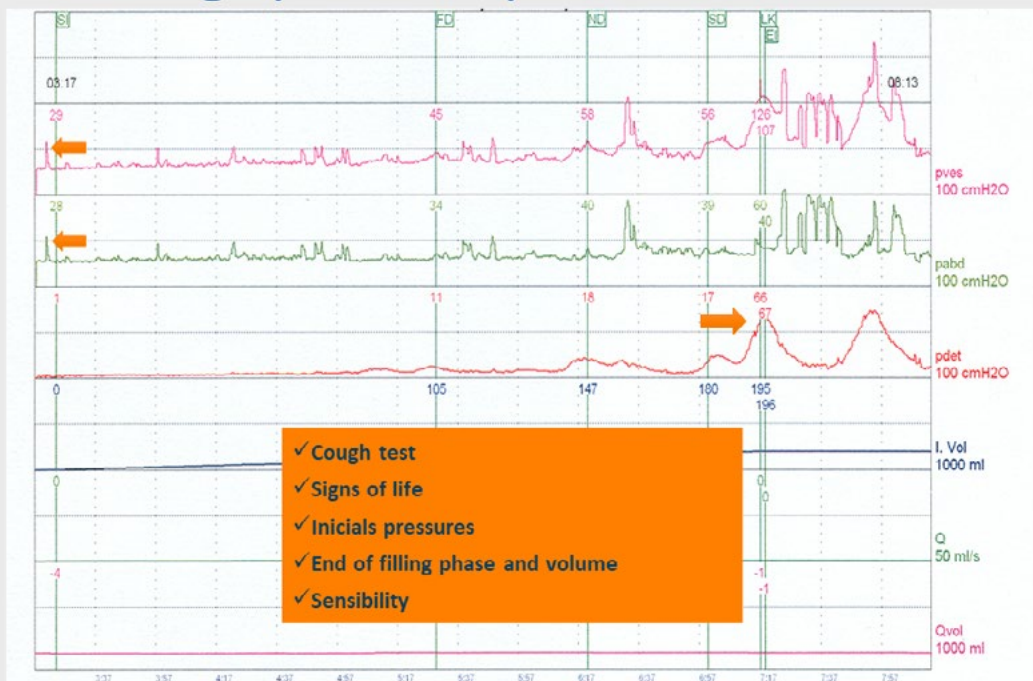
 ICS Educational Module



Bladder Compliance – Normal Values

- Not well defined
- (Neurogenic) LUT dysfunction:
 - (low) values 13 – 40 mL/cmH₂O, upper tract risk
- Normal >40 mL/cmH₂O
- Low <30 mL/cmH₂O
 - Relation with sensation, volume and leak point

Filling cystometry



Cystometry

- Patient should be relaxed and trustful
- Technically adequate
- Observe the pressures 'as an engineer'
- Perform the test as representative for the usual situation as possible
- Systematically report all observations

Thank You

ICS teaching module: Cystometry (basic module)

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Aims: To summarize the evidence background for education of good urodynamic practice, especially cystometry.

Methods: A search was done in PubMed for the last 5 years of publications selecting only clinical studies, utilizing the following keywords: cystometry 133 articles and filling cystometry 53 articles.

Results: The evidence with regard to clinical setting and cystometry technique, as well as for catheters and transducers type, infused solution and patient position is presented with recommendations. Also the practice of determining bladder filling sensation and capacity and the basis of detrusor storage function diagnosis is educated.

Conclusions: This manuscript provides the evidence background for the practice of cystometry.

KEYWORDS

cystometry, urodynamics

1 | INTRODUCTION

Cystometry is the method by which the storage function of the lower urinary tract (LUT) is measured during the filling of the bladder.^{1,3} The aim of urodynamics is to find an objective, pathophysiological, explanation for the patient's LUT symptoms and to answer the clinical (or research) question.^{3–5} Cystometry is an important part of invasive urodynamics as it evaluates the storage function of the bladder. Invasive urodynamics, that is, cystometry requires insertion of catheters and technical instrumentation and also depends on cooperation of the patient. Urodynamics is a replication of the LUT physiology in a laboratory situation and the interpretation should be made with specific attention to representativeness, technical details, as well as clinical relevance. Cystometry is the golden standard for LUT storage function assessment.^{1–5}

The ICS Urodynamics Committee presents this teaching module “Cystometry” as standard education of Good Urodynamic Practice^{2,3} for everyone involved with indicating,

performing, and analyzing urodynamic testing. The teaching module consists of a presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base, for the ICS PowerPoint presentation; available via <http://www.icsoffice.org/eLearning/.....> The presentation explains normal physiology, testing requirements, practice of testing, and analysis methods.

1.1 | Clinical setting

Cystometry is part of invasive urodynamic investigation and contemporary guidelines recommend that a LUT symptom questionnaire, a voiding diary, clinical examination, and laboratory urine exam preceded invasive testing. Usually uroflowmetry and a post void residual urine (PVR) are also recommended before further testing. The voiding diary informs about the range of the volume of micturition and the frequency of voiding. Uroflowmetry and PVR are recommended for clinical reasons but also relevant to evaluate the representativeness of pressure flow analysis (not further discussed here). For the practice of cystometry however, PVR is also informative to be aware of the “hidden” capacity of the bladder, not visible on the voiding diary.

Dr. Alan Wein led the peer-review process as the Associate Editor responsible for the paper.

Voided volumes (including PVR) provide a clue to the urodynamic capacity that can be expected. Cystometry should result in a diagnosis of detrusor (muscle volume-adaptation) function and bladder compliance as well as diagnoses of bladder filling sensation and cystometric (bladder) capacity.¹ Clinical stress-testing during examination can demonstrate urine loss however cystometry allows stress (urinary incontinence) testing while intravesical volume and pressures are monitored, allowing to control for detrusor activity.^{6,7} All this information gives the urodynamic diagnosis of storage phase function and is basis for management of patients with symptoms and signs of LUTD.⁵ The cystometry starts (after insertion of the catheters) when the infusion begins and ends when the infusion stops under the command of the patient and/or decision of the urodynamicist.¹⁻³ Cystometry may also end with loss (incontinence) of total bladder volume.

1.2 | Technique of cystometry

Catheterization is performed trans-urethral however, can also be done via the suprapubic route. ICS standard requires fluid filled catheters connected to an external pressure transducer. Simultaneous recording of abdominal pressure (Pabd) is also standard and can be obtained with the use of a catheter in the rectum and connected to a pressure transducer.¹⁻³

The external transducers are positioned at the level of the upper border of symphysis pubic and zeroed at atmospheric pressure before connecting to the catheters, or via a tree-way stopcock while connected.³ Air bubbles in the connecting tubes and catheters cause dampening of the pressure transmission and should be removed from the system before insertion and measuring.

Before and during the exam, it is necessary to verify that both pressures are registering by asking the patient to cough.³ The amplitude of pves and pabd should be similar. The vital signs of respiration, talking of the patient, and movement should be visible in pves and pabd throughout the entire cystometry as a sign of pressure registering quality.^{2,8,9} Rectal contractions may occur during cystometry and should not be misinterpreted as detrusor overactivity in the pdet trace.⁹ On the other hand classification of intensity and frequency of rectal contractions may be of relevance.¹⁰

1.3 | Types of catheters

A double lumen catheter, as thin as possible (usually 7-8F), is ICS good urodynamic practices standard. A double lumen catheter requires an infusion pump on the filling lumen. Using a double lumen catheter allows a smooth transition from storage to voiding and permits the exam to be repeated without reinsertion of a filling catheter.

A double lumen catheter may be considered too expensive in some health care systems and in that case a 6F catheter is

inserted together with a filling catheter (usually 8-10F) that is removed at the end of the filling to avoid excess obstruction during voiding. Abdominal pressure, surrounding the bladder in the lower pelvis, is measured with a, preferably punctured, balloon filled with a small amount of fluid to prevent clogging of the catheter by rectal content, but may also be an open fluid filled tube without balloon.^{2,3} Vaginal placing or via a stoma are alternatives when the rectum is closed. Although this is—especially stoma placement—less reliable.

The size of the abdominal pressure catheter is preferably similar to that of the Pves so that the same sensitiveness to transfer the pressure is present.

1.4 | Pressure transducer

Electronic external transducer, connected to the tubing via a pressure dome is the most frequently used in ICS standard urodynamic evaluation and all pressure parameters are based on this system. New microtip or air filled transducers have the advantage of no air bubbles in the fluid system or obstruction of measuring holes, but the results obtained with these systems are not entirely identical.¹¹ New studies should elucidate the magnitude of the differences and uncover practical methods to calibrate the clinical results with the alternative systems with the available reference values obtained with fluid filled systems.

1.5 | Solution infused

Saline solution is the commonly used fluid for bladder filling. When videourodynamics is performed, a contrast solution is added. Body temperature fluid and room temperature fluid do not differently affect bladder sensory thresholds and do not unequally provoke DO or LUT irritation^{12,13} but forced diuresis (without external filling) does lead to a higher incidence of DO.¹⁴

The infusion rate is, by ICS good urodynamic practices, divided into Physiological filling rate—less than predicted maximum; calculated with body weight in kg divided by four expressed in mL/min; Non-physiologic filling rate; defined as filling rate greater than the predicted maximum filling rate.¹ A fill rate of 10% of anticipated capacity, based on voiding diary and PVR, per minute may be an acceptable rule of thumb to select the (non-physiologic) fill rate.¹⁻³

1.6 | Patient position

The ICS standard position during cystometry is sitting upright or standing in all patients able to do. The initial resting pressures, if zeroed to the ICS reference, are 15-40 cmH₂O (sitting) or 30-50 cmH₂O (standing), both for the vesical as well as intrarectal pressure. In the supine position, the vesical pressure will be 5-20 cmH₂O and the intrarectal pressure in an individual, usually somewhat higher as a consequence of this

position.¹⁵ By consequence the subtracted detrusor pressures are around zero. Small differences ($< +$ or $- 10$ cmH₂O) can be considered to be a result from differences in catheter tip position of both catheters inside the body and are therefore acceptable.

1.6.1 | Bladder sensation

During the exam verbal communication is maintained with the patient so he/she can give information about the bladder sensation. This is a subjective parameter. ICS has defined three points to be evaluated: First sensation of bladder filling—is the feeling the patient has, during filling cystometry, when he/she first becomes aware of the bladder filling. First desire to void—defined as the feeling, during filling cystometry, that would lead the patient to pass urine at the next convenient moment, but voiding can be delayed if necessary. Strong desire to void—is defined, during filling cystometry, as a persistent desire to void without the fear of leakage.^{1,3} These definitions should be put in practice as follows: First Sensation should be separated from the sensations that the catheterization has caused, that usually diminishes after the first minutes; The patient is asked “Tell me when you become aware that the bladder is not empty anymore.” Normal desire is (if no or little chronic post void residual exists) usually roughly associated with “average” FVC-BD volumes and can be asked as: “Tell me when you have the sensation that normally tells you go to the toilet, without any hurry. Strong desire is “the moment that you, without any pain, will not likely postpone the voiding any more, and or will visit the nearest restroom, eg, while shopping.” Correlating the results of cystometry volume and sensations with FVC-BD may provide background information regarding day to day sensory findings and bladder volumes. Sensation volumes are “normally” occurring at respectively ± 30 and 60% of capacity, and are also associated with the dysfunction.^{16,17} Bladder sensation can be classified with the terms normal, absent, reduced, and increased sensations. Sensation is considered increased when the sensations, as described above, occur early, at relatively small volumes.¹ Bladder sensation can also be atypical, usually in patients with neurological abnormalities (not further discussed in this module).

1.6.2 | Bladder capacity during filling cystometry

Bladder capacity during filling cystometry is characterized by cystometric capacity and maximum cystometric capacity. Usually reported is capacity at strong desire which may be interpreted as maximum cystometric capacity that should be around 500 mL in women^{16,17} and somewhat less in elderly men.⁸ Filling of more than 800 mL is seldom useful.

Maximum anesthetic capacity; the volume to which the bladder can be filled under deep general or spinal anesthetic,

without urinary leakage, is rarely reported in scientific literature but may be of relevance in (ketamine) interstitial cystitis.

Cystometry is apart from urinary tract infection and urethral lesion not associated with excessive risks. In persons with a spinal cord lesion, however, autonomic dysreflexia may occur; immediate emptying of the bladder is the remedy (further discussed in specific ICS module). After cystoplasty or myectomy of the detrusor there is an increased risk of rupture of reservoir and especially in these patients (but not exclusively) the bladder should not be filled far beyond the usual volumes.^{18,19}

1.6.3 | Detrusor function

Detrusor function can be normal or overactive.¹ Normal detrusor function—allows bladder filling with little or no change in pressure. Detrusor overactivity—is characterized by phasic detrusor pressure increments, which may be spontaneous or provoked. Examples of provocative maneuvers: non-physiological fast, for example, 100 mL/min bladder filling, change of position, stress test, and washing hands.

Detrusor overactivity should be classified as neurogenic or idiopathic. Detrusor overactivity is a urodynamic diagnosis and clinical symptoms may be urgency, urgency and incontinence, or overactive bladder syndrome.^{1,7} When detrusor overactivity is observed in a patient with a relevant neurologic abnormality (should be diagnosed based on history and clinical examination) the detrusor overactivity is neurogenic.

1.6.4 | Bladder compliance

Bladder compliance represents the relationship between change in bladder volume and change in detrusor pressure and shows the capacity of the detrusor to relax and to stretch to accommodate to volume increment. Also reduced compliance may result in frequent voiding.

The module “cystometry advanced” discusses abnormalities of sensation and or detrusor function abnormalities.

2 | CONCLUSION

The evidence with regard to clinical setting and cystometry technique, as well as for catheters and transducers type, infused solution, and patient position is presented with recommendations. Also the practice of determining bladder filling sensation and capacity and the basis of detrusor storage function diagnosis is educated and provides the evidence background for the practice of cystometry shown in the ICS teaching module slides-set and presentation.

3 | POTENTIAL CONFLICTS OF INTEREST

Dr. Rosier reports grants from T-doc, grants from MMS/Laborie, grants from Astellas, outside the submitted work; Dr. D'Ancona reports grants from Astellas, outside the submitted work; Dr. Gomes has nothing to disclose.

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ICS Teaching Module: Measurement of Post-Void Residual Urine

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Tubaro, P Rosier & E Finazzi-Agro

 **ICS** International Continence Society
Education Module

1

Definitions

 **ICS** Education Module

2

PVR

“The amount of residual urine in the bladder after a voluntary void”

Kaplan SA et al. J Urol. 2008 Jul;180(1):47-54.

Increased in pts with:

1. BOO (BPH, poor sphincter relaxation, urethral/meatal stricture or bladder stones)
2. Detrusor underactivity
3. Bladder diverticulum
4. Large volume vesicourethral reflux → “pseudoresidual”

PVR and BOO

Limits

- I. Can be due to detrusor underactivity
- II. 1/3 of male patients with BPH and bladder outlet obstruction do NOT present PVR

More useful if used in combination with uroflowmetry or other parameters.

Belal M, Abrams P: J Urol 2006

PVR

- *Threshold values delineating what constitutes an abnormal PVR are poorly defined.*
- *Most urologists agree that volumes of 50-100 mL constitute the lower threshold to define an abnormal PVR.*

Abrams PH et al . Br Med J 1978; 2: 1258.

Measurement

PVR measurement

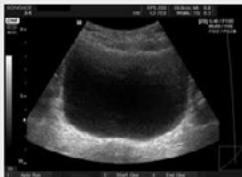
- Urethral catheterization has been accepted as the gold standard for PVR measurements, but this may cause discomfort for patients and carries a risk of urinary tract infection and trauma.

Schaeffer AJ, et al. J Urol 1983;130:1096–9.

- Non-invasive ultrasound bladder volume measurement has been used as an alternative to urethral catheterization, as a good compromise between accuracy and patients safety/comfort.

Griffiths CJ, et al. J Urol 1986;136:808-812

PVR measurement by US



Ultrasound bladder volume estimation can be performed in two ways:

1. By a real-time ultrasound to directly visualize the bladder.

Griffiths CJ, et al. J Urol 1986;136:808-812



2. By using a portable bladder scanner to calculate the volume automatically without directly visualizing the bladder.

Hartnell GG et al, Br J Radiol 60 (1987), pp. 1063–1065.



PVR measurement

Bladder scanner advantages:

1. easy to use;
2. requires only basic training;
3. can be carried out on the ward.

Reliability? (Better with additional real-time pre-scan imaging?)

Park YH: Neurourol Urodyn 2011; 30:335–8.

Significance

Significance of PVR

PVR and acute or chronic urinary retention

Chronic urinary retention has been widely accepted as corresponding to a PVR of more than 300 mL (nevertheless variable definitions).

Abrams PH, et al. Br Med J 1978; 2: 1258.

(Chronic) PVR does not seem to be a strong predictor of acute urinary retention (AUR).

Roehrborn CG, et al. J Urol, suppl., 2005; 173: 443, abstract 1638.

Significance of PVR BOO

- *It is commonly thought that the increase in PVR indicates the severity of BOO.*
- *However, abnormal measurements of free uroflowmetry or PVR can detect only voiding dysfunction without indicating BOO specifically.*
- *Nevertheless, PVR measurements are used as parameter of efficacy for medical and surgical treatments of BPO.*

Kaplan SA, et al. Eur Urol. 2007 Jun;51(6):1717-23. Epub 2007 Jan 16.

Significance of PVR

PVR and clinical progression of BPO

- *High PVR is associated with an increased risk of LUTS deterioration and should thus be reconsidered in practice as a predictor of BPO progression.*
- *According to the EAU guidelines on the Management of Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO) , very large PVRs may herald progression of disease and may indicate bladder dysfunction and predict a less favourable response to treatment.*

Oelke M, et al EAU Guidelines on the Management of Male LUTS, incl. BPO

Significance of PVR

PVR and clinical progression of BPO

- However, residual urine is not a contraindication to watchful waiting or medical therapy and no level of residual urine mandates invasive therapy and no PVR "cut-point" is yet established for decision-making.

Oelke M, et al EAU Guidelines on the Management of Male LUTS, incl. BPO

Significance of PVR

PVR and Antimuscarinics in men

- It is common belief that antimuscarinics should not be used in men with BOO for a potential of AUR.
- Some placebo controlled clinical trial data suggest that antimuscarinics (alone or in combination with an alpha-blocker) do not increase the risk of AUR and do not produce a clinically significant increase of PVR in men, even in presence of BPO.

Roehrborn CG, et al. Urology. 2008 Nov;72(5):1061-7; discussion 1067.
Athanasopoulos A, et al. Eur Urol. 2011 Jul;60(1):94-105.

However, patients with significant PVR were excluded from these studies and the safety of antimuscarinics in men remains to be confirmed.

Significance of PVR

PVR and bacteriuria

Large PVRs may be associated with UTIs, especially in persons at risk (children, patients with spinal cord injury or diabetes).

Kelly CE. Rev Urol. 2004;6 Suppl 1:S32-7.

Other studies, however, demonstrated that elevated PVR is not correlated to bacteriuria, incontinence, immobility, impaired cognition, or neurological disease.

Significance of PVR

PVR and Chronic kidney disease (CKD)

- Very large PVRs (>300 mL) may be associated with an increased risk of upper urinary tract dilation and renal insufficiency.

Kelly CE. Rev Urol. 2004;6 Suppl 1:S32-7.

- A PVR >100 mL has been associated with CKD, even if other studies do not suggest this association.

Significance of PVR

PVR and Female incontinence

Measurement of PVR is recommended in the management of female urinary incontinence.

Thüroff JW, et al. EAU guidelines on urinary incontinence. Eur Urol. 2011 Mar;59(3):387-400.

PVR should be measured during the assessment of women complaining of overactive bladder symptoms to exclude voiding dysfunction and anticholinergic medication should be used if PVR is low.

Milleman M, et al. J Urol. 2004 Nov;172(5 Pt 1):1911-4

Significance of PVR PVR and Children

Assessment of PVR is mandatory in a variety of pediatric patients, such as those with voiding LUTS, UTIs, vesicoureteral reflux, posterior urethral valves or neural tube defects.

Kelly CE. Rev Urol. 2004;6 Suppl 1:S32-7.

Recommendations and evidence summary

PVR

Actual recommendations

- The interval between voiding and PVR measurement should be as short as possible (eo). It is advisable to ask the patients if the voiding was similar to a typical micturition in his/her daily life (eo).
- Use preferably noninvasive ultrasound bladder volume measurement instead of urethral catheterization (LE 3).
- Measurement of PVR is recommended at the management of female urinary incontinence (LE 3).
- Assessment of PVR is considered mandatory in a variety of pediatric patients (LE 3).

PVR

Evidence summary

- Unrepresentative results may be obtained when voiding has to occur in unfamiliar surroundings or on command with an only partially filled or an overfilled bladder (eo).
- Portable bladder scanner may present some advantages over real-time ultrasound, especially if equipped with an additional real-time pre-scan imaging (LE 3).
- There is no universally accepted definition of a significant residual urine volume. For clinical practice, PVR <30 mL can be considered insignificant, while residual volumes persistently >50 mL could be regarded as relevant (eo).

PVR

Evidence summary

- Large PVR (>200–300 mL) often indicates LUTD and may predispose to unsatisfactory treatment results if invasive BOO treatment is undertaken (LE 3). Nevertheless, no level of residual urine, of itself, mandates invasive therapy and no PVR threshold is yet established for decision-making (LE 3).

PVR

Evidence summary

- PVR cannot be used as a robust predictor of acute urinary retention (LE 3).
- PVR can detect only voiding dysfunction without indicating BOO specifically (LE 2-3).

PVR

Evidence summary

- PVR is not increased significantly in patients treated with antimuscarinic drugs (LE 2). However, consider that patients with significant PVR were excluded from studies published up to now.
- PVR may be associated with UTI, especially in subjects at risk, such as children or patients with spinal cord injury or diabetes (LE 3). This association among adults is far from clear (LE 3).
- Large PVR may be associated with chronic kidney diseases (LE 3).

PVR

Conclusions

- Measurement of PVR is recommended in guidelines and recommendations on the management of LUTS and urinary incontinence.
- Increased PVR values may be associated with an increased risk of UTI, risk of upper urinary tract deterioration and renal failure, risk of progression in men with BPO, risk of AUR following antimuscarinic treatment and risk of poor outcome following surgery of BPO.
- Up to now, most of the ominous features associated with PVR are not evidence-based.



Measurement of Post-Void Residual Urine

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Aims: To present the teaching module "Measurement of Post-void residual urine." **Methods:** This module has been prepared by a Working Group of the ICS Urodynamics Committee. The methodology used included comprehensive literature review, consensus formation by the members of the Working Group, and review by members of the ICS Urodynamics Committee core panel. **Results:** In this ICS teaching module the evidence for and relevance of PVR measurement in patients with lower urinary tract dysfunction (LUTD) is summarized; in short: The interval between voiding and post-void residual (PVR) measurement should be of short duration and ultrasound bladder volume measurement is preferred to urethral catheterization. There is no universally accepted definition of a significant residual urine volume. Large PVR (>200–300 ml) may indicate marked bladder dysfunction and may predispose to unsatisfactory treatment results if for example, invasive treatment for bladder outlet obstruction (BOO) is undertaken. PVR does not seem to be a strong predictor of acute urinary retention and does not indicate presence of BOO specifically. Although the evidence base is limited, guidelines on assessment of LUTS generally include PVR measurement. **Conclusion:** Measurement of PVR is recommended in guidelines and recommendations on the management of LUTS and urinary incontinence, but the level of evidence for this measurement is not high. This manuscript summarizes the evidence and provides practice recommendations for teaching purposes in the framework of an ICS teaching module. *NeuroUrol. Urodynam.* 35:55–57, 2016. © 2014 Wiley Periodicals, Inc.

Key words: bladder outlet obstruction; measurement; post-void residual urine; urinary incontinence; urinary tract infections; urodynamics

INTRODUCTION

The incomplete evacuation of the bladder leads to post-void residual urine (PVR). PVR is defined as the volume (ml) of urine left in the bladder at the end of micturition.¹

The ICS Urodynamics Committee presents the teaching module "Measurement of post-void residual urine" to serve as a standard education of Good Urodynamic Practice for everyone involved in indicating, performing, and analyzing urodynamic testing in general and more specifically, performing analysis of voiding. The teaching module consists of a PowerPoint presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base for the ICS PowerPoint presentation is available via <http://www.icsoffice.org/eLearning/> or via the QR code on this page. The presentation explains testing requirements, clinical workup and analysis. The presentation and this manuscript are based on the highest-level available published evidence; evidence has been graded according to the modification of the Oxford Center for Evidence-Based Medicine levels of evidence used by the 5th International Consultation on Incontinence.² Where evidence is unavailable, experts' opinion has been used and the sentence is marked as "eo" (experts' opinion).

PATHOPHYSIOLOGY

PVR is very frequently the consequence of lower urinary tract dysfunction (LUTD), with bladder outlet obstruction (BOO) and underactive or acontractile detrusor as its most prevalent

examples. However, anatomical abnormalities for example, bladder diverticulum or large volume vesicourethral reflux may also cause PVR (in the latter case due to very early refilling of the bladder by the refluxed urine).³ BOO may be a consequence of prostate enlargement (BPE), urethral or meatal stricture, or incomplete or interrupted sphincter relaxation. Rarely a bladder stone or tumor is the cause of PVR.³ Underactive detrusor contraction can result from neurogenic, myogenic or psychogenic causes or be an effect or side effect of pharmacotherapy.³ In any individual, especially in the elderly, or the neurologically affected, the pathophysiology of PVR may be multifactorial.³ Furthermore, threshold values delineating what constitutes an abnormal PVR are poorly defined.^{4–7}

PREPARATION

PVR is measured after a flowmetry. However PVR can also be measured after visiting a normal toilet. No evidence exists about the reliability of PVR measurements in the last

Christopher Chapple led the peer-review process as the Associate Editor responsible for the paper.

Potential conflicts of interest: Nothing to disclose.

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(wileyonlinelibrary.com).

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mentioned situation. No specific patient preparation is needed. It may be reasonable to ask the patient if the voiding was similar to a typical micturition in his/her daily life.

TECHNIQUE

Ideally, the interval between voiding and PVR measurement is of short duration. Furthermore, unrepresentative results may be obtained when voiding has to occur in unfamiliar surroundings or on command with a partially filled or overfilled bladder. Although transurethral catheterization has been accepted as the gold standard for PVR measurements, this may cause discomfort for patients and carries a risk of urinary tract infection and trauma.⁸ To overcome these limitations, non-invasive ultrasound bladder volume measurement has been used as an alternative to urethral catheterization since it represents a good compromise between accuracy and patients' safety/comfort.^{9-11,31} Traditionally, ultrasound bladder volume estimation can be performed in two ways; either by using real-time ultrasound to directly visualize the bladder⁹⁻¹⁰ or by using a portable bladder scanner to calculate the volume automatically without directly visualizing the bladder.¹¹ Portable bladder scanners have many advantages over real-time ultrasound. They are easy to use, require only basic training, and can be used on the ward, freeing up precious radiology department resources. Furthermore, a bladder scanner may reduce catheterizations; minimize the threat of urethral injuries and causes less patient discomfort. Recently, in an aim to improve accuracy, a portable ultrasound bladder scanner equipped with an additional real-time pre-scan imaging (RPI) has been introduced. It seems to be able to enhance accuracy, as it can provide examiners with pre-localization of the central target point as well as information on the shape of the bladder prior to actual scanning, reducing the variability of the measured values.¹²

INTERPRETATION

PVR and Acute or Chronic Urinary Retention

Chronic post-void residual has been widely accepted as corresponding to a consistent PVR of more than 300 ml;⁴ however, some investigators have defined it as more than 400 ml,¹³ as 100–500 ml¹⁴ or have given it no definite number at all.¹⁵ On the other hand, (chronic) PVR does not seem to be a strong predictor of acute urinary retention (AUR).¹⁶

BOO

It is commonly thought that the increase in residual urine indicates the severity of BOO. However, abnormal measurements of free uroflowmetry or PVR can detect only a voiding dysfunction without indicating BOO specifically. Detrusor underactivity may be the only cause of a large PVR. Nevertheless, PVR measurements are used as parameter of efficacy for medical and surgical treatments for BPO.¹⁷⁻¹⁸

PVR and Clinical Progression Of BPO

High volume PVR is associated with an increased risk of LUTS deterioration and considered a predictor of BPO progression.¹⁹⁻²⁰ In the EAU Guidelines on the Management of Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO),²¹ it is paraphrased that very large PVRs may herald progression of disease. However, expert

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opinion prevails that very large PVR volumes (>200–300ml) may indicate detrusor underactivity and predict a less favorable response to treatment. PVR as such is not considered a stringent contraindication for watchful waiting or medical therapy. The use of PVR measurements is considered optional in men with uncomplicated LUTS undergoing noninvasive therapy. No level of residual urine, of itself, mandates invasive therapy²¹ and no PVR "cut-point" is yet established for decision-making.

PVR and Antimuscarinics in Men

Some recent placebo controlled clinical trial data suggest that anti-muscarinics (alone or in combination with tamsulosin) do not increase the risk of AUR and do not produce a clinically significant increase of PVR²²⁻²³ in men, even in the presence of BPO. However, patients with significant PVR were excluded from these studies and the safety of anti-muscarinics in men with BPO remains to be confirmed in long-term trials.

Bacteriuria

Large and/or persistent PVRs may be associated with urinary tract infections (UTI), especially in persons at risk, such as children or patients with spinal cord injury or diabetes.²⁴ Although this association is confirmed in a pediatric population²⁴ and in patients with neurogenic dysfunction,²⁵ other studies concluded that PVR does not correlate with bacteriuria, incontinence, immobility, impaired cognition, or neurological disease.²⁶⁻²⁷

Chronic Kidney Disease (CKD)

Very large PVRs (>300 ml) may increase the risk of upper urinary tract dilation and renal insufficiency.²⁴ A PVR > 100 ml has been associated with CKD in elderly men with LUTS;²⁸ however, other studies do not show a significant correlation between PVR and CKD.²⁹

Female Incontinence

It is currently recommended that PVR should be measured during the assessment of women with signs and symptoms of urinary incontinence and/or overactive bladder syndrome to exclude voiding dysfunction.³ Although the available evidence is still limited, antimuscarinic or anticholinergic medication should generally be considered if PVR is low.³⁰ Measurement of PVR is recommended in the management of female urinary incontinence.³¹

Children

Assessment of PVR is mandatory in a variety of pediatric patients, such as those with voiding LUTS, UTIs, vesicoureteral reflux, posterior urethral valves or neural tube defects.²⁴

ACTUAL RECOMMENDATIONS

- The interval between voiding and PVR measurement should be as short as possible (eo). It is advisable to ask the patients if the voiding was similar to a typical micturition in his/her daily life (eo).
- Preferably use non-invasive ultrasound bladder volume measurement instead of urethral catheterization (LE 3).
- Measurement of PVR is recommended in the management of female urinary incontinence (LE 3).

- Assessment of PVR is considered mandatory in a variety of pediatric patients (LE 3).

EVIDENCE SUMMARY

- Unrepresentative results may be obtained when voiding has to occur in unfamiliar surroundings or on command with an only partially filled or an overfilled bladder (eo).
- A portable bladder scanner may present some advantages over real-time ultrasound (LE 3), especially if equipped with additional real-time pre-scan imaging (LE 3).
- There is no universally accepted definition of a significant residual urine volume. For clinical practice, PVR <30 ml can be considered insignificant, while residual volumes persistently >50 ml could be regarded as important (eo).
- Large PVR (>200–300 ml) often indicates LUTD and may predispose to unsatisfactory treatment results if invasive BOO treatment is undertaken (LE 3). Nevertheless, no level of residual urine, of itself, mandates invasive therapy and no PVR threshold is yet established for decision-making (LE 3).
- PVR cannot be used as a robust predictor of acute urinary retention (LE 3).
- PVR can detect only voiding dysfunction without indicating BOO specifically (LE 2–3).
- There is no evidence that PVR increases significantly in patients treated with anti-muscarinic drugs (LE 2). However, consider that patients with significant PVR were excluded from studies published up to now.
- PVR may be associated with UTI, especially in persons at risk, such as children or patients with neurogenic dysfunction (LE 3). This association among adults is far from clear (LE 3).
- Large PVR may be associated with chronic kidney diseases (LE 3).

CONCLUSIONS

Measurement of PVR is recommended in guidelines and recommendations on the management of LUTS and urinary incontinence. However, there is still lack of evidence on the precise associations of PVR with most of the lower urinary tract dysfunctions and, consequently, most of the ominous features associated with PVR are not evidence-based. We have reviewed the evidence and provided recommendations for ICS standard teaching purposes.

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ICS Teaching Module: Pad Weight Testing in the Evaluation of Urinary Incontinence

J Krhut, A Martan, P Rosier, P Smith, L Valansky, R Zchoval, & P Zvara



International Continence Society
Teaching Module

1

Aims of the pad weight testing

- Qualitative assessment (continent vs incontinent)
- Quantitative assessment (how much)

Principle of the pad weight testing

- weight of the pads before and after test
- weight gain in g = urine loss in mls

Duration of the pad weight test

Short term tests

- 20 min – 2 hrs
- qualitative assessment

Long term tests

- 12 hrs – 72 hrs
- quantitative assessment

ICS pad weight test

- Only 1 hour pad weight test is standardized¹

0 -15 min:	drinking of 500 ml sodium-free liquid, resting
15 - 45 min:	walking, including stairs climbing to one flight up and down
45 - 60 min:	standing up from sitting (10 times) coughing vigorously (10 times) running on the spot (1 min) bending to pick up small object from the floor (5 times) washing hands in running water (1min)

¹Seventh report on the standardisation of terminology of lower urinary tract function: lower urinary tract rehabilitation techniques. International Continence Society Committee on Standardisation of Terminology. Scand J Urol Nephrol, **26**: 99, 1992

Preparation of the patient

Short term tests

- without retrograde filling
- with retrograde filling¹
(200-300 ml)
(50-75% of the bladder capacity)

Long term tests

- without retrograde filling

Performing the pad weight test

Short term tests

- set of standardized activities

Long term tests

- normal daily activity

The same technique for both men and women is usually used

Cut-off values

Short term tests

- weight gain $> 1g^1$

Long term tests

- weight gain $> 4g/24hrs^1$

¹Staskin D, Kelleher C, Bosch R, Coyne K, Cotteril N, Emmanuel A, Yoshida M, Kopp Z: Initial assessment of urinary and faecal incontinence in adult male and female patients. In: Incontinence. Ed.:Abrams P, Cardozo L, Khoury S, Wein A. 4th Ed. Health Publ.Ltd, Paris 2009, pp 333-412

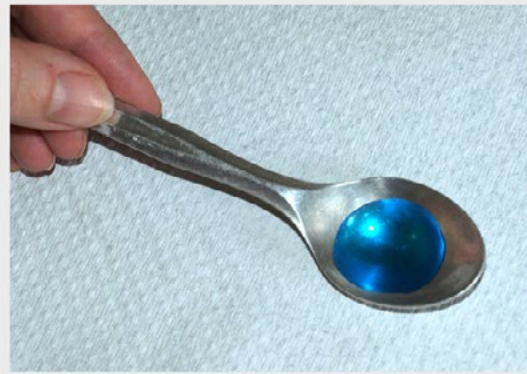
Quantification of the incontinence severity using the pad weight test

	<i>1-hour test</i>	<i>24-hour test</i>
<i>Mild incontinence</i>	< 10 mL	< 20 mL
<i>Moderate incontinence</i>	11-50 mL	21-74 mL
<i>Severe incontinence</i>	>50 mL	>75 mL

O'Sullivan R, Karantanis E, Stevermuer TI, et al.: Definition of mild, moderate and severe incontinence on the 24-hour pad test. BJOG 2004; 111: 859-862

Is leak of 1 mL significant?

1 mL of fluid = 25 drops



Is leak of 1 mL of fluid significant?

- 1 mL of fluid leaked into the pad
- 1 mL of fluid leaked into the cloth



Is leak of 5 mL of fluid significant?

- 5 mL of fluid absorbed by pad
- 5 mL of fluid leaked into the clothing



Sensitivity and specificity

Short term tests

- sensitivity: 34-83%^{1,2}
- specificity: 65-89%²

Long term tests

- sensitivity: no sufficient data
- specificity: no sufficient data

¹Wu, WY, Sheu, B. C., Lin, H. H.: Twenty-minute pad test: comparison of infusion of 250 ml of water with strong-desire amount in the bladder in women with stress urinary incontinence. Eur J Obstet Gynecol Reprod Biol, **136**: 121, 2008

²Costantini, F., Lazzeri, M., Bini, V. et al.: Sensitivity and specificity of one-hour pad test as a predictive value for female urinary incontinence. Urol Int, **81**: 153, 2008

Limitations

- lack of standardization
- results of the long term tests may be influenced by:
 - fluid intake
 - increased voiding frequency
 - sweating
 - vaginal discharge (up to 7g/24 hrs)¹
 - patient compliance
- no value in determining incontinence etiology
- weak correlation with the degree of patient's bother

¹Karantanis E, O'Sullivan R, Moore KH: The 24-hour pad test in continent women and men: normal values and cyclical alterations. BJOG 2003; 110: 567-571

Clinical conclusions

- pad-test can provide additional information about degree of patient's incontinence
- easy to perform, inexpensive, risk-free
- could be influenced by many factors, therefore

Outcomes should be interpreted in context of other diagnostic instruments

Recommendation for clinical use of the pad weight test

- detailed instruction and patient motivation are crucial
- use short term test for qualitative evaluation of incontinence
- if retrograde filling is to be used, bladder should be filled to 50-75% of bladder capacity
- use long term test for quantitative evaluation of incontinence
- interpret test results in conjunction with other relevant assessments (self-assessment, questionnaires, physical examination, etc.)
- pad weight test result doesn't always correlate with patient's bother



Pad Weight Testing in the Evaluation of Urinary Incontinence

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Aim: To present the teaching module “Pad Weight Testing in the Evaluation of Urinary Incontinence.” This teaching module embodies a presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base made available on ICS website to summarize current knowledge and recommendations. **Methods:** This review has been prepared by a Working Group of The ICS Urodynamics Committee. The methodology used included comprehensive literature review, consensus formation by the members of the Working Group, and review by members of the ICS Urodynamics Committee core panel. **Results:** The pad test is a non-invasive diagnostic tool for urinary incontinence. It is an easy to perform, inexpensive test with utilization in both the daily patient care and clinical research. Despite its clear value in initial diagnosis, selection of treatment, and follow-up evaluation, only less than 10% of urologists perform the test routinely. A number of testing protocols with varying lengths of recording time exist, however, only a 1-hr pad test has been standardized. One-hour pad tests are most suitable in establishing initial diagnosis, the 24-hr test serves most often for evaluation of treatment outcomes, and longer pad tests are used in clinical studies. **Conclusions:** The pad test is clearly underutilized. Well-designed studies providing level one evidence are lacking. Numerous variations in how the test is performed by individual urologists make the evaluation of published literature difficult. Future research goals should include randomized studies leading to establishment of optimal protocols of testing for clinical research and daily care. *NeuroUrol. Urodynam.* 33:507–510, 2014.

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Key words: diagnostics; ICS teaching module; urinary incontinence; urodynamics; pad weight test

INTRODUCTION

Pad testing is a non-invasive method of detecting and quantifying severity of urine leakage. The 4th International Consultation on Incontinence defined pad testing as “an optional test for evaluation of urinary incontinence.”¹ Diverse testing durations have been reported in the literature and only for the 1-hr pad test a specific test protocol has been standardized.^{2,3} Although it is generally believed that longer tests are more reproducible, evidence on the accuracy of different methods of pad testing is inconsistent. A 24-hr test is more reproducible than a 1-hr test, but longer testing requires more preparation and a greater commitment on the part of the patient. Twenty-four-hour testing is reported to be adequate in routine clinical settings while 48- to 72-hr testing is deemed necessary for clinical research.^{2,4}

MATERIALS AND METHODS

This review has been prepared by a Working Group of The ICS Urodynamics Committee. The methodology used included comprehensive literature review, consensus formation by the members of the Working Group, and review by members of the ICS Urodynamics Committee core panel.

The ICS Urodynamics Committee presents the teaching module “Pad Weight Testing in the Evaluation of Urinary

Incontinence” to serve as a standard education of Good Urodynamic Practice for everyone involved in indicating, performing and analyzing urodynamic testing in general and more specifically, performing analysis of voiding. The teaching module consists of a presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base, for the ICS Power Point presentation; available via <http://www.icsoffice.org/eLearning/> or via the QR code on this page. The presentation explains, testing requirements, clinical workup and analysis. The presentation and this manuscript contain experts’ opinion where evidence is, especially for the clinical practice aspects, unavailable and is marked” with: “eo” (experts opinion).

Heinz Koelbl led the peer-review process as the Associate Editor responsible for the paper.

Conflict of interest: none.

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RESULTS

Preparation

- (1) **Test selection:** The type of pad test selected is based on goals. A 1-hr test is usually administered during initial evaluation to select treatment and estimate prognosis for cure (*eo*). Twenty-four-hour or longer testing is necessary for quantifying the degree of urine leakage (*eo*).
- (2) **Instruction:** Detailed instruction is critical in order to elicit the full compliance of patients.
- (3) **Filling the bladder to a set starting volume:** The short duration pad test (1-hr or less) may be performed using an instilled starting bladder volume. Usually, the bladder is filled through a urethral catheter (or during cystoscopy). Most reported studies used 150–300 ml, some recommend a volume equivalent to 50–75% of the functional bladder capacity.^{5,6} Filling to the first desire to void or sensation of fullness has also been reported.⁷ Although studies have documented that this modification improves the quantitative value of the test, the consensus on the ideal starting volume is lacking.³

Technique

The test is administered in a same manner to both male and female patients (*eo*).

One-hour pad test. The testing protocol has been standardized by International Continence Society (ICS-pad test):

- the test is started by putting one pre-weighted pad without patient voiding,
- patient drinks 500 ml of sodium-free liquid in <15 min—then sits or rests,
- patient walks for 30 min, including climbing one flight of stairs (up and down),
- patient performs the following activities: standing up from sitting (10×), coughing vigorously (10×), running on the spot for 1 min, bending to pick up an object from the floor (5×), and washing hands in running water for 1 min (this activity program may be modified according to the patient's physical fitness),
- the total amount of urine leaked is determined by weighing the pad.

If a moderately full bladder cannot be maintained through the hour (if the patient must void), the test has to be started again.

Twenty-four-hour pad test.

- the test should be started with an empty bladder,
- normal daily activities should be followed and recorded in a voiding diary so that the same schedule will be observed during follow-up re-testing (*eo*),
- to avoid urine loss through leakage or evaporation the pads should be worn inside waterproof underpants and exchanged every 4–6 hr during daytime,
- pads should be weighed immediately. If weighing is performed at the clinic, pads must be stored in airtight bag.

Interpretation

The upper limit of weight increase for the 1-hr test in continent women is 1.4 g (equivalent to 1.4 ml) and 1.3–4.4 g for 24-hr test. These values may increase in situations of increased perspiration.⁸ In the analysis of 1-hr pad test, an

increase of 1–10 g is classified as representing mild incontinence, 11–50 g moderate and >50 g severe incontinence. The values for 24-hr pad test are classified as follows: Mild (4–20 g/24 hr), moderate (21–74 g/24 hr), and severe (>75 g/24 hr) incontinence.⁹

A weight gain of less than 1.4 g during 1-hr test or 4.4 g for 24-hr test could be a result of sweating or vaginal discharge. If the findings are inconclusive, oral phenazopyridine which colors the urine orange could be used.¹⁰ Listed cut-off values are based on studies performed in female patients. The values specific to males have not been yet determined.

The outcomes of studies which attempted to correlate the volume of leakage to the etiology (stress, urge, and mixed incontinence) showed significant variability, suggesting that the pad test is not appropriate for separating the types of incontinence based on their etiology.^{11,12} Ryhammer et al. compared weight gain between two groups of randomly selected women, 79 of whom reported continence and 38 reported incontinence. They found no difference in the outcome of 24-hr pad test, suggesting that pad test should not be used as a screening tool.¹³ The sensitivity and specificity of the 1-hr pad test reported in the literature varies significantly.¹⁴ The 1-hr pad test was shown to have a high positive predictive value, however the false positive results can occur in more than 50% of cases.¹⁵

Recommendations

-in the initial patient work-up, an objective measure of incontinence loss volume such as the pad test may help in treatment selection (e.g., male sling vs. artificial sphincter in the treatment of the post-prostatectomy incontinence) (Table I),¹⁶

-estimation of treatment prognosis (patients with high volume incontinence may experience lower cure rates) (*eo*),
 -objective measure of treatment outcome for anti-incontinence procedures,

-the volume of leakage does not always correlate with the degree of bother (e.g., 2 g of urine leakage, which is roughly equivalent to 40 drops, produces a large spot on the clothing), therefore pad tests should be always interpreted in conjunction with history, clinical examination and self-assessment questionnaires (*eo*),

-future research goals should include determination of the optimal technique and duration of testing for both clinical and research purposes with the ultimate goal of developing an appropriate individualized testing protocol for patients and their varying circumstances (*eo*).

One-hour pad test.

-the 1-hr pad test, using the ICS standardized protocol is appropriate in routine evaluation of patients during initial work up,

TABLE I. Basic Characteristics and Degree of Accuracy of Individual Types of Pad Tests

	Short-term tests (qualitative assessment)	Long-term tests (quantitative assessment)
Bladder filling	No artificial filling or retrograde filling	No artificial filling
Physical activity during test	Standardized activities	Normal daily activities
Evaluation	Weight gain >1 g	Weight gain >4 g/24 hr
Sensitivity	34–83% ²²	Insufficient data
Specificity	65–89% ²²	Insufficient data

-if either the patient or physician have doubts about the accuracy of the initial test, evaluation should be extended by an additional hour or repeated,
 -the test should always be interpreted in conjunction with standard self-assessment questionnaires including the bother index,
 -performing the test with a known start volume might increase the accuracy, but the data supporting this assumption is inconclusive and there is no consensus on what the volume should be (eo).

Twenty-four-hour pad test.

-it is more reproducible than 1-hr test,
 -highly dependent on patient compliance and therefore not suitable for all patients (eo),
 -detailed instruction and patient motivation are important, the test results depend on fluid intake, physical activity levels, hormonal status, sexual activity, and environmental factors (temperature, humidity),
 -the protocol should be personalized based on patient's physical status (eo),
 -the physical activity and detailed voiding diary should be recorded so that a similar protocol is followed during the initial and all follow-up (eo).

DISCUSSION

Pad weighing as a diagnostic method for incontinence was first described by James et al. in 1971.¹⁷ In 1981, Sutherst et al. were the first to publicize the use of the pad test with a prescribed set of activities and exercises.¹⁸ Since then, a number of published studies used various forms of the pad testing protocols. Pad testing is easy and inexpensive, yet recent surveys of the Society for Urodynamics and Female Urology members showed that only 4.5–8% of the members perform the pad test routinely in their practice.¹⁹ A number of studies have documented that the longer the testing, the better the correlation between the test results and the degree of incontinence. However, 24- to 72-hr pad tests are cumbersome and require high levels of patient compliance.^{15,20} Test outcomes are affected by many factors and therefore have to be interpreted in combination with other methods of evaluation. Caution has to be exercised especially in giving too much weight to a negative 1-hr pad test (eo). Repeated short term testing is recommended especially in cases where the test result does not correlate with subjective assessment provided by the patient.²¹ Good correlation has been reported by Abdel-Fattah et al.²² between the self-assessment questionnaires and the 1-hr pad test. The King's Health Questionnaire showed a 96% sensitivity and 93% specificity of a 1-hr pad test in identifying incontinent patients.²² The good correlation between self-assessment questionnaires and 1-hr pad test, but not the 24-hr pad test supports the value in standardization. Good correlation with the 24-hr pad test and the International Consultation on Incontinence Questionnaire—Short Form (ICIQ-SF) has been documented.²³ The biggest cost associated with the pad testing is the office visit, therefore home pad tests using the mail has been proposed.²⁴ Longer testing protocols could potentially increase the sensitivity and specificity, however, they require selection of highly motivated patients. The type of pad, leak, and evaporation could affect the outcome, therefore pad should be exchanged every 4–6 hr during the 24-hr and longer pad testing.²⁵

CONCLUSIONS

The pad test is non-invasive and easy to perform, yet factors such as embarrassment and behavioral changes to reduce

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incontinence severity (inactivity, fluid restriction) could affect the outcome significantly. The 1-hr pad test as standardized by ICS is currently the only tool with a set protocol, and we recommend using the original protocol. In the case that artificial bladder filling is used, the bladder should be filled to 50–75% of its functional capacity prior to the initiation of the test. The 24-hr test is sufficient in daily clinical practice. Performing this test in conjunction with a voiding diary, or simply recording fluid intake and frequency of incontinence episodes, will significantly increase its utility. A standard protocol for 24- to 72-hr pad testing does not exist at the present time, and we believe establishing one would be very helpful. Prescribing specific physical activity over 24–72 hr is problematic, therefore we recommend instructing the patient to follow a normal daily routine. Despite the above limitations, the pad test provides objective assessment of involuntary urine loss. Its optimal utility depends upon understanding the impact of these limitations for diagnostic and prognostic use. The correlations of specific testing protocols with subjective and objective measures must be performed so that the most appropriate testing protocol may be employed according to circumstance. We believe that standardization of testing is an important first step in improving the utilization of this simple and inexpensive testing method.

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510 Krhut et al.

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ICS Teaching Module: Urodynamic Artefacts 1

Common artefacts in water-filled systems

A Gammie, C D'Ancona, H-C Kuo & P Rosier.



International Continence Society
Teaching Module

1

International Continence Society (ICS) Guest Speaker: DISCLOSURES

- Andromeda, Digitimer, Laborie, Mediwatch
 - Project sponsorship
- T-Doc LLC
 - Trial sponsorship
- Astellas, Ono Pharma, Vysera, Flexicare
 - Consultancy
- E2L Ltd
 - Royalties from www.UrodynamicsTrainer.com

Common artefacts in water-filled systems

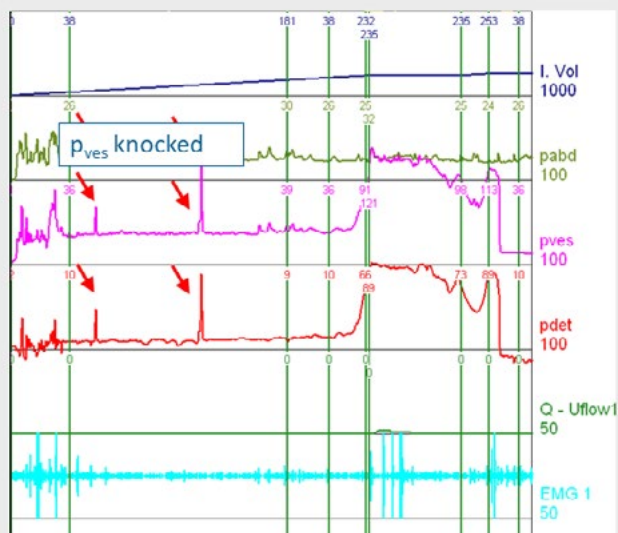
Artefact: 'Something ...that is not naturally present but occurs as a result of ...the procedure' (Oxford)

- Movement / tube knock
- Patient position change
- Expelled vesical catheter
- Expelled rectal catheter
- Flushed catheter
- Line open to syringe
- Empty bladder (poor response)
- Empty rectal catheter
- Poor cough response

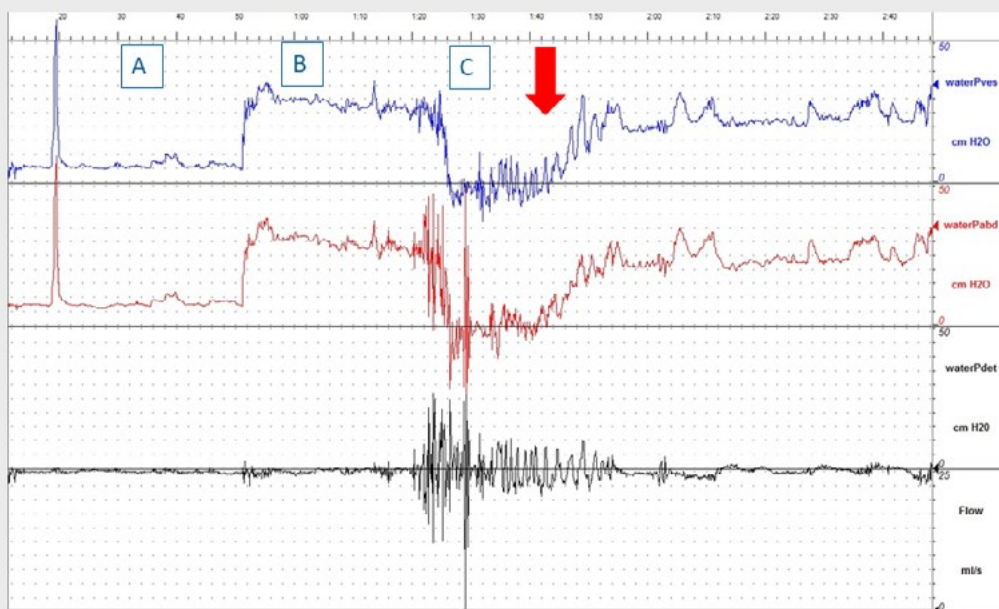
Movement / tube knock (water)



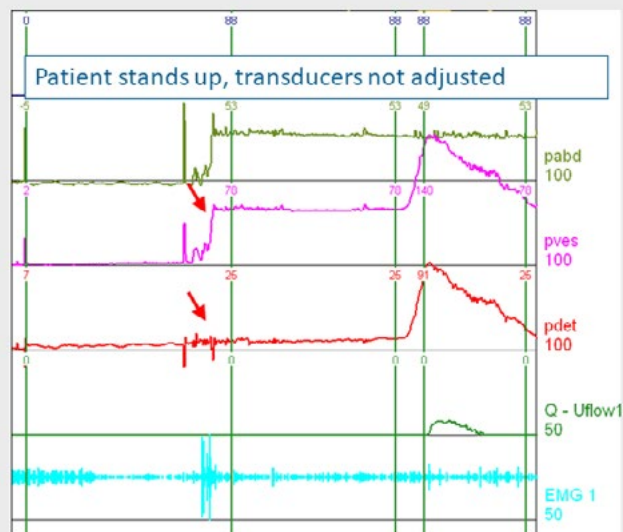
Movement / tube knock (water)



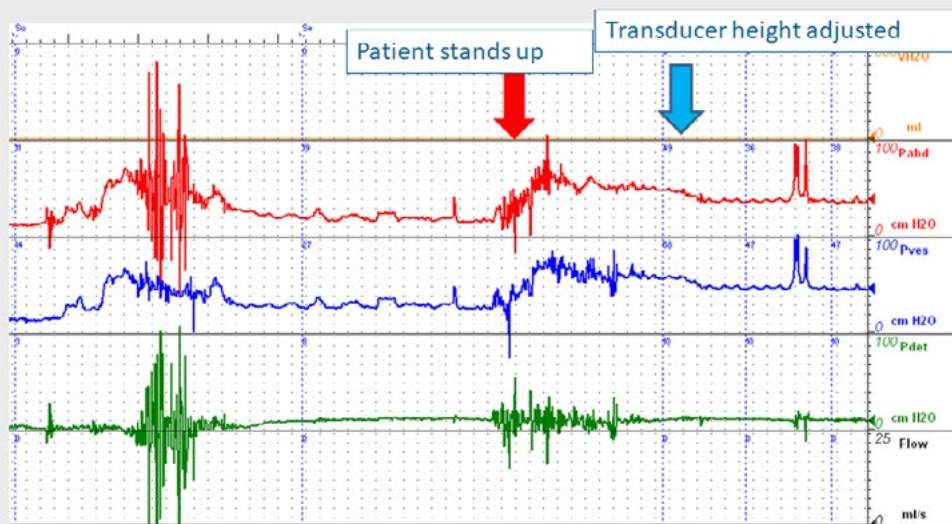
Patient position change (water filled)



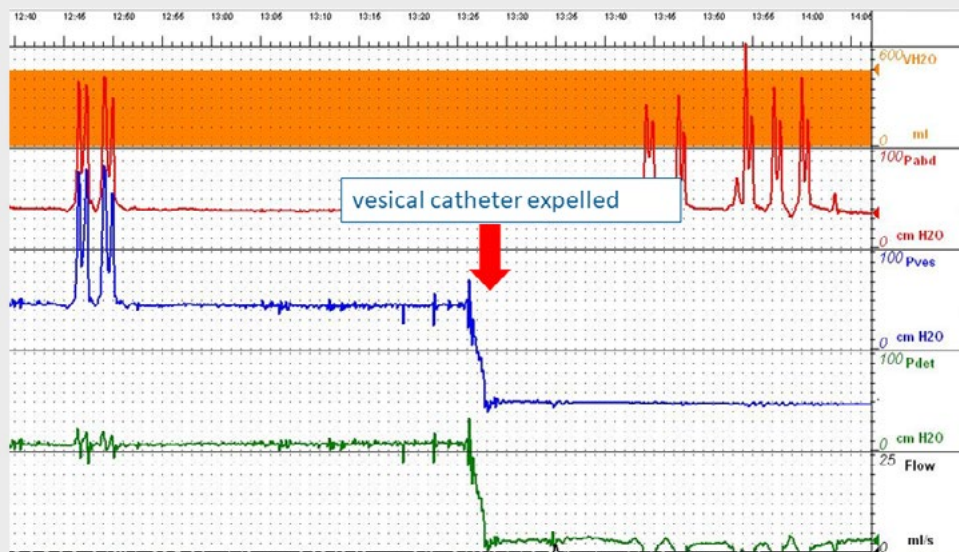
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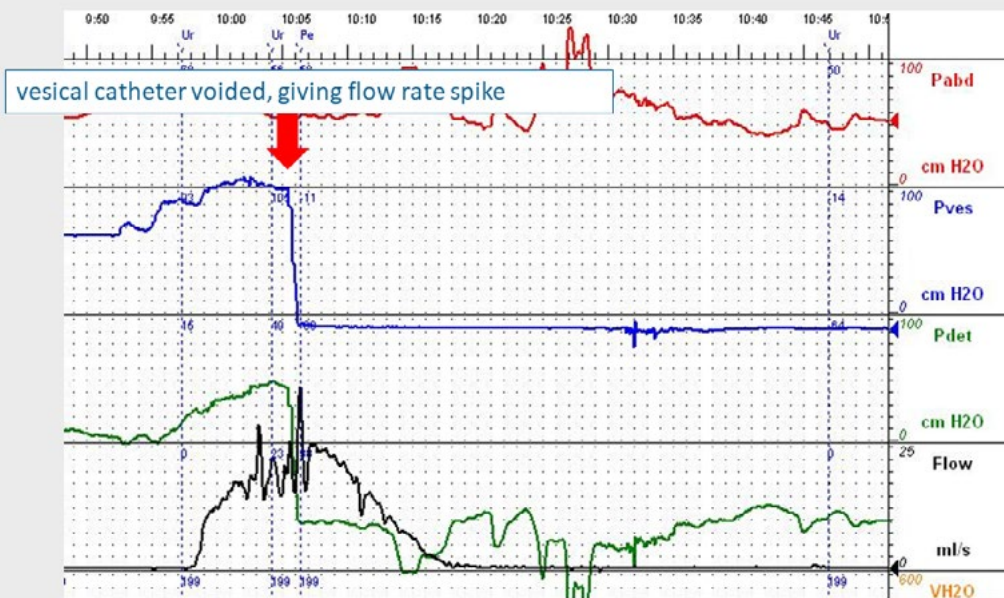
Patient position change (water filled)



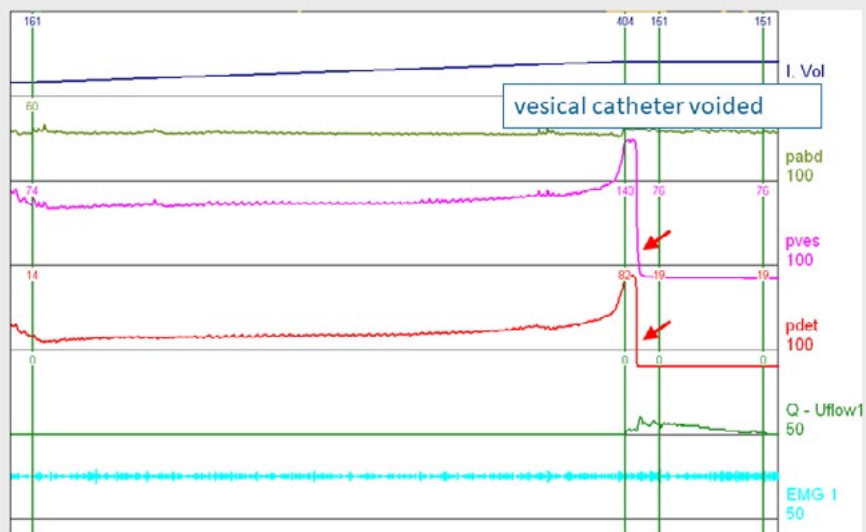
Expelled vesical catheter



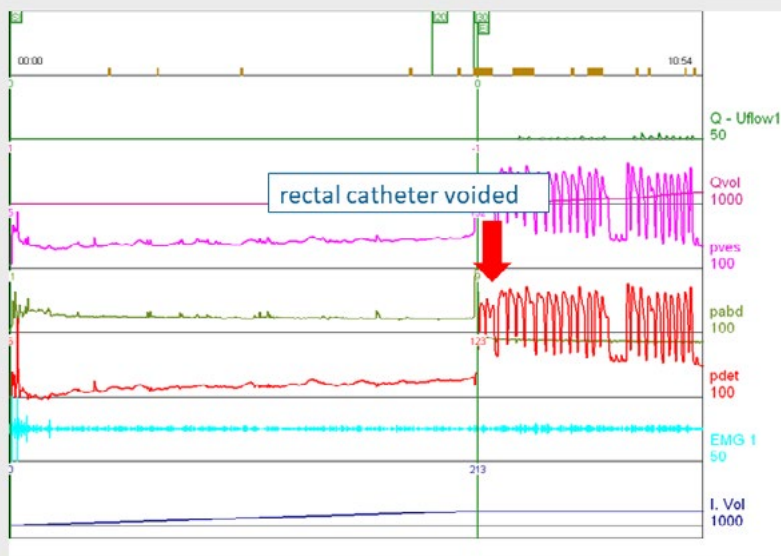
Expelled vesical catheter



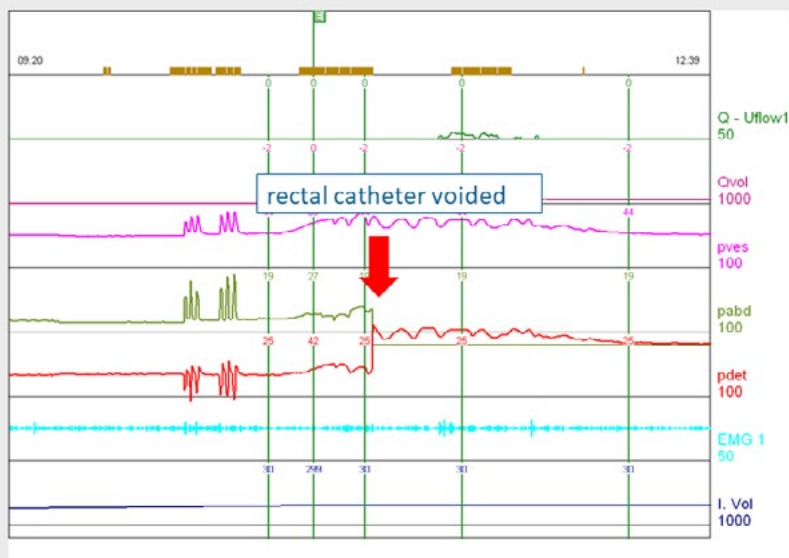
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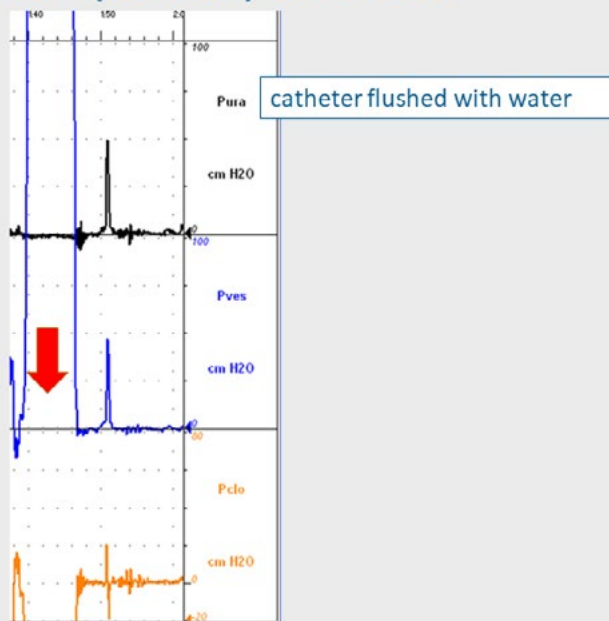
Expelled rectal catheter



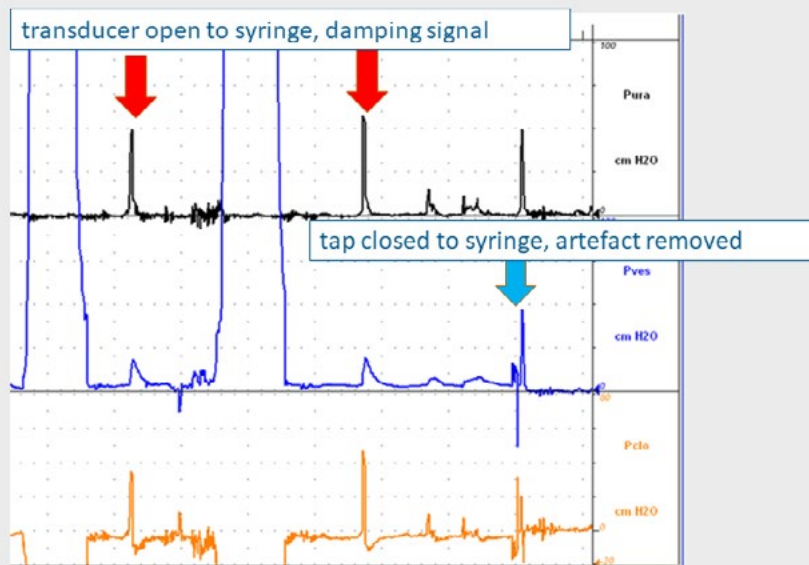
Expelled rectal catheter



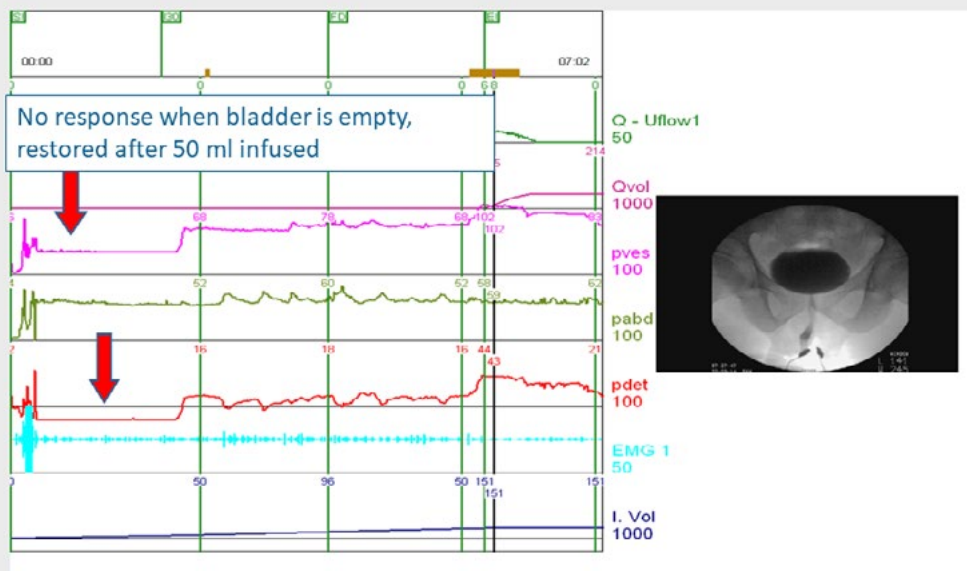
Flushed (water) catheter



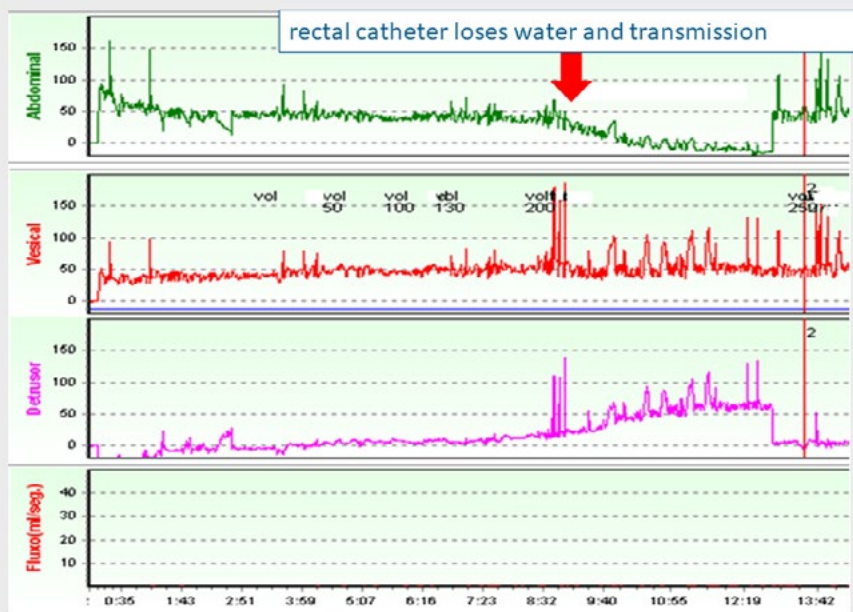
Line open to syringe (water)



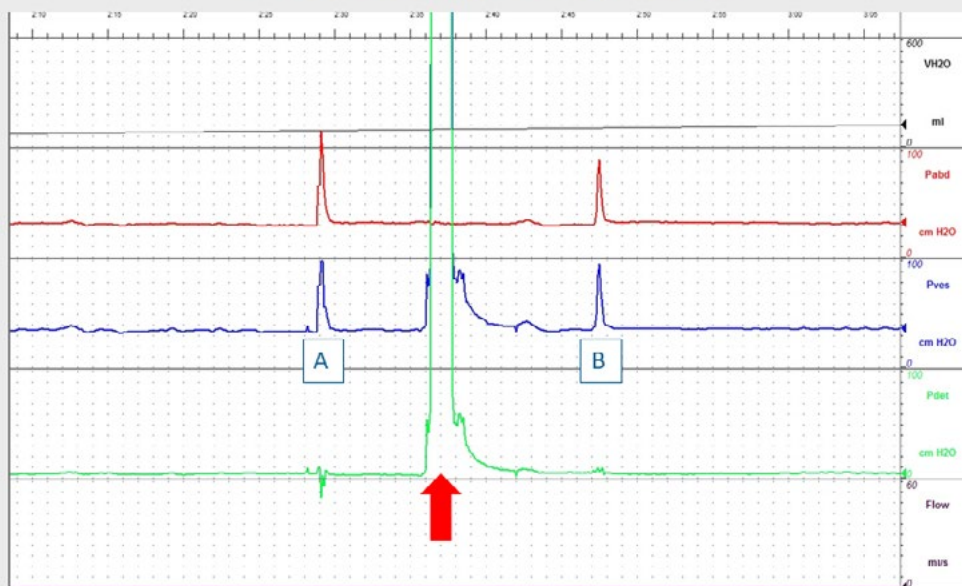
Empty bladder (poor response)



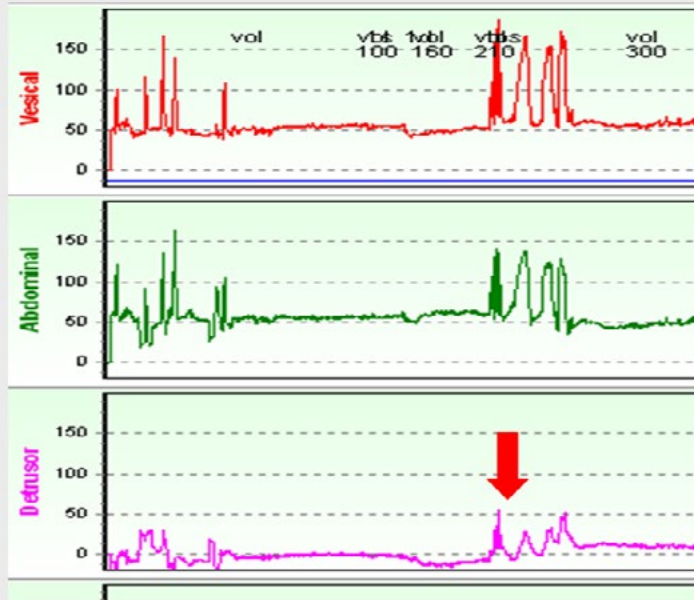
Empty rectal catheter (water)



Poor cough response



Poor cough response



Poor response to live signal





ICS Teaching Module: Artefacts in Urodynamic Pressure Traces (Basic Module)

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Aims: To present the ICS Teaching Module on artefacts in urodynamics pressure traces. **Methods:** Slides from three urodynamics centres were assembled. Descriptions and labels were agreed by the authors and the module presented at the ICS Annual Scientific Meeting in Brazil 2014. **Results:** Ten artefacts that should be recognized while using water-filled urodynamic systems are presented and remedial action described. **Conclusions:** This manuscript serves as a scientific background for the slide set made available on the ICS website. By following the guidelines in this teaching module, good quality urodynamics can be more readily achieved. *NeuroUrol. Urodynam.* 36:35–36, 2017.

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Key words: artefacts; pressure measurement; quality

INTRODUCTION

The International Continence Society (ICS) Urodynamics Committee presents the first teaching module of Artefacts in Urodynamic Pressure Traces as a resource to enhance good urodynamic practice.

An artefact is understood to be 'Something . . . that is not naturally present but occurs as a result of . . . the procedure.'¹ When artefacts arise during the test, they should be removed or can sometimes be compensated for, thus improving the quality of urodynamic results. If artefacts have not been corrected during the test they should be recognized during post-test evaluation. This module presents the artefacts that this working group has considered to be the most prevalent when water-filled urodynamic systems are used. They are described as patterns on the urodynamic traces, and all are recognizable and correctable during the test. Some artefacts may, however, necessitate repetition of the test.

We present ten artefact patterns with an explanation of their causes and a description of the remedies. Further understanding of the prevalence and nature of artefacts can be found in Hogan et al.,² and a full presentation of Good Urodynamic Practices is found in Schaefer et al.³ These underline that signal quality is only assured through using adequate equipment, with careful installation of the whole system and with skilled and alert staff performing the test. The teaching module referred to here consists of this manuscript and a slide presentation available at www.ics.org/eLearning. An advanced module will also be made available dealing with less common artefacts, along with those found in other types of pressure measurement systems.

CONTENTS

The ten artefacts described in this module are:

- Movement/tube knock
- Patient position change
- Expelled vesical catheter
- Expelled rectal catheter
- Flushed catheter
- Line open to syringe

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- Empty bladder (poor response)
- Empty rectal catheter
- Poor cough response
- Poor response to live signal

The descriptions below are all with reference to water-filled pressure measurement systems, although some of these artefacts do occur in other types of system. Each artefact has the observed effect, underlying cause and recommended remedy described.

ARTEFACT DESCRIPTIONS, CAUSES AND REMEDIES

Movement/Tube Knock

Effect observed. High frequency, short duration pressure spikes visible in p_{ves} , p_{abd} , or both, with spikes always visible in p_{det} .

Cause of artefact. Knocking of one or both tubes. In the example, the knock is first on the p_{ves} line, then on the p_{abd} line.

Remedial action. Ensure tubes are away from the cause of the knock. Ignore these spikes when analysing the trace.

Patient Position Change

Effect observed. A lasting change in p_{ves} and p_{abd} of equal magnitude on both, usually between 8 and 35 cmH₂O.² It is often accompanied by noisy signals as the lines are knocked.

Cause of artefact. A change in patient position. In the example, the patient has begun supine, stood up, then sat down on the

Prof. Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

Potential conflicts of interest: Nothing to disclose

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commode at a position below the level of the transducer. The level of the transducers was then adjusted to the level of the symphysis pubis.

Remedial action. Ensure the transducers are moved to the level of the symphysis pubis after any patient position change. Transmission of pressure should also be checked after patient movement.

Expelled Vesical Catheter

Effect observed. A sudden drop in p_{ves} , usually to well below zero, with no response to transmission checks.

Cause of artefact. The vesical catheter is expelled from the patient, normally by the pressure of voiding.

Remedial action. Recatheterise and repeat the test, if the urodynamic question has not been answered.

Expelled Rectal Catheter

Effect observed. A sudden drop in p_{abd} , usually to well below zero.

Cause of artefact. The abdominal catheter is expelled from the patient, normally by the pressure ofValsalva or straining.

Remedial action. Recatheterise and repeat the test, if the urodynamic question has not been answered.

Flushed Catheter

Effect observed. An abrupt large increase in a single pressure trace, maintained for some seconds, followed by a sudden normalisation of pressure.²

Cause of artefact. Water is pushed through the transducer dome in order to remove air from the catheter and tubing.

Remedial action. Check for good pressure transmission after the flush. Ignore the high pressure generated when analysing trace.

Line Open to Syringe

Effect observed. Repeated flushes of the line do not restore a good response to a cough signal.

Cause of artefact. The syringe inadvertently remains connected to the water line, and acts as a damper on the signal. Since an air bubble is not the problem, flushing fails to resolve it.

Remedial action. Set the taps correctly, so the syringe is not connected to dome. Repeat the cough test for good pressure transmission.

Empty Bladder (Poor Response)

Effect observed. Response of the intravesical catheter to a pressure transmission test is poor when bladder volume is low.

Cause of artefact. When the bladder is empty, the catheter may touch the bladder wall, so pressure changes within the lumen cannot be registered.

Remedial action. Fill the bladder slightly (e.g. 50 ml) and test the pressure transmission again.

Empty Rectal Catheter

Effect observed. Deterioration in abdominal pressure transmission, with or without a change in pressure, during filling or voiding.

Cause of artefact. Reduction of water in the rectal balloon. The balloon fails to connect effectively with the rectal wall as a result.

Remedial action. Refill balloon and test for good pressure transmission.

Poor Cough Response

Effect observed. One cough spike is visibly smaller than the other, despite a cough affecting p_{ves} and p_{abd} equally.

Cause of artefact. Usually an air bubble in the water-filled line, reducing the transmission of pressure from patient to transducer.

Remedial action. Flush the line through with water, pushing the air bubble from the tube. The next cough should be registered equally on both traces. If not, flushing should be repeated.

Poor Response to Live Signal

Effect. Live signal is observed on one trace (in this case p_{ves}) and on p_{det} , despite a previous cough test being satisfactory.

Cause. Usually an air bubble in the water-filled line, reducing the transmission of pressure from patient to transducer, in this case in the abdominal line. It could also be the pump or patient causing noise on the affected line.

Remedy. Check that there is no interference on the affected line by visual inspection and stopping the pump. If it is still present, flush the line through with water (not visible on this trace), pushing the air bubble from the tube.

CONCLUSIONS

Poor quality urodynamic testing may easily result in inadequate or wrong diagnosis. Maintaining good quality of pressure transmission, recording, and display, and being able to interpret the traces correctly are therefore critical for patient benefit. Recognising artefacts in the pressure signals and dealing with them appropriately is an essential component of maintaining this quality. By following the guidelines in this teaching module, good quality urodynamics can be more readily achieved.

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Self-Management of Indwelling Urinary Catheters

February 2016

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Member of the ICS Nurses' Committee



International Continence Society
Teaching Module

Objectives

- Our purpose is to educate continence nurses to improve patient care and health outcomes globally.

At the conclusion of this presentation, readers should be able to:

1. Examine evidence in research related to self-management in long-term urinary catheter users.
2. Describe best practices for promoting self-management in people using indwelling urinary catheters.
3. Use theoretical concepts related to catheter self-management.

Indications for long-term catheter use

- Intractable urinary retention for those who cannot manage an intermittent catheter (and no caregiver to do it)
- Bladder outlet obstruction, not surgically treated
- Improving comfort for end-of-life care if needed
- Alternatives to consider: toileting schedule (when no retention), intermittent catheter, condom/sheath catheter (for cooperative males without obstructed urine or persistent retention)

(USA CDC guidelines, Gould et al. 2009)


Long-term catheter use defined:

- Long term- over 1 months use but often extends over many years.
 - “Indefinite use” would be more accurate term, but no agreement on terminology.
- Both “catheter types” and “catheter use” for expected time of catheterization are called short and long-term, causing confusion. (Cottenden et al. 2013)

Little research in urinary catheter self-management

- Self-management research is common in chronic conditions – **but not with people with catheters**
- LT catheter users **learn by trial and error**, lack support groups.
- Catheters are **stigma**; can indicate decline in health.
- People with catheters often **told to drink**, but not how much, nor how to manage.


NIH/NINR R01 NR01553 & R21 NR012763

 ICS Teaching Module

My research developed inductively-- most in talking with patients

- **7 previous studies with indwelling catheters**
 - Experience of using a catheter
 - Descriptive studies to identify catheter problems
 - How UTI, blockage, fluids, urine flow were related
 - What catheter users do to prevent/address problems
- **2 studies with intermittent catheter users, expanding theoretical framework to this population. (next power-point presentation)**


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Catheter management problems

- Prevent **CAUTI**
- Avoid **leakage** (bypassing of urine)
- Minimize **catheter blockage** (& frequent changes)
- Prevent **accidental dislodgment** (catheter falling out or being pulled out)


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Quality of life disruption with indwelling catheters


- **Daily routines** of catheter users and their families. “It’s ok when it’s working right.” (Wilde, 2002)
 - Background to foreground with a problem: “Psshtt. You’re really soaked. It ruins the day. It ruins whatever you’re drivin’ in.” (p. 10, Wilde, 2003)
 - Troubleshooting in evening and weekend hours, causes excess health care expenses.
- **Choice of SP or urethral**: sexual activity can be more positive with SP, but not always (Chappel et al., 2014)
- Some developed **self-reliance**; others not so positive (Fowler et al. 2014)

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Key catheter problems in past two months (Wilde et al. 2013)	Percent %	Rate/1000 catheter days			
CAUTI	31	6.22			
Blockage	24	11.08			
Dislodgement	12	3.57			

Other catheter problems	Overall Percent %	% Daily	% Several times/ week to weekly	% Several times/ month to monthly	% Once in past 2 months
Leaking	43	9	10	51	29
Sediment	63	24	29	39	7
Kinks/twists	20	13	8	40	40
Bladder spasms	36	37	24	30	10
Autonomic dysreflexia	13	4	31	38	27

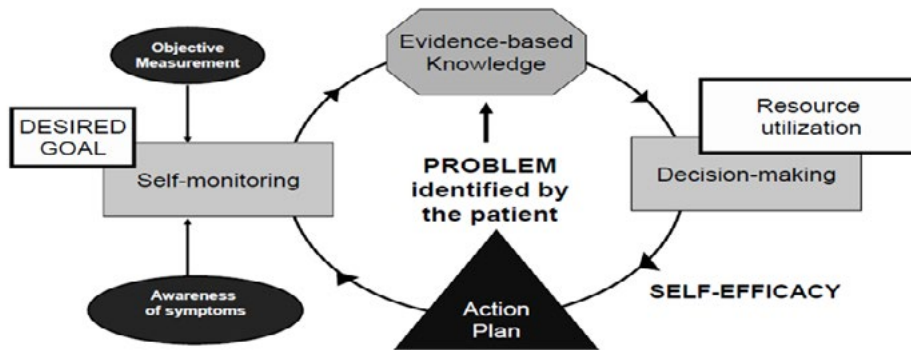
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Treatments (Wilde et al. 2013)	UTI	Blockage	Unscheduled catheter changes	Percent %
	Percent %	Percent %	Weekly	4
Extra home nurse visit	19	30	Several times a month	21
Extra office visit	25	23	Once a month	16
Emergency department	35	19	Once in past two months	59
Hospitalized	27		Changed by self	10
Catheter changed	65	70	Home care nurse	46
Urine cultured	65		Emergency department	31
Antibiotic prescribed	100			

 ICS Teaching Module

Self-management framework Wilde, M. H., Bliss, D.Z., Booth, J.,

Cheater, F.M., & Tannenbaum, C. (2014). Self management of urinary and fecal incontinence. *American Journal of Nursing*, 114(11), 38-45.




 ICS Teaching Module

Indwelling Urinary Catheter Self-management Randomized clinical trial

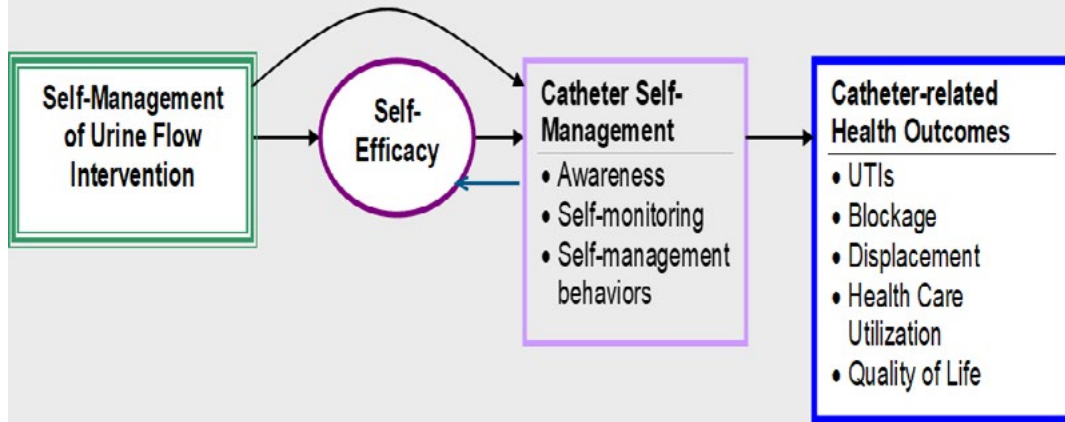
NIH/NINR R01 NR01553

Research team: Wilde, M. (PI), McMahon, J.M. (Co-I),
McDonald, M., Tang, W., Wang, W., Brasch, J., Fairbanks, E.,
Shah, S., Zhang, F., Chen, D.

 ICS Teaching Module

Theoretical model for Self-management of Urine Flow Intervention (RCT)

(Wilde, Zhang et al. 2013)



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ICS Teaching Module

Study design- RCT (N= 202)

- Four contacts with Intervention nurse: 3 home visits, 1 telephone call
- Teaching self-monitoring for 3 days
 - Urinary diary (I & O and catheter journal)
 - Educational booklet
- To increase awareness, self-monitoring and self-management behaviors
- Data collection bimonthly for a year (Wilde, McMahon, et al. 2015)


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Sample


- **Similar number males (51%) and females (49%)**
- **Age: 19-96, mean 61(SD 17.4) years**
- **Urethral 56%, Suprapubic 44%**
- **Use of catheter: 1-470 months, mean 6(SD 7) years**
- **Diverse by race and ethnicity**
 - white (57%), Black (30%), Asian (2%), American Indian or Alaskan Native (2%), biracial (2%), and unknown (9%). And 11% Hispanic
- **Highly disabled: 60% need help in bathing, dressing, toileting, and getting out of bed; 19% need help in feeding**

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 ICS Teaching Module

January 2009 Catheter Calendar						
SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
Problems: Done? B= Blockage U= Urinary Tract Infection D = Falls Out/Dislodged		Treatments: What Was		1		3
		A= Antibiotic O= Extra Office Visit HV= Extra Nurse Visit ER= Emergency Room H= Hospitalizations R= Rehabilitation				
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31


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Educational Booklet--Basic Catheter Self-Management--Fluids

- **Stay Aware.** stay aware of your body and how you feel.
- **Drink more water** than any other beverage! Limit caffeine.
- **Drink Consistently.** Optimal and consistent level all day to help prevent catheter blockage.
- **Your Body Needs Fluids.** Most people need 2000 to 3000 cc of fluid a day. For instance a 150 pound person would need 2045 cc which is equivalent to about 8½ glasses per day. More fluids are needed for hot weather or when exercising. My fluid goal is _____.
- **Pay attention** to the color of your urine. It should be light yellow all day long.


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 ICS Teaching Module

Basic Catheter Self-management- Prevent dislodgement

- **Notice Changes** in what you feel.
- **Notice Catheter Position** when you move and teach others.
- **Check for kinks and twists** by feeling with your hand.
- **Ask for Help.**

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 ICS Teaching Module

Tips from Catheter Users

“Drink the water and go!”

“I didn’t know amounts of intake and output.”

“I am paying attention to the color and quantity of the urine.”

“Now I drink more when I am out of the house.”

“I measure intake and caffeine and notice the color of urine, and sediment in the tubing. I am really being aware.”

“I check the position of the catheter when getting in and out of bed.”

“I think about how to best secure the catheter during activities

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ICS Teaching Module **“If a problem does not feel right, act on it quickly!”**

Quick Guide to Problems and Action Strategies

Problem	Action Strategies	See Page Number
Decreased/inconsistent fluid intake	Increase fluid intake	7
UTI	Increase fluid intake	7
	Recognize early symptoms of UTI and acting on it	8
Catheter blocks	Increase fluid intake	7
	Promote catheter changes at best intervals	11
Adjustment to living with a catheter	Approaches for living with a catheter	9
Not sure of the best schedule for catheter changes	Promote catheter changes at best intervals	11
Kinks, twists, or tugs on catheter	Prevent kinks, twists, or tugs on catheter	13
Too much caffeine	Decrease caffeine	14
Catheter leaks	Decrease catheter leakage	15
	Empty urine bag	16
Urine bag odor	Clean urine drainage bag	17
Changes with sex	Make adjustments for sexual activity	18
Autonomic Dysreflexia (for people with spinal cord injury)	Recognize early symptoms of Autonomic Dysreflexia	19

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Increase fluid intake

- “I am more conscious of what I drink. I am adamant about drinking 6 glasses of water.”
- Low fluid intake might be associated with blockage and urinary tract infection (UTI).

Paying Attention	Things You Can Do
Notice whether you are getting enough fluids throughout the day.	Drink 2000-3000 cc. fluids per day. If you like the water cold, keep several bottles in the fridge and refill them everyday. To add flavor to water, try 2 oz of cranberry or apple juice to 8-10oz of water. Keep glasses of water scattered in the house. Secure a jug of water to your wheelchair. You may want to drink around meal times and before bed. Have a caregiver remind you to drink water.
Notice changes in color or odor of urine.	If color gets dark or urine has foul smell, increase water.
If you are on fluid restriction, make sure that you stay within the restricted range.	Record occasionally to check that you are staying within range.
Be aware of changes in activities, such as stress and illness, I & O.	Use a journal to increase awareness of how activity affects fluid intake.



Symptoms CAUTI--long term catheters

Urine Changes:

- Color – Discolored, cloudy, dark, blood stained
- Odor – Foul smelling, change in smell from usual
- Sediment (grit) – Increased amount

Temperature – Fever, chills

Pain and/or pressure in bladder area or back (Burning possible, not common)

Autonomic dysreflexia Early, mild symptoms of autonomic dysreflexia (e.g., goosebumps, headaches, sweats) mainly in people with spinal cord injury.


(See next slide for details.)

General Symptoms Blahs!, feeling sick

- Functioning or mental changes – weakness, spasticity, change in the level of alertness (Wilde, McDonald et al., 2013)

Autonomic dysreflexia (AD)


- AD is a syndrome related to a reflex of imbalanced discharges at the level of the spinal cord injury above or at Thoracic 6.
- It can lead to **severe high blood pressure and a life threatening situation if not addressed quickly**.
- It is most often caused by a blocked or poorly functioning catheter or an overly full bag.
- Constipation or pressure ulcers can also cause AD.

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Results

- CAUTI and dislodgement outcomes did not differ by group.
- Blockage was significantly lower in the intervention group, but the result did not last the full 12 months.
- Rates showed both groups improved.
- The intervention group had more ED visits & hospitalizations for CAUTI and also higher self-reported CAUTI severity scores. Not powered for ED events. (Wilde, McMahon, et al. 2015)

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Conclusion

- Both groups improved over time--Self-monitoring r/t calendar (unintentional intervention).
- Unclear whether decreases in UTI, blockage, and dislodgement rates were related to the intervention.
- Symptom identification, severity of UTIs, & getting care early could be r/t higher hospitalization for CAUTI in the intervention group.

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Implications


- Recommend additional nurse support over time to sustain intervention.
- Value in optimal/consistent fluid intake.
- Catheter calendar, a minimal intervention, could be easily implemented.
- Dissemination for education and research (indwelling and intermittent catheter studies). Contract with University of Rochester email Mary Wilde:
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Thank You!

From Mary Wilde and the ICS Nurses' Committee

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Long-term Urinary Catheter Users Self-Care Practices and Problems

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Abstract

Aims—The aims were to characterize a sample of 202 adult community-living long-term indwelling urinary catheter users, to describe self-care practices and catheter problems, and to explore relationships among demographics, catheter practices, and problems.

Background—Long-term urinary catheter users have not been well studied, and persons using the device indefinitely for persistent urinary retention are likely to have different patterns of catheter practices and problems.

Design—The study was a cross-sectional descriptive and exploratory analysis.

Methods—Home interviews were conducted with catheter users who provided information by self-reported recall over the previous two months. Data were analyzed by descriptive statistics and tests of association between demographics, catheter practices, and catheter problems.

Results—The sample was widely diverse in age (19–96 years), race, and medical diagnosis. Urethral catheters were used slightly more often (56%) than suprapubic (44%), for a mean of 6 yrs. (SD 7 yrs.). Many persons were highly disabled, with 60% having difficulty in bathing, dressing, toileting, and getting out of the bed; 19% also required assistance in eating. A high percentage of catheter problems were reported with: 43% experiencing leakage (bypassing of urine), 31% having had a urinary tract infection, 24% blockage of the catheter, 23% catheter-associated pain, and 12% accidental dislodgment of the catheter. Treatments of catheter-related problems contributed to additional health care utilization including extra nurse or clinic visits, trips to the emergency department, or hospitalization. Symptoms of catheter associated urinary tract infections were most often related to changes in the color or character of urine or generalized symptoms.

Conclusions—Catheter related problems contribute to excess morbidity and health care utilization and costs.

Relevance to clinical practice—More research is needed in how to minimize catheter associated problems in long-term catheter users. Information from this study could help inform the development of interventions in this population.

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Study Design: MW, JM

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Keywords

urinary catheterization; nursing; urinary tract infection; urinary retention; complications; self-care

Introduction and Background

Living with an indwelling urinary catheter presents numerous challenges that must be addressed on a daily bases. Nevertheless, it can be indicated for persons unable to use any other bladder management method, including people with persistent urinary retention who lack sufficient cognition or hand dexterity for self-catheterizations and no one to do it for them. Also a catheter can be an option to improve quality of life in selected cases of severe incontinence or when a disability makes it difficult to use the bathroom (Cottenden et al., 2009). The majority of long-term catheter users have a neurogenic bladder dysfunction related to a disability, such as spinal cord injury (SCI) or multiple sclerosis (MS) (Wilde & Dougherty 2006, Wilde et al. 2010). While catheter problems are well known—recurrent and persistent blockage, catheter-related urinary tract infection (CAUTI), accidental dislodgment, and leakage of urine (bypassing)—data on the frequency and severity of these problems are limited. Information on catheter management, such as drainage bag replacement and/or cleaning and caregiver assistance, is even less well known. Moreover, community dwelling study samples are often small (<45) in persons with long-term use, (Wilde & Carrigan 2003, Wilde & Dougherty 2006, Wilde & Brasch 2008, Wilde et al. 2010), thus making it difficult to characterize the population and their needs.

This is a report of a cross-sectional analysis of data from 202 persons with long-term indwelling urinary catheters (urethral or suprapubic [SP]). The purpose of this analysis is to describe catheter care practices and catheter-related problems to inform clinicians and researchers. Having information from a large sample will help fill a gap in the literature in which small samples have been the norm.

Methods

Design

This analysis is based on baseline data collected for a single blinded randomized trial of an educational program in urinary catheter self-management with long-term catheter users. This analysis is based on data derived through a one-time home interview of 202 study participants, prior to randomization, conducted by trained interviewers from June 2009 through June 2011. The aims of this analysis were to:

1. Characterize the sample of 202 community-dwelling long-term adult indwelling urinary catheter users who had catheter problems in the past 6–12 months or those new to a catheter within the past year.
2. Depict how persons with catheters take care of the device on a day to day basis, including others who help in this care.
3. Describe the prevalence and incidence of self-reported catheter-related problems over a two month period.
4. Explore relationships among demographics, catheter practices, and catheter problems

Setting and sample—The study was conducted at two sites—the University of Rochester, NY (Utica to Buffalo region) and at the Visiting Nurse Service of New York (VNSNY) in New York City and parts of Nassau and Westchester Counties—with separate

teams conducting the study activities using the same procedures and tools. To be eligible for the study, participants had to: (1) be 18 years of age or older; (2) expect to use an indwelling urethral or SP catheter for at least one year; (3) report having a catheter-associated problem (UTI in the last year, or blockage or dislodgement in the last six months) OR report using a catheter for less than one year (4) complete study measurements alone or with the help of a family member; and (5) communicate in English. Despite the need in the parent study to include only persons who would benefit the most from the intervention, only 3.6% of those screened were excluded for criteria #3 above. Individuals were excluded if they had a terminal illness. Institutional approval was obtained and synchronized for human subject's ethics at both sites.

Data Collection

Measures—Two instruments were used for this cross sectional analysis: 1) *Demographics and Catheter Care Questionnaire (DMC)* and 2) *Catheter Problems Questionnaire (CPQ)*. Both instruments were developed by the Principal Investigator (PI) for research in similar populations (Wilde & Dougherty 2006, Wilde & Brasch 2008) and modified for this study. For the *DMC*, 50 items measured demographics and catheter-related variables to describe the sample, and included: 1) person/family--age, race/ethnicity, type/presence of caregivers (e.g., relative or paid person), education, employment, insurance; 2) chronic conditions--diagnosis, list of medications, and functional ability through the Katz score (Katz, Ford, Moskowitz, Jackson, & Jaffee 1963) and 3) catheter related-- catheter type (e.g., silicone or latex coated), interval for catheter changes, and bag care. The content validity scores were found to be acceptable in previous studies using the same instrument (Wilde & Dougherty 2006, Wilde & Brasch 2008).

Catheter related problems (e.g., UTI, blockage [encrustation within the catheter]) were measured using the *CPQ*. Content validity scores for a previous study (Wilde & Brasch 2008) indicated that the items were acceptable. *CPQ* was modified to include additional information related to CAUTIs, i.e., severity and symptoms. Frequency of catheter related problems was asked, and for CAUTI and blockage of the catheter, associated treatments were solicited. Information was recorded for up to six CAUTI events and up to 12 blockage events (as blockages were sometimes frequent).

Procedures—Study participants at the Rochester site were recruited through provider referral from clinics, home care agencies and private urological offices. In New York City, a database was used to identify people with catheters. Potential participants at both sites were screened for eligibility and interest by telephone call. At intake, participants provided informed consent, and subsequent to enrollment—but prior to random assignment-- home interviews were conducted. An electronic data collection system, Questionnaire Development System (QDS), was used to collect and manage data. Participants received an honorarium of \$20 for the interview.

Data Analysis

Prior to analysis, data were verified, cleaned and checked for consistency with a full range of logic checks. Decisions about how to code missing data and outliers (Yang, Xie, & Ngee Goh 2011) were made by the team, with input from the statistician. Data were analyzed descriptively for central tendency (mean, median), dispersion (SD, range), and distribution (skew, kurtosis). Specific emphasis was on describing prevalence and incidence of major catheter problems of CAUTI, blockage, and dislodgment of the catheter. Associations were explored (*t*-tests or Pearson's *r* for interval level data and Chi Sq. or odds ratios and confidence intervals (CI) for categorical data) among variables believed to contribute to

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these catheter-related problems. Analyses were performed using IBM Statistical Program for Social Sciences (SPSS) 19 and SAS 9.2.

Results

Demographics

The sample was diverse by age, race, and medical diagnosis. The male to female ratio was roughly equivalent at 51 and 49% respectively. Ages ranged from 19 to 96 with a mean and median age of 61, SD of 17.4 years. The race identified most often by participants was white (57%), followed by Black (30%), Asian (2%), American Indian or Alaskan Native (2%), biracial (2%), and unknown (9%). Eleven percent of the sample was Hispanic. Diversity was also demonstrated by the marital status selections, with approximately 34% of participants reporting never having been married, over 19% separated or divorced, 18% widowed, 27% married and 2 % common law married or living with a life partner. A single diagnosis believed to affect bladder function was identified for each person and we labeled them as “primary” in Table 1, categorizing by the order in the table. Many persons had other diagnoses affecting the bladder, and these were labeled “secondary.” Spinal cord injury (SCI) and multiple sclerosis (MS) were the most common medical diagnoses, with 40% and 23% respectively.

Medications included 26 different classes, and many persons took more than one medicine in a single category, for instance heart medicine was taken by 44%, but of these patients over half took more than one cardiac medicine. Eleven percent were on antibiotics and 4% on urinary antiseptics. Other bladder medicines included: anticholinergics (20%), antispasmodic/ antimuscarinics (3%), alpha blocker (5%), and muscle relaxants (39%). Frequent medicines were for MS (13%), anticonvulsants (30%), upper gastrointestinal ([GI] 33%), laxatives (34%), psychological/depression (44%), diuretics (24%), diabetes (17%), hypertension (25%), respiratory (19%). Pain medicine was taken by many, including NSAIDS/aspirin (38%), Tylenol (26%), and narcotics (34%). Smaller numbers took medicine for cancer (8%), sleep (5%), or steroids (5%). Eighty-four percent reported taking at least one vitamin or mineral, most typically a multivitamin, calcium or vitamin D.

The majority of participants lived with another person, generally family (55%); only 8% lived with paid caregivers, and 37% lived alone. Employment rates were minimal with only 11 persons working, six of them full time. Most individuals had some type of public insurance and 48% reported having private insurance. Education levels of the subjects varied greatly with 16 % not completing high school, 27% with high school or GED, 19% with some college, and 38 %with a college degree, including 12% with a graduate degree.

Activities of daily living (ADL)--in bathing, dressing, toileting, getting out of bed, and eating---were evaluated by the Katz scale, with item responses calculated as 1 point for independent and 2 points for needs assistance. The range was 5–10 for the total scale, with a higher score indicating less functional ability; the mean was 7.75 (SD1.9) and mode was 9. Twenty-four percent reported that they were independent in all activities, 24% needed assistance with 1–3 ADLs, 35% needed assistance with 4 ADLs and 17% needed help with all 5 ADLs.

Catheter Care Practices

Catheter characteristics—The length of time of catheter use varied considerably from 1 to 470 months (39 yrs.). The mean was 72.5 months or 6 yrs. (SD 85.4months, 7yrs.). Median use was 3.25 yrs. Urethral catheters were used more often than SP, with 112 (56%) and 89(44%), respectively; one person had both types (Table 2). Fifty-eight of those with SP

had used urethral catheters in the past; whereas, only two currently using a urethral catheter had tried a SP catheter. In the past, 35% had used an intermittent catheter, 16% an external condom catheter, 29% had used Crede, and 83% had used absorbent products.

Catheter sizes and the amount of water in the balloon varied. Catheter sizes ranged from 12–30 Fr. with a mean of 18.5 (SD 3.2), and in general urethral catheters were significantly smaller (mean 17.1 Fr., SD2.1) than SP catheters (mean 20Fr., SD 3.5; t test -7.29 ; df 182; $P < 0.01$). Balloon size varied from 5–30 mL with 70% being 5–10mL; the water within the balloon was reported as 2–50mL, with the majority (55%) using 5–10mL. Some people (8%) did not know the size of the catheter and 23% did not know the balloon size or amount of water instilled. (See Table 2 for details.)

Drainage bag use—Most persons (58%) used both leg and overnight (night) bags, switching between them. Some individuals used just one type, with leg bags used alone by 17% and night bags used alone by 23%. Three persons used other collection methods: one a belly bag, one connected tubing to empty the bladder directly from the catheter, and another used a plastic cover over the end and emptied the catheter (without a clamp). Only four persons (2%) used a leg bag continuously, connecting it to the night bag later in the day. The majority switched between leg and night bag, and most also cleaned them (leg bags by 54% and night bags by 59%). Solutions for cleaning bags and the frequency for replacing and cleaning the bags are in Table 3.

Catheter changes—Catheter changes were performed by professionals (nurses, physicians) in homes, clinics and offices (Table 4). Unscheduled changes were reported in the previous two months by 37% ($n=74$), with 3 who said this occurred weekly, 15 said several times a month, 12 monthly, and 43 once in two months. Catheter users changed it themselves 8% ($n=16$) of the time for routine changes and 10% ($n=20$) for unscheduled; likewise spouses/family members did so 8% ($n= 14$) of the time for routine changes and 10% ($n=19$) for unscheduled. For regularly scheduled changes, out of 12 males who did this, 2 changed urethral and 10 SP; out of 4 females, all changed urethral catheters. For unscheduled changes, out of 14 males who changed their own catheter, 2 had urethral and 12 had SP; out of 6 females, five had urethral catheters, and one had SP. Physicians or home attendants also changed or assisted with catheter changes, for routine changes for 4 persons and unscheduled for 9. Noteworthy is that in the previous two months, 3.5% had used the emergency department (ED) for routine changes, and 31% among those who reported unscheduled changes. Significant differences were found for routine changes in the ED by study sites, with 6 in the NYC site and 1 in Rochester (Chi Sq. 7.0; $df=1$; $P=.008$.) However, the unscheduled changes in the ED were not significantly different, with 52 in NYC and 11 in Rochester. (Chi Sq. 2.6; $df=1$; $P=.106$).

Catheter irrigations—Irrigating the catheter, which is not a recommended practice (Cottenden et al. 2009, Gould et al. 2009), was done by 42%. Of those who irrigated, 18% did so daily or more often, 13% did it one or more times a week, 43% did it one or more times a month, and 25% once in two months, and persons who irrigated daily were more likely to have had blockage (Chi-Sq. 13.50, $df=1$, $P=.019$). Preventive irrigations were done by 37%, for urine flow problems by 34%, and both preventively and for problems by 39%. Those who irrigated for prevention and problems were more likely to also have had blockage, (Chi-Sq. 13.57, $df=1$, $P=.001$). Solutions for irrigation included: saline 76%, sterile water 23%, tap water 9%, and Renacidin™ (an acidic solution for instillation) 4%. Irrigating the catheter was significantly related to blockage (Chi-Sq. 15.94, $df=1$, $P < .001$) but the pattern of irrigation and blockage vs. CAUTI varied by the individual. Out of 83 who irrigated, 14 had both blockage and CAUTI, 17 had only blockage, 18 had only CAUTI, 32 had no blockage or CAUTI, and 2 did not know.

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Catheter Problems

Prevalence and incidence of self-reported catheter related problems for the previous two months are described in Table 5, including means, SDs, and rates per 1000 catheter use days for CAUTI, blockage, and dislodgement. CAUTI was defined as a urinary infection treated with an antibiotic. Self-reported prevalence of CAUTI was 31% (63/202). In 63 persons, there were 75 episodes reported, with 54 persons having 1 event, seven having 2, one having 3 and one having 4. Blockage in the previous two months was reported by 48 persons (24% prevalence) and frequency of the event was reported by 47 of 48 persons: from 1–2 times in 31 persons, 3–4 times in 9, 7–9 times in 4, and 20 or more times in 3. Frequencies and other details are reported in Table 5 of leakage (bypassing), sediment, kinks/twists, bladder spasms, and autonomic dysreflexia (AD), a painful syndrome caused by injury to central nerves.

Relationships among demographics, catheter practices, and complications—

No significant associations were found related to CAUTI in the past two months (Yes/No) for catheter size, type of catheter (urethral or SP), leakage, kinks/twists or dislodgement of the catheter. Younger persons were more likely to have reported CAUTI, with a mean age of 57.5 years (SD 16.3) as compared with 63 years (SD 17.6) for those who did not (t test = 2.11, df 199, P = 0.036) and to have used the catheter for a longer period of time (Pearson's r = -.157, P = 0.026). Catheter size and length of time using a catheter were not significantly correlated with the number of CAUTIs.

All chi-square tests of associations were not significant for CAUTI or blockage (Yes/No) for catheter management issues related to caregivers who assist with catheter care (e.g., spouse, family, paid helpers); frequency of bag changes (night and/or leg bag); or cleaning the bag.

Blockage was significantly related to CAUTI, with the odds of having a CAUTI were 2.29 times as great (95% CI = 1.17, 4.48) among those with blockages compared with those reporting no blockages. Out of 47 persons reporting frequency of blockage at least once in two months, 22 had at least one UTI (46%); in contrast, out of 152 persons with no blockage, 41 reported UTI (27%).

Treatments—Treatments associated with excess healthcare utilization for UTI or blockage, such as extra nurse home visits or hospital visits, are listed in Table 6. All persons reporting UTI had associated treatments, 96% of those with blockage had excess treatments, and only one person out of 88 with either UTI or blockage had no excess treatments. Some treatments required additional family or patient time or use of extra supplies. For example, in those with blockage, the catheter position was adjusted by 19% in relation to blockages, and irrigation was done for blockages by 49%. Doubtless some of the irrigations also were done by the catheter users or caregivers in the home, not nurses. In the previous two months, 17 study participants reported they were hospitalized for UTI for a total of 165 days. The mean number of days hospitalized was 9.71 (SD 7.41), and if including all of those who had UTI but were not hospitalized, the mean days per hospitalization was 2.62 (SD 5.75).

Symptoms of UTI—Questions of frequency and severity of UTI symptoms were asked. Symptoms associated with 75 episodes of UTI were asked, with yes or no to each symptom (Table 7). The most frequent symptoms were related to a change in the color (#1) or character of the urine (odor #2; sediment #5). Generalized symptoms also were reported often (malaise #3, bladder spasm #4). Severity of UTI symptoms were reported also for 74 events in two months. On a scale of 1–10 with 1 being very mild and 10 being the most severe UTI you can imagine, a score of 1–4 was reported 22% of the time, a score of 5–7 was reported 43% of the time, and a score of 8–10 was reported 35% of the time.

Leaking/sediment—Of the 86 persons (43%) who reported leaking (bypassing of urine), 8% indicated it was not a problem, 31% a small problem, 29% a moderate problem, and 32% a large problem. Sediment was noticed by 127 (63%), of these 41% saying it was a small amount (hardly noticeable); 34% a moderate amount (can be seen in tubing and bag if looking for it); and 25% a large amount (very easy to see in tubing and bag. In the previous two months, presence of sediment was associated with blockage (Chi-Sq. 13.93, $df=1$, $P<.001$) but not CAUTI (Chi-Sq. .48, $df=1$, $P=0.49$).

Pain—Catheter related pain was reported by almost a quarter of the sample ($n=46$, 23%), and of those with catheter pain it was attributed to positioning (e.g., sitting on it) by 46%, bladder spasms 46%, some catheter changes 30%, and every catheter change 26%. Fifteen percent said that the pain bothered them very little, 46% said somewhat, and 39% said a great deal. Three percent ($n=6$) said they have catheter pain all the time. In addition, AD can be painful, and this was experienced by 41 persons (20%) at some time, most within the past two months (Table 5). Primarily those with AD had SCI (38 of 41).

Difficult insertions/removals—Twenty-four individuals (12%) reported having difficulty with the insertion of their catheter in the previous 2 month and 11 (5%) persons had difficulty during removal. While 31 of 35 people said this difficulty had occurred just once or twice in the past two months (mean 1.7, SD 1.1), four persons had experienced it between 3 and 6 times. For those reporting any difficulty, the level of difficulty for the most difficult insertion or removal experienced (defined as difficult or challenging for the patient) was assessed with a visual analogue scale from 1–10, with 1 being just a little more difficult than usual and 10 being a very challenging situation. The difficulty mean score was 6.9 (SD 3.0), and more than half (54%) were rated from 8–10.

When asked if the catheter interfered with daily life, 29% said not at all, 26% said very little, 29% said somewhat and 16% said it interfered a great deal. However, in further analyses, the catheter significantly interfered “a great deal” in persons with blockage (14 of 31; Chi Sq. 9.53, $df=3$, $P=0.023$) and those with difficult catheter changes (11 of 32; Chi Sq. 8.65, $df=3$, $P=0.034$).

Discussion

Although the majority of the persons enrolled in this study were recruited from a home care agency in New York City (75%), the sample is believed to be a good representation of this population because recruitment also took place through clinics and private offices in the Rochester site. Only 3.6% of the persons recruited were not eligible because of not having any major catheter problems, which is consistent with another study in this population in which not one of the 43 persons were problem free during the eight months’ study (Wilde et al. 2010). The sample was older than in some previous studies, with a mean of 61 yrs. as compared with a mean of 49yrs. in two recent studies (Wilde et al. 2010, Wilde & Brasch 2008) with similar populations that had more persons with SCI. The current sample, with a total of 87% recruited through home care agencies, may reflect a more vulnerable population than in earlier studies. Multiple secondary diagnoses and co-morbidities were reported as well as a wide range of medications. Often large studies with catheter users involve retrospective chart audits related to a single medical diagnosis, most often SCI, aimed at finding out about urinary health or catheter management strategies over time (Cameron et al. 2010, El-Masri, Chong, Kyriakider, & Wang 2011).

Catheter Practices and Care

This is the first known large study (N=202) providing great detail on catheter management practices and problems. Many people lacked knowledge about their catheters, such as the balloon size (47 persons/23%) and a few gave us information that was questionable for accuracy, such as catheter sizes of 15 and 17Fr, which are not known to exist. Also, 34% said the catheter was all latex; it is possible that some did not know it might have a Teflon™ coating, as this is a commonly used coating over latex and only one person indicated this type. It was of concern that 29 persons said the balloon was size 30 mL since this is only recommended for postoperative bleeding. The 8 persons who said their 30mL balloons were inflated part way might also be mistaken, but if they were correct, inflating between 16–29 mL could contribute to asymmetry of the balloon and possible erosion into the bladder mucosal lining (Cottenden et al. 2009). Patients and their caregivers need to know more about the proper size of catheters and balloons so that the sizes can be decreased if increased for a specific reason, such as bleeding.

It was not surprising that most people received help with managing their catheters (Table 2), given the large number of people with neurological disorders and the high mean Katz score of 7.8, which indicates a high level of disability. The level of disability is similar to the score of 7.6 (Wilde & Dougherty 2006) cited in a study of 30 catheter users, and in another study with 43 individuals, 44% required assistance from another to dress the upper body, and 91% were in wheelchairs (Wilde et al. 2010).

Drainage bag replacement and cleaning—There was much variation in how often the drainage bag was replaced by a brand new one and/or cleaned, but the reason for the frequency was not asked. Logically, the percentage of persons cleaning the leg bag increased as the number of days between replacements extended. However, some people replaced the bag infrequently (e.g., within 22–30 days or >30 days) and not all cleaned the bag between replacements (Table 3). It was unanticipated that so few used a bleach solution to clean since it is the only product recommended for cleaning drainage bags (Gould et al. 2009); however, bleach is caustic and it can damage clothing and irritate the skin or eyes. Nor was vinegar used much, and this had been the standard in home settings in the past (Wilde 1986, Wilde 1991). A lack of research in this area, as well as whether supplies are reimbursed, puts catheter users in a position to make their own decisions about cleaning and reuse of bags. Somewhat surprising was that only 2% indicated they kept the leg bag attached all the time, adding a night bag to it for continuous evening drainage. This practice is recommended at the VNSNY and it is commonly recommended in the United Kingdom due to a belief that this keeps the catheter less disturbed and more of a closed system. (Jones, Brooks, Foxley, & Dunkin 2007, Royal College of Nurses (England 2008). In contrast to our sample, in the U.K., leg and night bags are routinely changed every seven days or more often if needed, i.e., appear dirty or have an odor. (Personal communication, M. Fader, August 2011).

Catheter changes—This is the first time detailed information about who changes catheters was reported and that catheter users and family members sometimes changed it (Table 4). People in home settings with chronic illnesses often manage complex technology, even as complicated as total parenteral nutrition. Yet catheter changes are not always simple, particularly in men. However, significantly more males routinely changed their catheters more often than females, and SP catheters were significantly more often changed than urethral for unplanned changes. Providing careful teaching for those changing their own catheters is essential to prevent traumatic insertions, especially when taking into consideration the proportion of people who experienced difficult insertions (12%) and removals (5%). Home care nurses changed the great majority of catheters, understandably

since the majority of the sample came through home care agencies. Thus, it was particularly surprising that unscheduled changes were often done in the emergency department (31% of the time) and more often in NYC than in the Rochester site. Also ED visits for routine changes (3.5%) contribute to substantial costs that could be reduced through planning and use of home care agencies. The homebound restrictions in Medicare might have contributed to this as people who are able to get out, hold a job, etc. are not eligible for home care services under Medicare. Further research in reasons for catheter related ED use is warranted.

Catheter Problems

Even though this is a selected group of patients who experienced catheter related problems in the past year or were relatively new to catheter use, this analysis related to data from a two month period confirms the widespread prevalence of catheter related problems. The current report on nine catheter related problems, frequency of occurrence, and their associated professional treatments is the first with this level of detail. In just two months prior to study enrollment, 31% reported having had a CAUTI, blockage of the catheter was reported by 24%, dislodgement by 12%, leakage by 43%, and pain by 23%. Though the rates of CAUTI was 6.2/1000 catheter days (95% CI= 4.8, 7.6), lower than the 8.4/1000 days reported in a study of 43 long-term catheter users over a six month period (Wilde et al. 2010), it is much higher than the rate of 1.7/1000 days reported through a home care benchmarking project which includes short and long-term catheter users (MAHC 2011). In comparison with other research, (Maki & Tambyah 2001, Wilde et al. 2010) catheter size and gender were not associated with CAUTI.

The rates for blockage and dislodgment are the first known to be published. This report affirms the relationship of blockage and CAUTI reported in previous samples of 24 (Wilde & Carrigan 2003) and 30 (Wilde & Dougherty 2006). Research is needed to explicate the relationship between CAUTI and blockage, such as bladder mucosal bleeding from distension related to poor urine flow (Pearman 1984) or bladder stones.

Symptoms of CAUTI—In a recent report of a study in 43 community dwelling adults, the most frequently reported symptoms of CAUTI were urinary sediment, foul odor, general malaise and changes in the color of the urine. (Wilde et al. 2010) In three other studies, foul urine odor was a common symptom (Wilde 1986, Wilde & Dougherty 2006, Wilde & Brasch 2008) though other symptoms varied. These symptoms were confirmed in the current study with the top five being: changes in urine color and odor, malaise, weakness, and sediment. While there are individual differences, this population did not report as often the typical symptoms of UTI in the general public (i.e., burning, urgency, and fever). Of concern, in a study of patients with intermittent urinary catheters, accuracy in predicting UTIs based on their symptoms was not well validated (Massa, 2009). Although cloudy urine was the most accurately reported symptom of UTI, the researchers concluded that most patients were better at identifying when they did not have a UTI, rather than when it was present. This study underlines the need for further symptom research in long-term catheterized patients. Without better knowledge in this area, it is not known whether symptom awareness alone can prevent episodes of symptomatic CAUTI. Thus for patients to seek early treatment, they must know what symptoms to watch for and in particular which ones are their own valid symptoms. This could benefit their health and reduce excess healthcare utilization, especially if ED visits and/or hospitalization can be avoided.

Limitations

All data are self-reported, and thus we expect some errors. Also there were limitations in sampling because the majority was recruited through one large home care agency and there

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were differences in recruitment processes (referral versus database). Persons more bothered by catheter problems might have been more willing to join the study, contributing to selection bias. Some information from study participants might have been inaccurate, for instance catheter sizes of 15 and 17Fr. described above. However, we have confidence in the accuracy of our self-reported data. In a comparison of self-report to chart accuracy in a small sample of a similar population of catheter related problems, congruence was reported as 97% (Wilde et al. 2010).

Conclusion and Relevance to Clinical Practice

This report characterizes a diverse sample of the population of long-term indwelling urinary catheter users in a way not reported before, providing detailed information about demographics, catheter care practices, and numerous catheter related problems and associated healthcare utilization. The widespread report of catheter problems is of concern because the timeframe was just two months, this population is likely to need an indwelling catheter indefinitely, and many of these problems negatively impact personal health and associated healthcare expenditures. Gaps in research include optimal frequency for replacement and methods of cleaning urinary drainage bags, increasing the predictive value of CAUTI symptoms, decreasing excess ED use (especially for catheter changes), and best practices for educating caregivers (family and paid carers). To better portray this vulnerable population, prospective longitudinal research is needed with long-term catheter users having a range of diagnoses. Also, for surveillance, CAUTI rates for short and long-term users should be distinguished.

Implications for practice involve providing complete information about the catheter to those who use the device, using the appropriate catheter balloon size and water inflation, and consideration of criteria for teaching catheter changes to patients and caregivers. Moreover, since disability levels can change over time, such as in those with MS, monitoring catheter self-care capability over time could proactively identify people whose caregivers need to learn more about catheter management.

Many of the catheter-related problems reported in this study could be prevented or minimized with more attention to catheter management, early identification of problems, and more evidence-based catheter practices. Therefore, information from this study is critical to researchers who wish to plan interventions to address the persistent catheter related problems that affect large proportions of long-term indwelling urinary catheter users.

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Table 1

Primary and secondary diagnoses

	Primary		Secondary					
	#	%	MS	Diabetes	Stroke	Prostate	Spina bifida	Neurogenic bladder
SCI	81	40	1	20	9	8	1	39
MS	46	23		7	4	3		23
Diabetes	25	12	7		7	5		10
Stroke	4	2	4	7		3		2
Prostate	20	10	3	5	3			13
Spina bifida	2	1						1
Neurogenic Bladder	16	8	23	15	2	13	1	
Parkinsons	3	2						
Other	5	3						

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Table 2

Catheter characteristics and catheter care practices

Time using catheter	%	Catheter material	# (%)	Catheter size (Fr)		SP #	SP #
				all # (%)	Urethral #		
Up to 1 yr.	22	All latex	69/34				
> 1 to 3 yrs.	26	Teflon™ coated latex	1/1				
> 3 to 5 yrs.	13	Silicone coated	71/35				
> 5 to 10 yrs.	22	All silicone	12/6				
>10 to 15 yrs.	8	Hydrogel coated	3/2				
>15 to 20 yrs.	6	Silver coated	5/3				
> 20 to 40 yrs.	5						
Catheter size (Fr)	Urethral #	SP #	Balloon size all # (%)	SP #	SP #	Urethral #	SP #
12	1 (1)	0	5-10 mL, 124(61)	62	62	62	62
14	8(4)	7	30 mL, 29(14)	19	10	19	10
15-16	62(31)	45	Don't know, 47(23)				
17-18	57(28)	34	Other, 2(1)				
20	16(8)	7	Amount of water in balloon all # (%)	9		Urethral #	SP #
			<5cc, 2(1)	16		1	1
22	18(9)	2	5-10, 110(55)	14		54	56
24	17(8)	3	11-15, 10(5)	3		8	2
26	3(2)	0	16-29, 12(5)	1		8	4
28	1(1)	0	30, 9(5)	2		7	2
30	2(1)	0	40-50, 2(1)	3		2	0
Not known	17(8)	14					
Helps with catheter # (%) (some selected more than one)							
No one		47(23)	Friend			7(4)	
Spouse/partner		38(19)	Paid aide			126(62)	

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Time using catheter	%	Catheter material	# (%)
Other family member	34(17)	Other	1(1)

Table 3

Drainage bag cleaning and replacements

Type of bag used	(%)	Cleaning solutions	Percentage in leg bag users	Percentage in night bag users
Leg bag only	17	Soap & water	29	27
Night bag only	23	Water alone	35	31
Both leg and night bag	58	Vinegar & Water	33	36
Leg bag always attached, & adds night bag	2	Bleach and water	16	22
Other (e.g., homemade clamp)	2	Commercial product, e.g., Urolux™	1	1
		Household cleaners, e.g., Lysol™	12	12
		Other	1	2
Replacement with brand new bag, within:	Leg bag users (%)		Night bag users (%)	
	Replacement	Also cleans leg bag (%)	Replacement	Also cleans night bag (%)
1–7 days	49	62	31	64
8–14 days	20	77	26	69
15–21 days	11	88	14	83
22–30 days	16	75	20	76
>30 days	5	86	9	93

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Table 4

Routine & unscheduled catheter changes

Person changing catheter	Routine changes # (%)			Unscheduled changes # (%)		
	#(%) all	# UR-SP	# M-F	#(%) all	# UR-SP	# M-F
(some selected more than one)						
Self	16(8)	6-10	*12-4	20(10)	*7-13	14-6
Spouse-partner	7(4)	3-4	4-3	9(5)	4-5	6-3
Family member	7(4)	5-2	2-5	10(5)	7-3	4-6
Home care Nurse	112 (55)	**73/39	***42-70	96(46)	**63-33	38-58
Nurse or physician at clinic	45(22)	*19-26	31-14	45(22)	20-25	25-20
Nurse or physician at private medical office	29(14)	12-17	19-10	22(11)	9-13	16-6
Emergency department	7(4)	6-1	3-4	63(31)	32-31	40-23

UR= urethral; SP= suprapubic catheter. Significant differences in Chi Square tests

* P= .05

** ≤.01

*** <.001

Table 5

Catheter problems

Key catheter problems in past two months	Number persons	Percentage *	Mean (SD) entire sample	Rate/1000 catheter days
UTI	63	31	0.37 (0.63)	6.22
Blockage	48	24**	0.67 (1.71)	6.22
Dislodgement	25	12	0.21 (0.68)	11.08
Other catheter problems in past two months	Number persons	Percentage *	Frequency of those with problem (%)	
			Daily	Once - several Times week
				Once - in past 2 months
Leaking (bypassing urine)	86	43	9	10
Sediment	127	63	24	29
Kinks/twists	40	20	13	8
Bladder spasms	72	36	37	24
Autonomic dysreflexia	26	13	4	31
				51
				29
				7
				40
				10
				38
				27

* Indicates the percentage of study participants who had this happen at any time during the previous two months, rounded to nearest percent.

** The outlier test based on zero-inflated Poisson models (Yang et al. 2011) identified three observations in blockage variable. Outliers were replaced with the observations closest to them, 9, for the calculation of means.

Table 6

Treatments associated with catheter problems in two months

Treatments/	UTI (n=63)			Blockage (n=47)*		
	Total # events	% affected	**Mean (SD)	Total # events	% affected	**Mean (SD)
Extra nurse home visit	14	19	0.22 (0.49)	26	30	0.55(.99)
Extra office visit	18	25	0.29 (0.52)	13	23	0.28 (0.54)
ED visit	25	35	0.40 (0.61)	16	19	0.34 (0.84)
Hospitalized**	20	27	0.32 (0.56)	N/A		
Rehab or nursing home stay						
Catheter changed	48	65	0.76 (0.64)	58	70	1.23 (1.22)
Urine cultured	54	76	0.86 (0.59)	N/A		
Antibiotic prescribed	75	100	1.19 (0.53)	N/A		

* One additional person had blockage but did not know the frequency.

** Means (SDs) calculated only for those affected with the problem, i.e., 63 with UTI and 47 with blockage. Treatments were not asked for blockages over 12 events/person, which was reported by three persons.

Table 7

Symptoms of UTI (n=63)

Symptom	Mean (SD)	Times reported	Percent with symptom *	Rank order of frequency
Urine color change	0.94 (0.74)	59	76	1
Odor in urine	0.84 (0.77)	53	68	2
Malaise	0.71 (0.77)	45	59	3
Weakness	0.60 (0.73)	38	51	4
Sediment	0.59 (0.75)	37	48	5
Pain Bladder	0.57 (0.76)	36	46	6
Burning	0.57 (0.78)	36	44	7
Bladder Spasm	0.51 (0.64)	32	43	8
Chills	0.49 (0.72)	31	41	9
Blood	0.49 (0.69)	31	40	10
Fever	0.44 (0.62)	28	40	11
Pain Back/Side	0.44 (0.67)	28	37	12
Muscle Spasm	0.40 (0.71)	25	32	13
Other	0.29 (0.52)	18	25	14
Mental Changes	0.27 (0.51)	17	24	15
Leakage	0.25 (0.47)	16	24	16
Autonomic dysreflexia	0.21 (0.63)	13	14	17

* Percentage with symptom rounded to a whole number.



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Self-Management Intervention for Long-Term Indwelling Urinary Catheter Users: Randomized Clinical Trial

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Clinical Trial Registration number from clinicaltrials.gov is NCT00883220.

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Abstract

Background—People using long-term indwelling urinary catheters experience multiple recurrent catheter problems. Self-management approaches are needed to avoid catheter-related problems.

Objectives—The aim was to determine effectiveness of a self-management intervention in prevention of adverse outcomes (catheter-related urinary tract infection, blockage, and accidental dislodgement). Healthcare treatment associated with the adverse outcomes and catheter-related quality of life was also studied.

Method—A randomized clinical trial was conducted. The intervention involved learning catheter-related self-monitoring and self-management skills during home visits by a study nurse (twice during the first month and at four months—with a phone call at two months). The control group received usual care. Data were collected during an initial face-to-face home interview followed by bimonthly phone interviews. A total of 202 adult long-term urinary catheter users participated. Participants were randomized to treatment or control groups following collection of baseline data. Generalized estimating equations (GEE) were used for the analysis of treatment effect.

Results—In the intervention group, there was a significant decrease in reported blockage in the first six months ($p = .02$), but the effect did not persist. There were no significant effects for catheter-related urinary tract infection or dislodgment. Comparison of baseline rates of adverse outcomes with subsequent periods suggested that both groups improved over 12 months.

Discussion—A simple-to-use catheter problems calendar and the bimonthly interviews might have functioned as a modest self-monitoring intervention for persons in the control group. A simplified intervention using a self-monitoring calendar is suggested—with optimal and consistent fluid intake likely to add value.

Keywords

longitudinal research; quality of life; randomized clinical trial; self-management; urinary catheterization

Indwelling urethral or suprapubic catheters are used by individuals with chronic urinary retention who are unable to perform intermittent-catheterization because of poor hand dexterity, no caregiver assistance, difficulty in using the bathroom, or in select cases of incontinence. While many catheter users have spinal cord injury (SCI) or multiple sclerosis (MS), the population also includes those with other neurological disorders, diabetes, or disease/injury to the bladder region. Unfortunately, indwelling urinary catheters are seldom trouble free (Cottenden et al., 2013; Wilde, McDonald et al., 2013). Data collected in a longitudinal study of 43 long-term catheter users indicated that recurrent problems affect the great majority. Prevalence rates during eight months of catheter use were 70% for catheter-associated urinary tract infection (CAUTI) with a rate of 8.4/1000 catheter days; 74% for

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blockage; and 33% for catheter expulsion or dislodgement (Wilde, et al., 2010). For a two-month period prior to the beginning of this randomized clinical trial (RCT), catheter problems were reported as: 31% for CAUTI, 24% blockage, and 12% dislodgment (Wilde, McDonald et al., 2013).

These complications are distressing to patients/families (Wilde & Cameron, 2003; Wilde, 2003) and contribute to increased healthcare expenses, such as additional clinic, home care, or emergency department visits or hospitalization (Wilde, McDonald et al., 2013). Interventions to address prevention of CAUTI in long-term catheter users such as the use of silver coated or antimicrobial coatings on the catheter (Parker et al., 2009) installations to the drainage bag (Thompson et al., 1984), or special cleaning of the urinary meatus (Burke, Jacobson, Garibaldi, Conti, & Alling, 1983) have not been successful. Although research in self-management of chronic conditions in diabetes (Coyle, Francis, & Chapman, 2013), stroke (Lennon, McKenna, & Jones, 2013), and asthma (van Gaalen et al., 2013) has grown, no self-management clinical trials have been found in catheter users (Cottenden et al., 2013; Niël-Weise, van den Broek, Peterhans, da Silva, & Silva, 2012).

The research clinical trial (RCT) for the current report was developed inductively through six previous studies conducted primarily by the first author (MHW). These studies included research with 30 individuals who kept a urinary diary and were interviewed twice to determine what their self-care practices were (Wilde & Dougherty, 2006). A concept analysis was next conducted of self-monitoring, delineating key attributes and how it fit within self-management literature (Wilde & Garvin, 2007). Then a pilot study teaching self-monitoring of urine flow in long-term catheter users was conducted. The results of the pilot study indicated that optimal fluid intake and preventing dislodgment were the most useful self-management components reported by study participants. Importantly, CAUTI decreased in the six months during the single group pilot (Wilde & Brasch, 2008a). Taken together, the theoretical model for the current study proposed that the intervention would affect catheter self-management indirectly through self-efficacy, and directly; and that higher levels of awareness, monitoring, and behaviors related to catheter care would improve outcomes (Figure 1; Wilde, Zhang et al., 2013).

The aim of the study was to determine the effect of the self-management intervention on health outcomes compared to the usual care control. It was hypothesized that the self-management group would: (a) have fewer episodes of UTI (and severity), blockage, and dislodgement of the catheter; (b) have decreased unplanned catheter-related healthcare utilization, including hospitalizations, emergency department visits, and fewer nurse home/or clinic visits; and (c) report higher catheter-related quality of life.

Methods

Design

The study was a randomized, single-blinded experimental design with repeated measures every two months over a 12-month period. The design called for 101 individuals to receive the self-management intervention and 101 to receive usual care (catheter-related care provided by home care nurses, clinics, or private providers).

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Inclusion/Exclusion Criteria

Eligible participants were adults age 18 and over. Inclusion criteria were: (a) expect to use an indwelling urethral or suprapubic catheter for at least one year, and will be in the study region for at least four months; (b) can complete study measurements alone or with the help of a caregiver; (c) speak English; and (d) have access to a telephone for data collection. Because we wanted to target only individuals who might benefit from this study and, thus, better determine effectiveness, our participants also must have had a catheter problem of CAUTI within the last year, or blockage or dislodgement within the last six months, or be new to a catheter within the last year. Individuals were excluded for terminal illness or cognitive impairments. Children under 18 were not included because they might not have the capacity for self-care, which includes directing others.

Setting and Recruitment

Participants consisted of community-dwelling individuals recruited in two distinct regions by two study sites: (a) a university in a large northeastern U.S. state, and (b) a home care agency which conducts research in a large metropolitan area in the same state. For the university site, participants were recruited through nurses or physicians in home care agencies, medical center clinics, hospitals, and private medical offices (e.g., urology). Screening for eligibility and interest in participation was conducted by phone by the first author (MHW) or the project coordinator after contact information was received from providers who had permission to do so from potential participants. Some catheter users contacted the researchers themselves. In the home care agency, their database was used to identify potential participants with a catheter for telephone call screenings and recruitment by trained study interviewers. Using data from the agency's U.S. Outcome and Assessment Information Set (OASIS) for home care, catheter users were screened and excluded if they had a poor prognosis/life expectancy, cognitive impairment, confused, severe speech impairment, behavior problems, diagnosis indicating dementia, or had been previously interviewed (in another study or declined). Data were collected from June 2009-June 2012 in the homes of community-dwelling individuals and through telephone contacts over 12 months of participation.

Sample Size and Power Calculations

Power calculations were performed to determine a sample size for an adequately powered study to detect clinically meaningful effects across multiple outcomes. For each of the primary outcomes, *a priori* range of clinically meaningful effect sizes was determined based on previous research. All calculations employed a significance level of .05 and 80% power. Power analyses were performed with SAS 9.1 using Monte Carlo simulation resampling techniques for general estimating equation (GEE) analysis (Gastañaga, McLaren, & Delfino, 2006; Yuan & Hayashi, 2003). The analysis indicated that a sample of 220 (160 completers) would provide sufficient power to detect medium effect sizes (15% to 30% differences between groups) for the primary health status outcomes. However, health care utilization measures, such as hospitalizations and ED visits, require larger samples due to their relatively rare frequency of occurrence.

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Ethics/Human Subjects

The study was approved at each site by their respective bodies for protection of human subjects. A coordinated approach assured that the same processes were used, including the same consent form with stamps and contact information from both sites. A Data Safety Monitoring Board was formed and convened annually to assess interim results and potential adverse events.

Randomization and Blinding

Randomization was conducted by the main study statistician who directed the processes with the study coordinators at each site—each of whom subsequently enrolled participants at their own site and allocated them to treatment or usual care after completion of the baseline home visit (HV) interview. Participants were stratified by site to balance the large number of study subjects in the large metropolitan area (75% of participants), as compared with the university site (25% of participants) which was a combination of urban, suburban, and rural areas. Block randomization with random block sizes of 4, 6, or 8 was carried out independently at the two sites to balance the two treatment groups. For each site, a sequence of random assignments was generated by the study statistician and sealed in sequentially numbered envelopes by the study coordinator. The participants were sequentially assigned the treatment after completing the consent and initial HV interview; then, the study nurse called those allocated to the intervention and made arrangements for the first nurse contact in the home. Study investigators, data gathering teams, and statisticians were blinded to allocation status until the final analyses were completed.

The Urinary Catheter Self-Management Intervention

The intervention designed to improve self-management in people with long-term, indwelling urinary catheters was based on self-efficacy theory (Bandura, 1997). Sources of urinary catheter self-efficacy were targeted in the nurse home visit interventions—specifically mastery experiences—vicarious observation, verbal persuasion, and knowledge about physiological status.

Each of the two study sites followed identical intervention protocols, which consisted of three home visits and one telephone call by a trained registered nurse to deliver the intervention. Two home visits took place in the first month and a third (booster) visit occurred at four months. During the first home visit, participants were taught to conduct self-monitoring using a three-day urinary diary to record observations and measurements of fluid intake and output (I & O), urine characteristics, and sensations of flow. This was to teach awareness of urine flow, basic self-monitoring skills, and to increase their level of mastery, thus, contributing to increased catheter related self-efficacy. During the second home visit, about a week later, self-management skills were taught first by reviewing the information from the urinary diary, calculating the intake and output averages and comparing these to an optimal volume (30ml/kg body weight), and identifying the individual's catheter-related problems. Anything notable about I & O, the color/character of urine, or of urinary sensations, was discussed and implications for self-management pointed out.

An educational booklet which had been piloted and viewed as very helpful (Wilde, Zhang, et al., 2013) was then provided and discussed, which focused on basic catheter self-management skills related to: (a) maintaining optimal and consistent fluid intake; and (b) preventing catheter dislodgement—which were the key components of the intervention. In the presence of certain bacteria which cause urea in the urine to split, sodium, magnesium, and calcium will precipitate from the urine—often at about a pH of 6.8, causing sediment and encrustation. However, researchers found that urine pH could increase to as high as 9 or 10, and the catheter might not block if fluid intake is increased to dilute the concentration of minerals (Khan, Housami, Melotti, Timoney, & Stickler, 2010). This is our foundation for the fluid intake requirements, which we set at 30ml/kg body weight (Gray & Krissovic, 2003).

Other modules of the booklet were reviewed briefly or in-depth, depending on interest or need. These were: recognizing early symptoms of CAUTI; living with the catheter; promoting optimal catheter change intervals; decreasing caffeine; decreasing leakage; emptying and cleaning the drainage bag; making adjustments for sex; and recognizing early symptoms of autonomic dysreflexia (for people with spinal cord injury/disease). Goals, if any, were written in the educational booklet. A motivational bookmark with quotes and pictures was reviewed to help encourage participants to be attentive to urine flow.

Two weeks later, the study nurses called to answer questions and, if needed, helped the participants revise goals or plans. At four months, a third home visit served as a booster of the intervention to further refine or modify goals/plans as the catheter user desired. Family or caregivers were encouraged to be present, but the intervention was delivered to the catheter user.

Intervention compliance and fidelity—Two study nurses (one at each site), who were trained together at the beginning of the project, delivered all the intervention components. Multiple strategies were used to establish and sustain the fidelity and integrity of the intervention. These involved: (a) standardization of the intervention and training, including use of a detailed training manual that incorporated Bandura's self-efficacy concepts (Bandura, 1997); (b) randomly selected fidelity assessments of 10% of the interventions—half by audiotape and half in-person home observations; (c) at least monthly conference calls; (d) training study nurses together; (e) tracking study nurse activities and responsiveness of the participants; (f) assessment of participant skills at the end of the study; and (g) inclusion of fidelity assessment in the analysis plan. The results of the audiotape and in person fidelity assessment indicated that competence and adherence to the intervention parameters were highly scored with most means between 4–5 (5 was the highest possible score). Also, because there was little variability in the proportion of the intervention participants who received the intervention contacts (i.e., 98% for HV1, 95% for HV2, 93% TC at two weeks, and 91% HV3 at four months), we decided it was not necessary to adjust for fidelity in the main outcomes analysis. All participants, regardless of group allocation, continued to receive usual nursing and medical care.

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Usual Care

Participants randomized to the control group received usual care.

Measures

Measures were developed for this study based on previous research of the first-author's team (Wilde & Brasch, 2008a; Wilde & Dougherty, 2006). Instrumentation was modeled on the Stanford Chronic Disease Self-Management programs (<http://patienteducation.stanford.edu/>). Participants in both groups were administered identical data collection instruments. At baseline, self-report was used for data collection related to the two-month timeframe prior to the study (for evaluating equivalence of the groups), and every two months for 12 months thereafter through telephone call interviews. To improve accuracy of recall, all participants were asked to maintain an ongoing catheter calendar over the 12 months of the study, using letter symbols for problems: CAUTI (U), blockage (B), and dislodgement (D). Treatments were identified as antibiotic (A), extra nurse home visit (HV), extra office visit (O), hospitalization (H), and emergency department visit (ED). For missed interviews, data were collected for the primary outcomes at the next scheduled interview—if the study participant had kept track of problems in their catheter calendar. This occurred only nine times.

Outcomes

Primary outcomes consisted of catheter-related complications of CAUTI, blockage, and dislodgement. CAUTI was defined as a urinary tract infection that was treated with an antibiotic prescribed by the person's healthcare provider. Blockage was defined as an occurrence in which the urine would not flow through the catheter due to an obstruction of the catheter tube. Blockage was distinguished from kinks or twists that are external to the catheter tube. Dislodgement occurred when the catheter fell out or became displaced accidentally due to traction (i.e., pulling on it). Catheter-related quality of life was also a primary outcome using our previously developed measure with a five-point Likert scale from 1 = *strongly agree* to 5 = *strongly disagree*; higher scores reflect better quality of life (Wilde, Brasch, Getliffe, McMahon et al., 2010).

Excess healthcare expenditures (treatments) related to catheter problems were also primary outcomes; these included extra nurse or clinic visits, hospitalizations, rehabilitation, and emergency department visits. Additional information was asked about each episode of CAUTI regarding the perceived severity of the infection (on a scale of 1–10, with 1 = *very mild* and 10 = *most severe imaginable*), and the number of days hospitalized or in rehabilitation specifically related to the CAUTI.

Data Analysis

Standard data cleaning procedures were applied to screen for errors and potential univariate and multivariate outliers. These procedures led to the removal of blockage data (percentages/month, counts, treatments) for one participant due to inconsistent and contradictory responses. All other data were used; several outliers for blockage were

adjusted by windsorizing to 9 as the maximum number of events in a two-month period for testing group differences.

Intention-to-treat analysis was used. Data were analyzed with SAS 9.3 (SAS Institute Inc., Cary, NC, USA). Generalized linear models were utilized with an identity link function for continuous outcomes (CAUTI severity and QOL) and a logit link function for binary outcomes. Randomization achieved comparability on demographic characteristics of participants and aspects of catheter use (Tables 1 and 2) in treatment and usual care groups. The groups were similar on key outcome variables during the two months prior to the study, except for catheter blockage ($p < .05$) and days hospitalized ($p < .01$) (Table 2). Thus, we fitted each of the models with and without controlling for baseline information on the outcome variable. First, data for the first six months were modeled; then, data from the entire 12 month period of the study were modeled.

First six months—We let “group” be the indicator of treatment assignment (0 = *usual care*; 1 = *treatment*), and y_{it} be the outcome for the i^{th} subject at month t . Three models were developed for each outcome over the first six months of the study: a group differences model, a model for interaction of group and time; and a model controlling for baseline and time. The group differences model is

$$\mu_{it} = E(y_{it}) = f(\beta_0 + \beta_1 * \text{group}) \quad (1)$$

where f is the appropriate link function, the intercept β_0 is the y -intercept in the usual care group when f is an identity function and mean log odds for the usual care group when f is the logit link, β_1 is the treatment effect, and the “*” symbol denotes multiplication. The interaction model, controlling for baseline and time is

$$\mu_{it} = E(y_{it}) = f(\beta_0 + \beta_1 * \text{group} + \beta_2 * y_{i0} + \beta_3 * \text{month} + \beta_4 * \text{group} * \text{month}). \quad (2)$$

When the interactions in Equation 2 were not significant, we further modeled the data controlling for baseline and time, with

$$\mu_{it} = E(y_{it}) = f(\beta_0 + \beta_1 * \text{group} + \beta_2 * y_{i0} + \beta_3 * \text{month}). \quad (3)$$

In the models given in Equations 1 and 3, inference about β_1 provides information about the treatment effect, either as difference in outcome (CAUTI severity, quality of life) or difference in log odds of the outcome (binary outcomes) as a function of group (Equation 1) or group, baseline, and time in months (Equation 3).

Complete 12 month outcomes—We applied the same group difference model in Equation 1 to the 12-month data (i.e., $t = 2, 4, 6, 8, 10$ and 12). For the models controlling for baseline and time (Equations 2 and 3), an indicator variable “second” was added to allow modeling differences between the first and second six months of the study (scored 0 when $t = 2, 4$, or 6 months and 1 when $t = 8, 10$, and 12 months). An interaction term between

“second” and “group” was added to the models described in Equations 2 and 3 to detect possible treatment effects between the first and last six months of the study, shown as

$$\mu_{it} = E(y_{it}) = f(\beta_0 + \beta_1 * \text{group} + \beta_2 * y_{i0} + \beta_3 * \text{month} + \beta_4 * \text{second} + \beta_5 * \text{group} * \text{second}) \quad (4)$$

and

$$\mu_{it} = E(y_{it}) = f(\beta_0 + \beta_1 * \text{group} + \beta_2 * y_{i0} + \beta_3 * \text{month} + \beta_4 * \text{second}). \quad (5)$$

To deal with the dependency among the repeated measures, generalized estimating equations (GEE) with a first order autoregressive structure for the working correlation were utilized. We chose to use GEE because of the complexity and difficulty in modeling the correlations among the repeated measures—especially for discrete outcomes. As a semiparametric approach, GEE has the advantage that the inference is robust to the misspecification of the working correlation matrix—in the sense that estimates are consistent even when the working correlation departs from the true correlations among repeated measures (Diggle, Heagerty, Liang, & Zeger, 2002). Nominal *p*-values of .05 for two-tailed tests were used.

Results

Sample Description

Baseline characteristics of participants are displayed in Table 1. Ages ranged from 19–96 years (*Mdn* = 61). The range in duration of catheter use was 1 to 470 months (39 years). Self-reported diagnoses involved SCI (40%), MS (23%), diabetes (12%), stroke (2%), prostate (10%), spina bifida (1%), neurogenic bladder not otherwise reported (8%), Parkinson’s disease (2%), and other (3%). Indications for indwelling catheter use were: immobility or difficulty moving around (58%), incontinence (57%), neurogenic bladder (54%), obstructed urine (32%), healing wounds (11%), and other reasons (11%). More than one indication could be listed. Additional detailed information about the participants at baseline is available in Wilde, McDonald et al. (2013).

Table 2 lists catheter-related health status, healthcare related to CAUTI, healthcare related to blockage, and quality of life at baseline by treatment group. Following randomization, groups appeared equivalent except that, during the two months prior to the study, the percentage of participants who had catheter dislodgement and the number of days hospitalized for a catheter-related CAUTI were higher in the control group.

Attrition was similar in both groups (Figure 2). There were more deaths in the experimental group than the control group (10 vs. 7). More participants whose catheters were removed were in the control group, mostly late in the study (3 vs. 10). Three persons withdrew from each arm of the study.

Treatment Effects

Table 3 lists treatment effects for primary outcomes for models depicted in Equation 3 (short term effects during the first six months of the study, controlling for baseline value and time) and Equation 5 (longer-term effects, controlling for baseline value, time, and first vs. second half of study). Complete statistical results are available from the authors (MHW).

First six months—Without controlling for any covariates, the overall short-term effect of the intervention relative to the control condition was assessed over the first six months (Equation 1). During the first six months, patients in the experimental group were less likely to report catheter blockage ($p < .05$) and fewer blockage-related nurse visits ($p < .05$), but they reported experiencing more severe CAUTI ($p < .001$) and significantly more CAUTI-related emergency room visits ($p < .05$), in terms of the percentage reporting such events. As shown in Table 3, we obtained similar conclusions controlling for the outcome variables at baseline (such as CAUTI) as well as time (Equation 3).

Complete 12 month outcomes—Without controlling for any covariates, the overall long-term effect of the intervention compared to the control condition was assessed over the whole 12-month period (Equation 1, with $t = 2, 4, 6, 8, 10, 12$). However, the overall difference in blockage between the two groups was not significant over this longer period. The experimental group continued to report significantly higher CAUTI severity scores ($p < .01$) and CAUTI-related emergency room visits (percentage reporting these events [$p < .001$] and frequencies of events [$p < .01$], as well as more hospitalizations for CAUTI (percentage [$p < .01$], frequencies [$p < .01$], and days hospitalized [$p < .05$]; Table 3; Table 4 [days hospitalized]).

Additional statistical tests of treatment effect controlling for baseline outcomes, time, and study period (“second”) were conducted (Equation 4, not shown in a table.). The experimental group tended to report more CAUTI compared to the control group in the second half ($\hat{\beta}_1 = 0.66$; 95% CI [0.03, 1.30], $p = .04$), and no difference between the two groups during the first half year. The experimental group reported higher CAUTI severity than the control group in the first half year ($\hat{\beta}_1 = -2.80$; 95% CI [-4.62, -0.97], $p < .0001$), but no difference between the two groups during the second half. This indicates that the experimental group’s CAUTI severity scores decreased relative to the control group from the first to the second half of the year. Blockages were fewer in the experimental group (by percentage) compared with the control group in the first half of the year ($\hat{\beta}_1 = 1.17$, 95% CI [0.38, 1.97], $p < .05$), but not in the second half of the year.

For other outcomes, the interaction was not significant, and was therefore removed. Treatment effect was estimated controlling for baseline outcomes and time. The experimental group had higher hospitalization for CAUTI ($p < .01$) and emergency room visits ($p < .001$; Table 3). Catheter-related quality of life did not differ significantly by group (Table 3).

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Rates Comparisons

Table 4 provides detailed information about rates of blockage, CAUTI, dislodgement, and hospitalizations within groups over the course of the study and between groups. See Table 4 for a figure displaying the percentage of persons who reported experiencing catheter adverse outcomes of blockage, CAUTI, or dislodgement by group over time.

Catheter-related health status—Comparison of between- and within-groups rates per 1000 catheter days from baseline provided further details about changes in the primary outcomes over the first six months, second six months, and full study of 12 months. Blockage rates were significantly lower in the experimental group during the first six months ($p < .01$) and for the full study ($p = .03$), but there were no differences during the second half of the study ($p = .31$). Blockage improved significantly within each group at each assessment time from baseline.

For CAUTI, there were significant rate differences favoring the control group during the second half of the study ($p = .01$), but no differences for the first half ($p = .55$) or the full study ($p = .16$). Compared with baseline rate estimates, the experimental group had significant decreases in CAUTI rates during the first half of the study ($p = .02$), and for the overall full study time period of 12 months ($p = .05$). The control group had a significant decrease in CAUTI during the second half of the study ($p = .02$).

For dislodgement, rates decreased steadily in both groups by six months and 12 months, and there were no significant group differences. Dislodgement rates were lower in the experimental group at baseline, and larger decreases in dislodgement took place over time in the control group. During the second half of the study, the experimental group rate was slightly better than the control, but not significantly so ($p = .06$).

Hospitalization rates—Hospitalizations were significantly higher in the experimental group for most time points (Table 4). While the hospitalization rates favored the control group, rates decreased in both groups compared with their respective rates at baseline. Slight increases in rates were found during the second six months in the experimental group, compared with the first six months, but control group rates continued to decrease during the second six months. With further analysis at the individual level, we found that one person (in the experimental group) was hospitalized six times during the study, and five of these occurred in the second six months of the study. All others hospitalized in either group were hospitalized either once or twice during the study.

Discussion

Key Findings

Four Cochrane reviews concluded that there was an astounding lack of evidence to guide practice in long-term catheter use (Cottenden et al., 2013). Almost all intervention research in the past has focused on applications such as silver or antibiotic coatings (Johnson, Kuskowski, & Wilt, 2006) to the catheter, special cleaning of the urinary meatus (Burke, Jacobson, Garibaldi, Conti, & Alling, 1983), or drainage bag additives (Washington, 2001). None have proven effective in long-term catheter users. We believe this study is a unique

contribution because it is the first known study of its kind using a randomized clinical trial with an inductively derived, theory-based behavioral intervention (Wilde, 2002; Wilde & Brasch, 2008b; Wilde and Dougherty, 2006; Wilde & Garvin, 2007) to assess whether teaching catheter users self-management skills could decrease short-term, catheter-related problems, and whether improvements could be sustained over 12 months.

The GEE analyses indicated that there was a significant group difference in the first six months only for the blockage outcome—favoring the experimental group. Several interactions suggested that effects of the intervention were stronger for the first six months than the long-term effects over 12 months. Comparisons of rates for the first six months, second six months, and full study of 12 months—as well as the changes in rates from baseline—provided additional information suggesting that both groups improved over time. The line graphs (see Supplemental Digital Content) also indicate a general downward trend for both groups over the 12-month study.

The decreases in rates for CAUTI and blockage are believed to be clinically meaningful in both groups. In a recent report from the Agency on Healthcare Research and Quality (2013, p. 26), decreases in CAUTI in hospitalized persons went down in two months from 2.56 to 2.39/1000 catheter days—a relative reduction of 6.3%. The rate decreased even further at 14 months to 2.14/1000 catheter days—a 16.1% relative reduction in 14 months. These changes reflected that “progress has been made” toward national goals. CAUTI rates in community-dwelling persons can be as high as 8.4/1000 catheter days (Wilde, Brasch, Getliffe, Brown et al., 2010). In our study in the experimental group, the baseline CAUTI rate of 6.93/1000 catheter days decreased to 4.89 (a 29% relative reduction) and in the control group from 5.5/1000 catheter days to 4.12 (a 25% relative reduction; see Table 4).

Blockage prevalence is often cited as about 50% (Getliffe, 2003), but our previous research reflects a wide range of 74% over eight months in 43 persons (Wilde, Brasch, Getliffe, Brown et al., 2010) to 24% in our cross-sectional analysis—before random assignment at baseline in the current study (Wilde, McDonald et al., 2013). Importantly, there is no agreement of whether blockage is a one-time occurrence or a persistent pattern, and this might explain the wide range in blockage prevalence. Because our study tested group differences in this randomized trial, the blockage rates reported should be viewed with caution because blockage outliers were adjusted statistically to a maximum of 9 in a two-month time period. Prior to our study, there were no known reports of dislodgement rates. Therefore, we recommend that in future research, rates per 1000 catheter days should be calculated for blockage and dislodgement, as well as CAUTI.

Although blockage decreased significantly in the first six months in the experimental group—as compared with the control group—it is not known whether this was truly of benefit since the control group also improved and started with more blockages. In addition, since this effect did not last over the full 12 months, and the three nurse home visits took place in months one and four, there might be a benefit in expanding the intervention dose over time.

One major issue remains: whether the self-management intervention contributed to more hospitalizations, whether the experimental group was sicker and more prone to severe

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CAUTIs requiring hospitalization, or whether this group simply noticed signs of CAUTI and acted on them more quickly. A priori, we had identified hospitalization as an indicator of CAUTI severity. Nevertheless, we had hypothesized that the intervention participants would contact care providers earlier and, thus, avoid some of the hospitalizations. However, if the experimental group were to have been more prone to serious CAUTIs—as severity scores suggested—then seeking early care—even if it included hospitalization—might have kept them from more serious consequences, such as long hospitalizations, sepsis, or death. There is no way to know this.

In a recent analysis addressing reasons for rehospitalization, chronic disease and vulnerability in patients' conditions seem to play a big role. Also, morbidity and mortality appeared to be inversely related, meaning sicker patients were treated more often at a hospital and extending their lives. Thus, hospitalization is not necessarily an indicator of poor quality in care (American Hospital Association, 2011). As with the other primary outcomes, we found a pattern of both groups improving over time in relation to hospitalization. That is, rates in hospitalization (times hospitalized and days hospitalized) decreased in both groups, and there were larger decreases in the first six months of the study (see Supplemental Digital Content).

The experimental and control groups both appeared to have improved during the study. Simple self-monitoring through use of the catheter calendar for bimonthly data collection by study participants in both groups could have contributed to fewer catheter problems overall. Essentially, it is possible that study participants in both groups became more aware of catheter problems due to the calendar, and were reminded of their catheter through the phone call interviews every two months. This could have contributed to changes in self-management behaviors, such as increasing fluids for early CAUTI symptoms. Teaching people with indwelling urinary catheters to keep track of key catheter problems (self-monitoring) in a simple notation calendar could be easy and practical to implement in practice. Because blockage decreased significantly in the first six months of the study, in the intervention group, there could be added value in teaching about optimal and consistent fluid intake.

Research implications include replication with additional nurse contacts over time, simplifying the intervention to focus on optimal fluid intake and preventing dislodgement, and using a simple catheter calendar as a self-monitoring intervention. Testing in a multisite RCT using data collection forms embedded in the home care patient records could eliminate self-reported data for outcomes. Evidence-based policies will lag until more randomized trials—or other forms of scientifically sound research—are conducted in this understudied and vulnerable population that use indwelling catheters for long-term bladder management.

Limitations

Self-reported data were used because standardized health records were not available. The catheter calendar was used to minimize self-report error. In addition, recall during the pilot study was excellent using bimonthly telephone interviews (Wilde & Brasch, 2008a). Agreement between self-reported catheter problems (CAUTI, blockage, dislodgement) and chart data was high in another study (97%; Wilde, Brasch, Getliffe, Brown et al., 2010).

Use of a medical diagnosis with antibiotic treatment for defining CAUTI could include some inaccurate diagnoses because some providers could have treated asymptomatic bacteriuria. Because bacteriuria is universal in this population after 30 days, colony counts would be useless. It was not possible to review multiple sources of data in multiple agencies to determine symptoms which might have been used for treatment decision making. Moreover, symptoms vary among individuals and over time. Thus, the decision for treating symptomatic CAUTI is complex, and it requires clinical judgment of the provider.

Attrition was similar in both groups. It was addressed regularly by the team during monthly meetings. Each of the 17 deaths that occurred during the study was evaluated. At the large home care agency site, charts were audited to determine whether there was any person whose death might have been related to the study. In one or two instances, details about comorbidities were discussed with the urologist on the team. The data safety monitoring board (DSMB) met annually with the lead investigators, statistician, urologist, and an outside researcher to review information about each death. The DSMB conclusion was that no deaths were related to the study, and that comorbidities contributed to each event.

Conclusions

Adults with a variety of health conditions are challenged with managing urinary catheter self-care to avoid complications and enhance quality of life. In a one-year RCT setting, participants receiving a self-monitoring, self-management intervention had less catheter blockage during the first six months. No other differences between treatment and control groups were noted. Participants in experimental and control groups improved over 12 months, compared with baseline. The simple-to-use catheter problems calendar and bimonthly interviews used for data collection may have served as a modest intervention in both groups.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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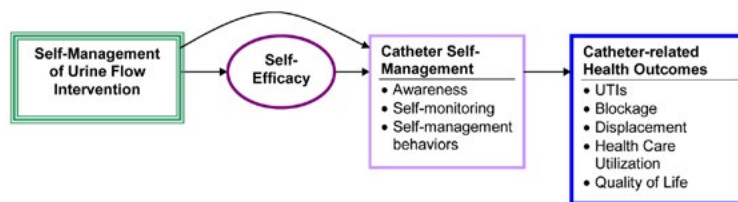


FIGURE 1. Theoretical model for self-management of urine flow intervention (Wilde, Zhang et al., 2013). Used with permission.

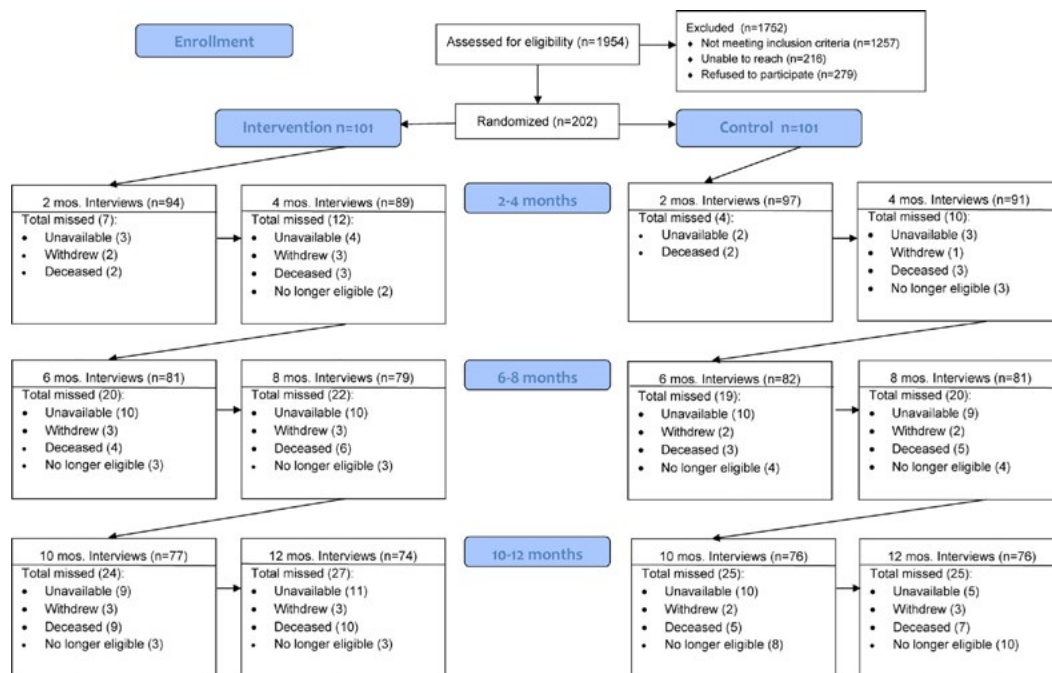


FIGURE 2.
CONSORT flow diagram

TABLE 1

Baseline Characteristics by Group

Characteristic	Intervention		Control	
	<i>M</i>	(<i>SD</i>)	<i>M</i>	(<i>SD</i>)
Age (years)	60.6	(16.6)	62.2	(18.2)
Catheter (months)	73.1	(87.4)	71.9	(83.8)
Catheter size (Fr)	18.4	(3.3)	18.7	(3.2)
	<i>n</i>	(%)	<i>n</i>	(%)
Gender (male)	53	(52.4)	50	(50.0)
Catheter type				
Urethral	57	(56.4)	55	(54.5)
Suprapubic	43	(42.6)	46	(45.5)
Both	1	(0.0)	0	(0.0)
Catheter balloon size				
5–10 ml	64	(63.4)	60	(59.4)
30 ml	11	(10.9)	18	(17.8)
Other	1	(1.0)	1	(1.0)
Unknown/no answer	25	(24.8)	22	(21.8)

Note. There were 101 participants in each group. None of the characteristics was significantly associated with treatment group assignment. Median duration of catheter use in the intervention group was 42 months; control group median was 37 months. Additional detailed information about the sample is available in Wilde, McDonald et al. (2013).

TABLE 2
Baseline Comparison of Key Outcomes by Group (For the Two Months Prior to the Study)

Outcome	Intervention				Control				p		
	M	SD	% ^a	Rate ^b	95% CI	M	SD	% ^a		Rate ^b	95% CI
Catheter-related health status											
Urinary tract infection (yes)	.42	(0.71)	33	6.9	[5.0, 9.4]	.33	(0.53)	30	5.50	[3.8, 7.7]	ns
Catheter blockage (yes)	.56	(1.55)	21	9.3	[7.0, 12.1]	.69	(1.67)	26	11.50	[9.0, 14.6]	.05
Dislodgement (yes)	.17	(0.68)	8	2.8	[1.6, 4.5]	.26	(0.68)	17	4.33	[2.8, 6.4]	ns
Healthcare related to CAUTI											
Hospitalization (number)	0.11	(0.37)	9	1.8	[0.9, 3.3]	0.1	(0.32)	8	1.50	[0.69, 2.85]	ns
Hospitalization (days)	0.61	(2.33)	9	10.2	[7.8, 13.1]	1.0	(4.26)	8	17.17	[14.01, 20.82]	.01

Note. CAUTI = catheter-associated urinary tract infection; CI = confidence interval; ns = not significant at $p < .05$; SD = standard deviation.

^aPercent experiencing the event during the two months prior to the study.

^bRate per 1000 catheter days.

TABLE 3

Treatment Effects for Primary Outcomes

Outcome	First six months ^a			Full 12 months ^b				
	$\hat{\beta}_1$	(SE)	p	95% CI	$\hat{\beta}_1$	(SE)	p	95% CI
Catheter-related health status								
CAUTI (yes)	-0.17	(0.266)	ns	[-0.69, 0.35]	0.16	(0.222)	ns	[-0.27, 0.60]
CAUTI severity ^c	2.76	(0.590)	<.001	[1.60, 3.92]	1.60	(0.467)	<.01	[0.68, 2.51]
Blockage (yes)	-0.74	(0.343)	<.05	[-1.42, -0.07]	-0.23	(0.291)	ns	[-0.81, 0.34]
Dislodgment (yes)	0.29	(0.328)	ns	[-0.36, 0.93]	0.01	(0.287)	ns	[-0.55, 0.57]
Healthcare for CAUTI								
Hospitalized (yes)	0.81	(0.527)	ns	[-0.23, 1.84]	1.33	(0.428)	<.01	[0.49, 2.17]
Emergency visit (yes)	0.88	(0.373)	<.05	[0.15, 1.61]	1.06	(0.337)	<.001	[0.40, 1.72]
Nurse home visit (yes)	-0.06	(0.402)	ns	[-0.85, 0.73]	0.00	(0.317)	ns	[-0.62, 0.62]
Clinic visit (yes)	-0.37	(0.408)	ns	[-1.17, 0.43]	-0.06	(0.333)	ns	[-0.71, 0.59]
Healthcare for blockage								
Emergency visit (yes)	-0.62	(0.978)	ns	[-2.53, 1.30]	1.10	(0.575)	ns	[-0.02, 2.23]
Nurse home visit (yes)	-1.35	(0.642)	<.05	[-2.61, -0.09]	-1.02	(0.470)	<.05	[-1.95, -0.10]
Clinic visit (yes)	-0.62	(0.629)	ns	[-1.86, 0.61]	-0.42	(0.560)	ns	[-1.52, 0.68]
Quality of life ^d	-1.66	(1.581)	ns	[-4.76, 1.44]	-2.03	(1.389)	ns	[-4.75, 0.69]

Note. CAUTI = catheter-associated urinary tract infection; CI = confidence interval; ns = not significant at $p < .05$; SE = standard error. A positive sign for β_1 favors the control (usual care group); a negative sign favors the intervention group. Complete statistical results are available from the authors (MHW).

^aTreatment effects were obtained controlling for baseline outcomes and time (Equation 3).

^bTreatment effects were obtained controlling for baseline outcomes, time from 2 to 12 months, and first vs. second half of the study (Equation 5).

^cScored from 1 = very mild to 10 = most severe imaginable.

^dScored from 1 = strongly agree to 5 = strongly disagree; higher scores reflect better self-rated quality of life.

TABLE 4

Rates of Blockage, CAUTI, Dislodgement and Hospitalization in Treatment and Control Groups Over Time

Outcome	Experimental		Control		p	Within groups ^a (p)	
	Rate ^b	95% CI	Rate ^b	95% CI		E	C
Blockage							
Baseline	9.26	[6.98, 12.05]	11.50	[8.95, 14.55]	ns		
First 6 months	4.28	[3.32, 5.43]	7.41	[6.14, 8.86]	<.01	<.0001	.004
Second 6 months	5.31	[4.15, 6.67]	4.45	[3.41, 5.71]	ns	<.0001	<.0001
Full 12 months	4.76	[4.00, 5.62]	6.04	[5.20, 6.99]	.03	<.0001	<.0001
CAUTI							
Baseline	6.93	[5.00, 9.37]	5.50	[3.79, 7.72]	ns		
First 6 months	4.37	[3.40, 5.53]	4.83	[3.82, 6.03]	ns	.02	ns
Second 6 months	5.48	[4.31, 6.87]	3.29	[2.41, 4.39]	.01	ns	.02
Full 12 months	4.89	[4.12, 5.75]	4.12	[3.42, 4.91]	ns	.05	ns
Dislodgement							
Baseline	2.80	[1.63, 4.49]	4.33	[2.83, 6.35]	ns		
First 6 months	2.60	[1.86, 3.52]	2.74	[1.99, 3.67]	ns	ns	ns
Second 6 months	1.45	[0.89, 2.24]	2.44	[1.69, 3.41]	ns	.05	.03
Full 12 months	2.06	[1.58, 2.65]	2.60	[2.06, 3.24]	ns	ns	.02
Hospitalizations (number)							
Baseline	1.82	[0.91, 3.25]	1.50	[0.69, 2.85]	ns		
First 6 months	1.01	[0.58, 1.65]	0.43	[0.17, 0.89]	ns	ns	.01
Second 6 months	1.68	[1.07, 2.52]	0.22	[0.04, 0.63]	<.001	ns	.004
Full 12 months	1.32	[0.94, 1.81]	0.33	[0.16, 0.61]	<.001	ns	.001
Hospitalization (days)							
Baseline	10.23	[7.84, 13.12]	17.17	[14.01, 20.82]	.01		
First 6 months	7.73	[6.4, 9.23]	4.03	[3.11, 5.13]	.01	ns	<.0001
Second 6 months	8.26	[6.81, 9.93]	1.01	[0.55, 1.69]	.001	ns	<.0001
Full 12 months	7.98	[6.99, 9.06]	2.63	[2.08, 3.28]	.001	ns	<.0001

Note. C = control; E = experimental.

^a Change from baseline.

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^bRate is per 1000 catheter days.

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Perceived Value of a Urinary Catheter Self-Management Program in the Home

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Abstract

A long-term indwelling urinary catheter intervention was tested in a randomized trial that is described in this article. The perceived value of the intervention to the catheter users, one of the study's specific aims, was assessed at the end of their 12-month participation and is reported here. Study participants' responses, our findings, and implications for home healthcare are discussed.

Introduction and Purpose of the Study

There is limited evidence to guide long-term urinary catheter users for self-management. They ordinarily are not in support groups of any sort and might not know others using such a device, yet many use an indwelling urinary catheter (suprapubic or urethral) for years (Wilde et al., 2013) or indefinitely. Those with intractable urinary retention who are unable to perform intermittent catheterization or have no one to do it are sometimes without other options. This type of urinary retention is most often caused by a neurologically based injury or disease, such as a spinal cord injury, multiple sclerosis, diabetes, or by obstructive prostate disease (Cottenden et al., 2013). In our experience, individuals with long-term catheters often learn about self-managing through piecemeal instruction from healthcare providers and by trial and error.

This report describes a new intervention to teach self-management to community-living long-term indwelling urinary catheter users and their perceived value of the intervention.

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Understanding how the study participants responded provides information that could be useful in dissemination and/or changes in the research.

Background and Literature Review

Although policies and procedures are well developed for patients with indwelling urinary catheters in home care and in clinics, an emphasis on self-management is not the norm. Self-management is a form of collaborative care with a healthcare provider (nurse or physician) in which the patient learns to pay attention to bodily symptoms, makes observations and recordings (e.g., diaries), and determines how behavioral changes they are making affect the condition. Self-management research is often conducted with people having chronic conditions, such as arthritis (Ackerman et al., 2013), diabetes (Rothman et al., 2008), or asthma (Kaptein et al., 2010), but self-management research has not been done in indwelling urinary catheter users.

The National Home and Hospice Care Study conducted in 2000 by U.S. National Center for Health Statistics estimated that there are 148,400 urinary catheter users in the United States, for a prevalence of 0.05% in the adult population in community settings (CDC, 2013a). A more recent National Home and Hospice Care Survey in 2007 reported catheter prevalence in home care (excluding hospice) at 9% ($n = 4683$) (CDC, 2013b) or 135,000 people with catheters of the 1.5 million home care patients in 2007 (<http://www.cdc.gov/nchs/fastats/homehealthcare.htm>). However, it is not known how many of them have long-term catheters nor whether they use indwelling or nonindwelling catheters (Lisa Dwyer, National Center for Health Statistics, personal communication, June 20, 2013).

Persistent catheter-related problems are common in long-term catheter users. In one recent study of 43 people over an 8-month period, 74% experienced blockage of the catheter from encrustations, 70% had catheter-associated urinary tract infection (CAUTI), 79% had leakage of urine (bypassing), and 33% had accidental dislodgement (Wilde et al., 2010). In a larger study with 202 long-term indwelling urinary catheter users, catheter problems were recorded by recall for the previous 2-month period, and in this short period of time, 31% had experienced CAUTI, 24% had blockage, 12% had accidental dislodgement, 43% had leakage of urine, and 23% had catheter-associated pain (Wilde et al., 2013).

Most research in the past has focused on improving the catheter itself through: coatings, such as silver or antibiotic (Johnson et al., 2006), catheter materials like silicone (Schumm & Lam, 2008), instillations into the drainage bag (Washington, 2001), and special care to the urinary meatus (Burke et al., 1983), but none have proven effective in preventing blockage or CAUTI (Parker et al., 2009). Other interventions, commonly believed to be of value, such as smaller catheter size, cranberry juice consumption (Jepson & Craig, 2008), and acidic instillations or irrigations, have not been tested in randomized controlled trials in people with catheters (Moore et al., 2009). Closed drainage, which has been shown to significantly reduce the rate of CAUTI, is the only critical innovation in the last 40 years to prove beneficial (Stickler & Feneley, 2010). However, many persons with catheters open them daily to switch from leg to night bags or to clean the bags between uses. In the aforementioned larger study of 202 long-term catheter users, 58% used both leg and overnight bags, and a majority cleaned their bags, using water, soap and water, or a solution of water with bleach or vinegar (Wilde et al., 2013). Cleaning with a diluted bleach solution was shown in a seminal study to increase bag life to 1 month; however, rates of CAUTI remained unchanged (Dille et al., 1993). Consumption of a citrated drink (water with lemon juice) or additional fluids was tested in one study, and results are promising that either can decrease catheter blockage (Khan et al., 2010), but trials have not been done. Thus, evidence-based self-management strategies for persons using indwelling urinary catheters remain in a preliminary stage.

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A first step for catheter users to prevent or minimize catheter-related problems (e.g., CAUTI, blockage, or accidental dislodgement) is to become aware of what to notice and how to self-monitor urine flow. Strategies can then be selected for self-managing the catheter based on this knowledge to address problems early to prevent more serious complications, such as an insidious CAUTI requiring intravenous antibiotics and hospitalization.

Study Description

A research study was conducted, building on the prior investigations. A new catheter self-management educational intervention was piloted (Wilde & Brasch, 2008a, 2008b) and tested for effectiveness in a randomized clinical trial in long-term indwelling urinary catheter users. The 4-year study was conducted in one northeastern U.S. state, including a large city and a mix of urban/suburban and rural areas. Two hundred and two adult persons with long-term indwelling catheters (56% urethral and 44% suprapubic) who were expecting to use catheters indefinitely, or at least for a year, were enrolled in the study for 12 months. Equal numbers of 101 were assigned to the intervention group or the control group. One hundred seventy-five study participants (87%) were recruited through home care agencies (one large city agency enrolled 152 persons); the rest were referred through a combination of clinics or private urological offices. Approximately equal numbers of men and women were enrolled, aged 19 to 96 years (mean 61, SD 17.4), with racial and ethnic diversity (White 57%, Black 30%, other races 13%).

The self-management intervention was theoretically based on Bandura's self-efficacy theory (Bandura, 1997). Self-efficacy is the confidence to perform a specific behavior and, in this study, optimal and consistent levels of fluid intake and preventing accidental dislodgment were the key behaviors targeted. Study participants were taught to pay attention to urine flow, self-monitor bodily changes, and choose appropriate self-management behaviors. The theoretical concepts of awareness, self-monitoring, and self-management (Wilde & Garvin, 2007) were central to the intervention, and Stanford's Chronic Disease Self-management program (Lorig et al., 2001) provided the overall model (Figure 1). The intervention was designed to enhance self-management of urine flow in the intervention group. The control group received only their usual care.

Study outcomes were: (a) catheter-related complications (CAUTI, catheter blockage, and accidental dislodgement), (b) complications' associated costs, and (c) quality of life. To measure study outcomes, data were collected from both groups about catheter-related problems for a year, once face to face in their homes when enrolled and then in six follow-up bimonthly telephone interviews with trained interviewers.

The intervention group was visited by a study nurse in their home three times, for a total of three home visits. Two of them occurred in the first month. The first home visit was to teach about self-monitoring using a urinary diary, and the second home visit was to use this information to plan for improved self-management and to introduce an educational booklet. This was followed by one phone call 2 weeks later to identify any additional issues and to reinforce the teaching. The third home visit was a "booster" of the intervention at 4 months to further refine teaching.

Specifically, study participants were taught to increase their awareness of sensations of urine flow and to learn how these change with daily activities or catheter-related problems. Problem areas were identified in conjunction with information from the 3-day urinary diary (intake and output and open-ended journal). After learning about basic catheter self-management (Table 1 from the Paying Attention Educational Booklet), all were taught to pay attention to fluid intake and catheter position to prevent dislodgement. Then the study

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nurse reviewed all sections of the educational booklet, focusing on areas of individual interest (Table 2 and Figure 2). The study nurse filled out forms after each encounter, which were similar to a care plan, to remind her of the participant's catheter problems and interests or goals. Whenever possible, measurable goals were set and written into the educational booklet.

Below is a report of one of the specific aims of this study, to describe the perceived value of the self-management intervention received by the intervention group. A full report of the main outcomes for this research will be published elsewhere.

Perceived Value of the Catheter Self-Management Program

Methods

Study participants who received the catheter self-management intervention were contacted by phone by one of the two study coordinators within a month of their year-long study participation to assess their perceived value of the intervention. Not everyone was able to be reached or was not able to be interviewed; therefore, out of the 74 persons who completed the intervention arm of the study, 60 brief telephone interviews were conducted. Study participants were asked several quantitative questions about helpfulness of each component of the intervention, using a modification of items previously piloted (Wilde & Brasch, 2008a, 2008b), on a scale of 1 to 10, with 1 being not helpful at all and 10 being very helpful. Study participants were also asked five open-ended questions, allowing for comments to be shared, related: (a) goals, (b) changes to behavior, (c) impact on self-management, (d) helpfulness of the program, and (e) suggestions for improving the program. The interviewers took brief notes to obtain the comments data, which were entered into a spreadsheet and SPSS.

Data Analysis

Quantitative items were analyzed descriptively for means and standard deviations. For the comments data, a descriptive analysis was conducted using simple coding by two researchers, the principal investigator and a doctoral student. Coded comments were then organized into tables before writing a descriptive summary of responses for each item. Both coders agreed on the final codes, the organization of data, and the summary.

Results

Based on the scores, the study nurse visits and the intake and output part of the urinary diary were the most favored elements of the intervention (Table 3). A large majority of the persons rated each component of the intervention (i.e., intake and output, journal, educational booklet, study nurse encounters, and learning self-management) between 8 and 10 on the 10-point scale. The means (SD) for each component ranged from 7.25 (2.40) to 8.33 (3.15). The open-ended journal, which was identified in the study nurses' process recordings (not reported in this article) as being used by only 2% of the intervention sample, was valued less with the lowest mean score 7.25 (3.15).

Out of the 60 persons interviewed, goals were recalled by 21 persons (35%), not set by 36 (60%), and 3 (5%) did not remember. Responses to whether they were doing anything differently with the catheter because of the study were: 25 (42%) said no, 18 (30%) said yes somewhat, and 17 (28%) said yes greatly. 43 (71%) had suggestions for improving the program and 17 (29%) did not.

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Goals Set During the Study

Fifteen persons had goals related to hygiene or preventing urinary tract infections (UTI), specifically cleaning near the catheter, drinking adequate fluids, and preventing UTI. Self-monitoring goals by 14 persons involved noticing changes in the urine, such as watching for sediment or urine color, or in paying attention to the catheter to maintain an appropriate position, or prevent dislodgment, kinks/twists, or leaks. Two persons also stated they wanted to stay healthy urologically.

Changes to Behavior

Study participants who had said they were doing things differently because of the study were asked to describe in what ways. Some reported changes that were similar to the goals they cited. Self-monitoring of the catheter was identified by nine persons related to repositioning the catheter to prevent leakage and twists, or checking the catheter position in relation to the bag or body; or watching for changes in the urine, sediment, or color. Eight said they paid attention more often to urine output or to avoid letting the bag get too full. Nine said they have increased their fluid intake and two said they keep better track of fluids. Eleven were focused more on the catheter itself, such as knowing the exact amount of water in the balloon, about irrigation or cleaning the bag, changing the catheter more often, and in managing the catheter when traveling by using a larger bag at home and smaller one for travelling, or knowing the locations of available bathrooms. Two stated they knew better when to call the provider for catheter problems. One worked on bowel management more and one stays away from caffeine. One reported fewer UTIs.

Impact on Self-Management

Participants also were asked how the study affected their catheter self-management. Six said they were more aware in relation to: cleaning the catheter, noticing urine color, emptying the bag to prevent urine buildup, and knowing where bathrooms were. Six reported having fewer UTIs, and two had less sediment, blockage, or mucus. One individual had more catheter comfort and was pain-free. Five people spoke of being more knowledgeable about and supported with the catheter, or knew when to call the provider. A few recognized patterns of problems, such as burning sensations and kinks. One noted being hospitalized four times recently (but we are not sure what that meant).

Helpfulness of the Program

The comments related to whether learning self-management was helpful or not were aimed at understanding more about the value of the catheter self-management intervention. Comments from 17 individuals were primarily about catheter-related knowledge gained, skills acquisition (including enhanced awareness of their bodily symptoms related to the catheter), and feeling cared for by the study nurse making home visits. There were just four negative comments: three who did not learn anything new and one who did not think program helped. Also three persons said they do not self-manage, but one said it was helpful to know.

Suggestions for Improving the Self-Management Program

Many suggestions and comments were received also, including more use of Web sites, combining the urinary diary forms (i.e., intake and output forms with the journal), managing pain, and sketches of instructions. Several asked for better designed catheters and equipment.

Home Healthc Nurse. Author manuscript; available in PMC 2014 October 01.

Discussion

For the quantitative assessment of intervention components, there was a possible small ceiling effect with higher percentages reporting 10 (very helpful) for the study nurse encounters and intake and output, by 41% and 32% of the sample respectively. The open-ended journal was not used by most study participants (2%) and this was the case also during the pilot study (Wilde & Brasch, 2008a, 2008b), and thus it should probably be eliminated from future tests of this intervention.

The information solicited about goals at the end of this 12-month intervention with 60 individuals is in stark contrast to the information collected by the study nurses in their process forms in which 82 persons set initial goals (81% of 101 in the self-management intervention group), and over 70% said they met their goals during the phone call in month 2 or the home visit in month 4. Perhaps goal setting was not a high priority or there was insufficient recall at 12 months, when so much time had passed after the intervention visits. However, those persons who did set goals used language to reflect the key components taught in the intervention, such as goals about fluid intake, preventing UTI, and noticing changes in urine or in the position of the catheter.

Intervention participants showed that they understood key study concepts because they described activities that demonstrated awareness, self-monitoring, and self-management related to fluid intake, preventing CAUTI, and proper positioning of the catheter. Some seemed to have an emotional connection with the study nurse, saying they felt “cared for” by her. A few said that no one else has talked with them like this about the catheter and in such depth, and this made them feel valued as persons. Responses also illustrated individual variation in how much the self-management intervention was liked and for what reasons.

Implications for Practice

Long-term indwelling catheter users can be taught to pay attention to urine flow. Specifically they should know how much fluid intake is right for them and what types of fluids should be monitored (e.g., caffeine). By noticing catheter-related changes—such as the color or character of the urine, catheter position, or kinks/twists in the tubing—and by responding quickly, catheter-related problems might be avoided or minimized. In this study, catheter users’ comments indicated how they valued and learned from the self-management intervention. Home care nurses are in an important and unique position to partner with their patients with catheters and their families to improve care and quality of life.

Conclusion

This may be the first self-management intervention in long-term indwelling urinary catheter users. Knowing how the study participants responded to the intervention is critical in determining its dissemination and overall research value. In summary, research participants seemed to like the intervention, were able to identify what they should pay attention to, and told us what they were doing differently related to their catheter. These new behaviors should be beneficial in their catheter-related health. Although this intervention is not ready yet for full dissemination—due to ongoing analysis and writing reports of the main study results—many of the components, such as the urinary diary (I and O), the basic self-management tips in Table 1, and the sample educational page on identifying UTI, could be useful for home care nurses teaching catheter self-management to long-term indwelling urinary catheter users.

Acknowledgments

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Home Healthc Nurse. Author manuscript; available in PMC 2014 October 01.

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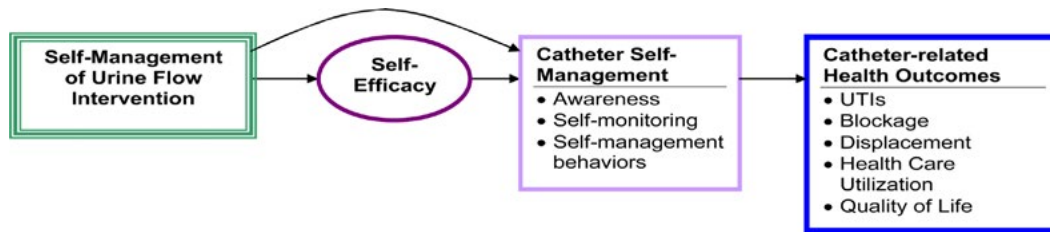


Figure 1.
Theoretical Model of the Study. UTI = urinary tract infection.

Recognize early symptoms of urinary tract infections (UTI) and act on it

- Early recognition might prevent serious problems, such as severe UTI requiring hospitalization.
- Quote from catheter user: “I think about how much I am drinking. It has become a way of life. The study made me more aware and I changed bad habits. A couple of times, I did not do what I was supposed to do and had a UTI.”


Paying Attention	Things You Can Do
<p>Signs of UTI:</p> <p>Urine Changes: Color—discolored, cloudy, dark, blood stained Odor—foul smelling, change in smell from usual Sediment (grit)—increased amount</p> <p>Pain and/or pressure in bladder area or back (burning possible, not common)</p> <p>Temperature—fever chills, sweaty/clammy General Symptoms—blahs!, feeling sick</p> <p>Functioning or mental changes—weakness, spasticity, change in the level of alertness</p> <p>Early, mild symptoms of autonomic dysreflexia (e.g., goosebumps, headaches, sweats) mainly in people with spinal cord injury</p>	<p><i>“Stay on top of it psychologically.”</i></p> <p>Be sure you know when and how to contact your physician or nurse if you suspect that you are getting a UTI.</p> <p>Increase fluid intake especially water.</p> <p>Record in journal when you have a difficult catheter insertion and notice if a UTI develops afterward.</p> <p>Keep urine bag below bladder level. The tubing should be above the bag.</p> <p>Ask your healthcare provider about whether cranberry tablets or juice might help you.</p> <p><i>“If something doesn’t feel right, act on it quickly.”</i></p> 

Figure 2. Sample of educational module (Note: the quotes are from previous study participants (Wilde & Brasch, 2008a, 2008b).¹ UTI = urinary tract infection.

Table 1

Basic Catheter Self-Management

-
- **Stay aware.** Having a catheter requires that you *stay aware of your body* and how you feel.
-
- **Drink more water** than any other beverage! Limit coffee, and consider substituting tea and decaffeinated beverages.
 - **Drink consistently.** Fluid intake needs to be at a good *level for your weight* and you need to drink in a *consistent* way to help prevent catheter blockage.
 - **Your body needs fluids.** Most people need 2,000 to 3,000 cc of fluid a day. For instance, a 150-lb person would need 2,550 cc that is equivalent to about 10.5 glasses per day. More fluids are needed for hot weather or when exercising. My fluid goal is _____.
 - **Pay attention** to the *color* of your urine. It should be light yellow all day long. The color of urine can be used a quick way to know whether you are drinking enough during the day.
 - **Notice changes.** If the urine color changes, notice if you are doing something different, such as drinking less water or more caffeinated beverages or are using a diuretic medicine or water pill, such as furosemide or chlorothiazide.
 - **Notice catheter position.** Notice where the catheter is after each change in your position and reposition it if needed. If you have others who help you, teach them to do this.
 - **Check for kinks and twists** in the catheter by feeling with your hand from where the catheter leaves your body all the way to the drainage bag.
 - **Ask for help.** If you need assistance with the catheter, learn to ask for help.
-

Table 2

Quick Guide to Catheter Problems (from the Paying Attention Educational Booklet)

Problem	Action Strategies
Decreased/inconsistent fluid intake	Increase fluid intake
Urinary tract infection	Increase fluid intake Recognize early symptoms of urinary tract infection and act on it
Catheter blocks	Increase fluid intake Promote catheter changes at best intervals
Adjustment to living with a catheter	Approaches for living with a catheter
Not sure of the best schedule for catheter changes	Promote catheter changes at best intervals
Kinks, twists, or tugs on catheter	Prevent kinks, twists, or tugs on catheter
Too much caffeine	Decrease caffeine
Catheter leaks	Decrease catheter leakage Empty urine bag
Urine bag odor	Clean urine drainage bag
Changes with sex	Make adjustments for sexual activity

Table 3

Helpfulness of the Self-Management Program Components

On a scale of 1–10, With 1 Being Almost No Help, and 10 Meaning It Was a Very Big Help	<i>n</i>	M	SDs	1–4	5–7	8–10
1. Intake and output	56	8.04	2.40	11%	12%	77%
2. Catheter journal	56	7.25	3.15	20%	14%	66%
3. Educational booklet	57	7.72	2.79	12%	19%	68%
4. Study nurse's home visits and TC	58	8.33	2.53	10%	12%	78%
5. How helpful was learning self-management	60	8.18	2.65	10%	18%	63%

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Self-Management of Intermittent Urinary Catheters

February 2016

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Rochester, USA

Member of the ICS Nurses' Committee



International Continence Society
Teaching Module

Objectives

- Our purpose is to educate continence nurses to improve patient care and health outcomes globally.


At the conclusion of this presentation, readers should be able to:

1. Describe an approach to intermittent catheter self-management using a **web-based application** (related to a recent research study).
2. **Evaluate its usefulness** in promoting self-management in clinical practice and/or further research.

Study: A Web-Based Self-Management Intervention for Intermittent Urinary Catheter Users

NIH/NINR funding: R21 NR012763

Wilde, M.H. (PI), Fairbanks, E., Parshall, R., Zhang, F., Miner, S., Thayer, D., Harrington, B., Brasch, J., Schneiderman, D., McMahon, J. M. (Co-I).


 ICS Teaching Module

Intermittent catheter problems

- Psychological concerns, including stigma. (Shaw et al., 2008).
- Worries about CAUTIs
- Inconvenience in everyday activities
 - Inaccessible bathrooms-too small, lacking in privacy, and/or unclean (Wilde et al., 2011)
- Inadequate insurance, choice catheters/supplies
- Catheter type varies by individual; some find lubricated catheters hard to manage.

(Kelly et al., 2014; Wilde, et al., 2011)


NIH/NINR R21 NR012763

 ICS Teaching Module

Aims and Goals of new online self-management intervention for people with spinal cord injury (SCI) using CIC)

- Feasibility (acceptability and usability)
- Preliminary effectiveness of the intervention
- Develop and test new measures of CIC self-efficacy and self-management
- Goals :
 - Learn more about own patterns with CIC
 - Obtain support and information for self-management
 - Sustain CIC over time


NIH/NINR R21 NR012763

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Design

- Interventional study – teaching awareness, self-monitoring, self-management
- Web resources—catheter products; educational booklet
- Online urinary diary: I&O, observation of self-cathing
- 3 phone calls with study nurses
- Pretesting group of 4 people with SCI to refine intervention.
- Discussion forums with peer leaders


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Sample at baseline N=29

- SCI- 45% complete, 45% incomplete, 10% other SC disease
- 48% female
- Age 44 (SD 13) years; median 47 years
- Use of CIC- 16 years (range 1-39, SD 16 years; n=28)
- Diverse by race and ethnicity: 72% white, 14% black, 3% Asian, 10% more than one race; 3% Hispanic
- ADL - Katz score = 5.97 (SD 1.6), range 5-10; lower scores indicate more independent function.
 - 28/29 chair-fast but wheel independently
 - 1 used assistive device and/or person

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Managing an Intermittent Catheter

A Web-Based Self-Management Intervention

Mary Wilde as example Person One

Home
Product Advisor
Commercial Products
Educational Materials
Personal Data
Forum
Contact Us
Help
Logout

Personal Database for example Person One

Weekly Pattern

To better plan for cathing and fluid intake requirements, it might be helpful to think about your typical week. If you wish, use the box to describe your typical week Monday through Friday, as well as Saturday through Sunday, because daily patterns often change on the weekend.

I work every afternoon M-F, so my mornings are at home and afternoons are out.

My time to drink is more in the early morning and later in the evening when I get home so I do not have to cath so often when out.

Weekends vary a lot, and I sometimes don't drink enough when out.

Links to Other Pages


- Make I/O Datasheet entries.
- Make Journal entries.
- View chart & all entries.

Goals

Goal	Edit	Delete
Increase catheter frequency to 4-5 times a day, even on weekends.	<input type="button" value="✎"/>	<input type="button" value="✖"/>
Will drink 2 liters of fluid daily	<input type="button" value="✎"/>	<input type="button" value="✖"/>

Enter or Edit Goals here:

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 ICS Teaching Module

Choose Display Days

Select Day(s)

Days	<div style="border: 1px solid gray; padding: 2px;"> <p>Wed 29 Jan 2014 ▲</p> <p>Thu 26 Sep 2013</p> <p>Wed 25 Sep 2013</p> <p>Tue 17 Sep 2013</p> <p>Fri 16 Aug 2013</p> <p>Tue 13 Aug 2013</p> <p>Thu 08 Aug 2013</p> <p>Tue 06 Aug 2013</p> <p>Mon 05 Aug 2013 ▼</p> </div>	<p>To select more than one day, hold the Ctrl key down while clicking on the selections. To select a range of dates, click on the first date, and then hold the Shift key down while clicking the last date in the range.</p>
-------------	---	---

Display Days Selected

Listing I/O Entries: Total Count is: 3

Display

Date/Time		Fluid Intake				Urine Output						Journal Entry	Edit	Delete
Date	Time	Fluid	Intake Amount	Amount in mL	Caffein	Urine Amount	Amount in mL	Leakage	Color	Mucus	Bloodclot			
Sept. 25, 2013	2:22 p.m.					450 mL/cc	450 mL	medium	Clear	No	No	No		
Sept. 26, 2013	3:42 p.m.	water	240.00 mL/cc	240 mL	No							No		
Sept. 26, 2013	3:45 p.m.					500 mL/cc	500 mL	none	Yellow	Yes	No	Yes		

darker than usual maybe from too much coffee. I will try to drink more water.

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Add/Edit I/O Entry

Journal Entry

Record what you noticed. Then what is going on or what you did about it. Consider the following which might affect fluid intake and urine output:

1. Do you feel less well today than usual?
2. Is this an unusual fluid intake or urine output?
3. Were your activities different from normal?
4. On a new medicine?
5. Describe sensations in the bladder area or abdomen on scale of 1-10.
6. Urine leakage or "accident" and what you could do to prevent it in the future.

Date/Time

Date

 MM/DD/YYYY or click field to see calendar

Enter Time

 ex: 10:30AM

Notice

What was noticed?

Save Journal Entry Cancel

Action

What is going on or what was done?

Because research like this is very limited, this study has the potential to provide important knowledge about how people with spinal cord injuries use intermittent catheters to self-manage their care. Thank you very much for considering this important study.

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This study has been approved by the University of Rochester Research Subjects Review Board #00035781.

NIH/NINR R21 2763



Managing an Intermittent Catheter

A Web-Based Self-Management Intervention

Mary Wilde as example Person One

Home Product Advisor Commercial Products Educational Materials Personal Data Forum Contact Us Help Logout

Journal Listing

Display

Listing Journal Entries: Total Count is: 4

Date	Time	Noticed	Action Taken	Edit	Delete
Aug. 6, 2013	6 p.m.	Urine still doesn't look right, but not as brown as this morning. Still smells strong. Not as much mucus.	Looking back on the list, I see that some of my fluids today have had caffeine. Will try for more water before I go to bed.		
Aug. 13, 2013		I was out and did not cath enough that day.	Being busy and will have to change this behavior.		
Sept. 25, 2013	2:35 p.m.	Urine is dark today. Had too much beer yesterday.			
Sept. 26, 2013	3:45 p.m.	darker than usual maybe from too much coffee.	I will try to drink more water.		

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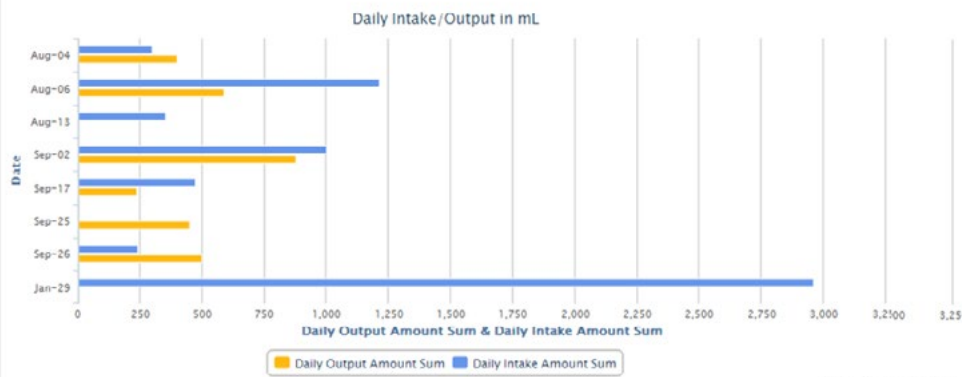
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A Web-Based Self-Management Intervention

example Person One

Home Product Advisor Commercial Products Educational Materials Personal Data Forum Contact Us Help

Logout



O and Journal Entries: Total Count is: 18

Date/Time	Intake	Output
-----------	--------	--------

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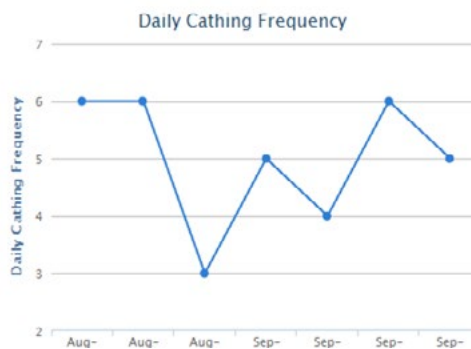
Daily Summary of Intake/Output Amounts: Total Count is: 8

Daily		
Date	Intake Amount in mL	Output Urine in mL
Aug. 4, 2013	300mL	400mL
Aug. 6, 2013	1214mL	589mL
Aug. 13, 2013	354mL	0mL
Sept. 2, 2013	1000mL	875mL
Sept. 17, 2013	473mL	236mL
Sept. 25, 2013	0mL	450mL
Sept. 26, 2013	240mL	500mL
Jan. 29, 2014	2957mL	0mL

Daily Cathing Frequency

Date	Frequency	Journal
Aug. 4, 2013	6	No
Aug. 6, 2013	6	No
Aug. 13, 2013	3	Yes
Sept. 2, 2013	5	No
Sept. 17, 2013	4	No
Sept. 25, 2013	6	No
Sept. 26, 2013	5	No

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Feasibility evaluation

- Several people withdrew or were lost to follow up early. 26 of 30 had nurse consultations for the intervention.
- Websites (recruitment and intervention sites) worked well, little difficulty navigating.
- Forums used by 10 of 26 but rated positively. Most posts r/t travel, insurance, mediations, treatments for SCI.
- Liked intervention: educational materials, urinary diary, nurse consultations, and discussion forums.

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Results

- Frequency catheterizing 4-6 times a day increased slightly, 69-77% (NS)
- Self-management of the intermittent catheter increased significantly (P= .032)
- Self-efficacy and quality of life scores improved (NS).
- CAUTI, leakage and pain decreased (NS.)
- Measures performed adequately-- need further development in larger sample with more power.
- Increases in fluid intake biggest self-management change.

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One person said:


- “I’m probably more conscious of my intake of fluids than anything because I was one that was really slacking on taking fluids and I needed to- I needed to do something about it and I just sort of was lazy...[and] after the 2nd time we talked [with the study nurse] I really cranked up my intake of water because I was not a water drinker. And now I’m probably drinking probably 36 ounces of water a day. And I’ve cut out carbonated drinks.”

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Conclusion and Implications

- Multi-site larger study in SCI units
- Newly injured and experienced people with CIC; plus others
- Compare web-urinary diary with paper and pencil
- Cohort enrollments for forum of about 10 people
- More information for logins, actions taken etc.
- Evaluation of this web-based approach will require more use of it, and for evidence of its value, more research.
- Dissemination for education and research (indwelling and intermittent catheter studies). Contract with University of Rochester email Mary Wilde: Mary_wilde@urmc.rochester.edu


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NIH/NINR R21 NR012763

 ICS Teaching Module

Thank You!

From Mary Wilde and the ICS Nurses' Committee

General Clinical Practice

A Web-Based Self-Management Intervention for Intermittent Catheter Users

Mary H. Wilde, Eileen Fairbanks, Robert Parshall, Feng Zhang, Sarah Miner, Deborah Thayer, Brian Harrington, Judith Brasch, Dan Schneiderman, and James M. McMahon

Spinal cord injury (SCI) affects the bladder's storage and emptying, often contributing to persistent urinary retention (National Spinal Cord Injury Statistical Center, 2014). Intermittent catheterization (IC), by which the bladder is drained several times a day, is the preferred bladder management method (Cottenden et al., 2013). While the exact frequency of IC is individualized, people with full retention are ordinarily taught to catheterize four to five times a day or every four to six hours (Cottenden et al., 2013). Learning to manage this procedure takes time, with rehabilitation lengths of stay shorter in recent years (Christopher & Dana Reeve Foundation, 2015; National Spinal Cord Injury Statistical

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Wilde, M.H., Fairbanks, E., Parshall, R., Zhang, F., Miner, S., Thayer, D., ... McMahon, J.M. (2015). A Web-based self-management intervention for intermittent catheter users. *Urologic Nursing, 35*(3), 127-133, 138. doi:10.7257/1053-816X.2015.35.3.127

A new Web-based self-management intervention was developed for persons with spinal cord injury who use intermittent urinary catheters. Included are a description of the components, examples from the educational book, and multiple screen shots of the online urinary diary.

Key Words: Self-management, spinal cord injury, Internet, intervention research.

Center, 2014), individuals with SCI must develop skill in the method at the same time they are adjusting to this major life-changing event.

Research reports suggest there are many problems associated with living with IC that can influence the acceptance and continued use of it, including managing the frequency and technique of

the procedure (Logan, Shaw, Webber, Samuel, & Broome, 2008; Shaw, Logan, Webber, Broome, & Samuel, 2008; van Achterberg, Holleman, Cobussen-Boekhorst, Arts, & Heesakkers, 2008), impact on sex (Shaw et al., 2008), inconvenience of catheterizing (Wilde, Brasch, & Zhang, 2011), urinary tract infection (Wilde et al., 2011; Woodbury, Hayes, & Askes, 2008),

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urine leakage, inaccessible bathrooms, and a lack of optimal catheter supplies (Al-Jadid, Al-Asmari, & Al-Moutaery, 2004; Wilde et al., 2011). Thus, managing IC issues can be a daily struggle (Kelly, Spencer, & Barrett, 2014; Logan et al., 2008; Shaw et al., 2008).

Moreover, not being well prepared to incorporate catheterizing into everyday life can lead to the use of a long-term indwelling urinary catheter or non-adherence to optimal IC frequency, which can adversely affect the bladder and kidneys (El-Masri, Chong, Kyriakides, & Wang, 2011). People with SCI, who are often injured while young, need to learn to live with IC as a part of their normal routines. Bladder self-management is integral to engaging in and maintaining social and employment opportunities. Restriction in travel due to urine leakage can interfere with quality of life (Brillhart, 2004) and full employment. Sadly, about 65% of adults with SCI are not employed (Wehman, 2010). Therefore, people using IC need excellent self-management skills, such as learning how to 1) adhere to their IC regime; 2) self-monitor fluid intake to prevent leakage while maintain optimal hydration; 3) notice early symptoms of UTI; 4) perform IC in a variety of situations with good technique; 5) choose most advantageous catheters, supplies, and lubrication; and 6) adapt to social needs (Wilde et al., 2011).

Web-based interventions, which are currently expanding, are likely to continue to be developed and disseminated after testing and proven feasible. All activities in this study were approved by our university department for the protection of human subjects. The sample was diverse by race and ethnicity, and was composed of almost equal numbers of males and females, ranging in age from 22 to 79 years ($M = 44$, $SD = 13.1$, $Md = 47$). The research findings will be reported elsewhere in two other articles related to 1) the development of the web-based intervention (under peer review),

Table 1.
Basic Intermittent Catheter Self-Management

<ul style="list-style-type: none"> • Stay aware. Using an intermittent catheter requires that you stay aware of your body and how you feel.
<ul style="list-style-type: none"> • Drink more water than any other beverage! Limit coffee, and consider substituting tea and decaffeinated beverages.
<ul style="list-style-type: none"> • Balance fluids with cathing volumes. You may find it helpful to do a two to three-day intake and output diary to know how much you are drinking. While it will vary by individual, drinking more than about 2 liters could cause over-distention of the bladder, but it depends on the type of fluids. Over-distention is a major contributor to urinary tract infection (UTI). You do not need to focus on the amount taken each day as long as your volumes for catheterization do not go over 500 mL. If your volumes are consistently over 500 mL, then you should either drink less or catheterize more frequently.
<ul style="list-style-type: none"> • Pay attention to the color of your urine. It should be light yellow to yellow all day long. The color of urine can be a quick way to know whether you are drinking enough or too much during the day. If the urine color changes, notice if you are doing something different, such as drinking more caffeinated beverages or taking a diuretic medicine or water pill, such as furosemide (Lasix®) or chlorothiazide sodium (Diuril®).
<ul style="list-style-type: none"> • Notice how often you are catheterizing. Most people need to do this four to five times a day, approximately every four to six hours. If you do not do it often enough, you are more susceptible to UTIs or leakage of urine. You should have less than 500 cc. in each catheterization.
<ul style="list-style-type: none"> • Pay attention to how fluids affect your activities, the time between intermittent catheterization (IC), and how the amount and what you drank contribute to urine leakage and accidents.
<ul style="list-style-type: none"> • Consider other catheters. You can try other types of catheters if you wish. Not one catheter will work with all people. Contact your physician after you have considered options.
<ul style="list-style-type: none"> • Prepare for getting out. You may need to learn different positions for cathing or where the bathrooms are. You might need to assemble your own IC kit.
<ul style="list-style-type: none"> • Ask for help. If you need assistance with IC or bathroom access, ask for help.

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and 2) testing its feasibility/usability, with a full description of the sample and procedures (in progress, not submitted yet).

Purpose

A new Web-based intervention for people using intermittent urinary catheterization to empty the bladder periodically throughout the day is a part of a single-group trial funded by the National Institutes of Research/ National Institute of Nursing Research to evaluate feasibility of a new web-based approach in 34 individuals with SCI who use IC. This report is expected to provide urological practitioners with

information about IC self-management using web-based materials and processes, including use of the tables and figures. However, the authors maintain copyright of the figures and tables, and therefore, the content should not be modified or used without permission of the first author.

Intervention Website

The intervention website includes content on a number of pages: a Home Page, Continence Product Advisor, Commercial Products, Educational Materials, Personal Data, Forum, Contact Us, Help, and Logout. The Home Page is a welcome/introductory page

Figure 1.
Goals and Catheterization Frequency

Managing an Intermittent Catheter
A Web-Based Self-Management Intervention
Nurse One as example Person One

Home Product Advisor Commercial Products Educational Materials Personal Goals Forum Contact Us Help Logout

Personal Database for example Person One

Weekly Pattern
To better plan for caring and fluid intake requirements, it might be helpful to think about your typical week. If you wish, use the box to describe your typical week Monday through Friday, as well as Saturday through Sunday, because daily patterns often change on the weekend.

I work every afternoon M-F, so my mornings are at home and afternoons are out.
My time to drink is more in the early morning and later in the evening when I get home so I do not have to cath so often when out.
Weekends vary a bit, and I sometimes don't drink enough when out.

Links to Other Pages
Make I/O Dashboard entries.
Make Journal entries.
View chart & all entries.

Goals

Goal	Edit	Delete
Increase catheter frequency to 4-5 times a day, even on weekends.		
Will drink 2 liters of fluid daily.		

Enter or Edit Goals here

Save Goal Cancel

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Figure 2.
Intake and Output Entries

Date/Time		Fluid Intake			Urine Output									
Date	Time	Fluid	Intake Amount	Amount in mL	Catheter	Urine Amount	Amount in mL	Leakage	Color	Mucus	Blood/Clot	Journal Entry	Edit	Delete
Aug 5, 2013	10:30 a.m.	water	120.00 mL/No	100 mL	No							No		
Aug 5, 2013	11:43 p.m.			275 mL/No		275 mL	none	4	No	No	No	No		

Add/Edit I/O Entry

Date/Time
Fill out Date and Time (below) for each Fluid Intake and Urine Output entry. You can make both an Intake and an Output entry at the same time or you can enter them at separate times (just Intake or just Output) and then Save Entry.

Date: MM/DD/YYYY or click field to see calendar

Enter Time: 1:00 PM
ex: 10:30AM

Journal Entry: (No.)

Fluid Intake
Fluid Intake is something in a liquid form at room temperature, including ice cream, pudding, or gelatin, as well as typical fluids like water or tea. Do not include piggy.
List all fluid intakes, such as milk, water, juice, decaffeinated coffee, caffeinated coffee, or soda. For example, you might write 8 oz. milk, 12 oz. soda. List acids by brand name, and include if caffeinated or decaffeinated.

Fluid Intake: (No.)
FL, Qt: (No.)

Fluid Type: Other or Brand: (No.)

Caffeinated: (No.)

Type of Drink	Caffeine	Type of Drink	Caffeine
Brewed coffee (8 oz)	95 mg	Dark Pilsner (12 oz)	20 mg
Instant coffee (8 oz)	60 mg	7-Up (12 oz)	0 mg
Decaf coffee (8 oz)	3 mg	Beer & Root Beer (12 oz)	23 mg
Double espresso (2 oz)	178 mg	Red Bull (8.2 oz)	80 mg
Tea - black (8 oz)	47 mg	Mauritan Dew	20 mg
Tea - green (8 oz)	40 mg	Sunkist Orange	40 mg
Coca-Cola Classic (12 oz)	35 mg	Strawberry Flavored Tea	0 mg
Hot Coke (12 oz)	47 mg	Light Beer, all	9 mg
Pepsi (12 oz)	38 mg	Hot coffee	14 mg

Urine Output
Note the color of the urine and if present: mucus, blood clots. You may use the Journal pages for details.

Urine Output: (No.)
FL, Qt: (No.)

Leakage: (No.)
Mucus: (No.)
Blood/Clot: (No.)

Color: (No.)

Clear
Light Yellow
Yellow
Amber

Save Entry Cancel

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with links across the top menu bar to the other pages. The Continence Product Advisor introduces study participants to a website that is a collaboration between the International Consultation on Incontinence (ICI) and the International Continence Society (ICS) (<http://www.continenceproductadvisor.org/>) that describes continence products and how they are used. With permission from these website developers, we made a table with links to the sections related to IC products to help people navigate this site. In the Commercial Products section, we provided links to a number of common IC-related products about which people might not have been known, such as catheters attached to a bag for use when going out of the home, and special adaptive aids, like a knee spreader for women and penis holder for men to help with hand dexterity.

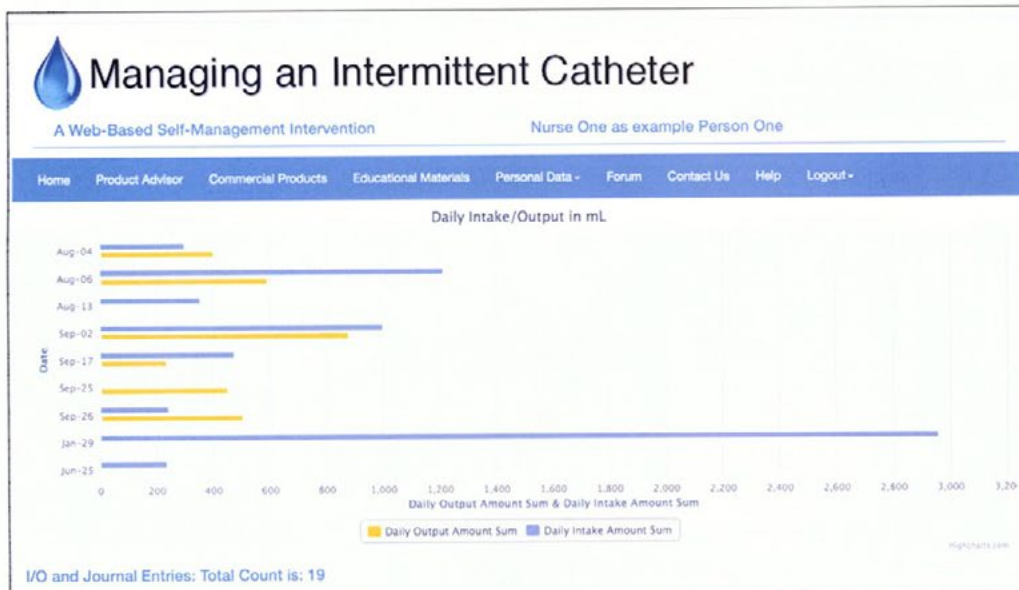
The Educational Materials page is linked to the Educational Booklet, which is a 23-page illustrated booklet created by the first author based on a previous self-management program for indwelling catheter users (Wilde et al., 2013, 2015; Wilde & Brasch, 2008). The content was modified using literature and information obtained in the research team's qualitative study about issues and concerns in IC users (Wilde et al., 2011). After an introduction and description of basic IC self-management (see Table 1), specific topics follow:

- Balance fluids with activities – optimal fluid intake.
- Balance fluids with activities – promote best IC interval.
- Negotiate and select catheters and supplies.
- Choose best positions for catheterization.
- Learn about travel and bathroom issues.
- Prevent leaking.
- Recognize early symptoms of UTI.
- Seek social support.
- Make adjustments for sexual activity.
- Work with caregivers.
- Prevent autonomic dysreflexia.

Figure 3.
Journal Page

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Figure 4.
Intake and Output in a Bar Graph

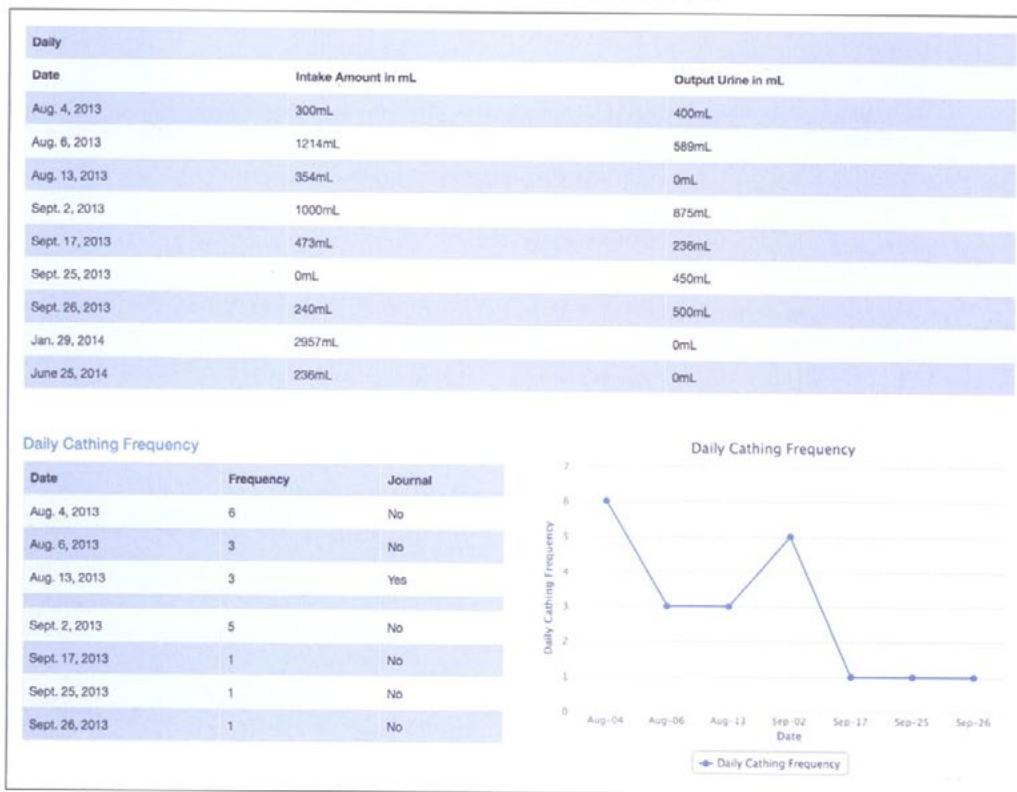


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- Manage painful catheterizations.
- Decrease caffeine.
- Am I dehydrated? (Urine Color Chart).

The Personal Data page (viewed only by the study participant and the study nurses) is the most interactive section of the intervention website and involves links to four webpages: goals and catheterization frequency, intake and output (I&O) entries, journal, and an overview with summary tables and graphs (see Figures 1 to 5). The *goals and catheterization frequency* (see Figure 1) has a textbox for writing, revising, and deleting goals, and places to select a date and frequency of catheterization for that date. The *I&O entries* (see Figure 2) include options for entering volumes and characteristics. For fluid intake, options are mL/cc, ounces, cup, pint, or quart; type of fluids (such as water, milk, juice, beer, soda); and if the fluid was caffeinated or not (with a table listing the amount of caffeine). For urine output, the amounts are in mL/cc

Figure 5.
Daily Amounts in Tables and Line Graphs



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or ounces, and characteristics can be selected, such as mucus, blood clots, or urine color (using a simplified color chart with options that include clear, light yellow, yellow, and amber). Leakage can be monitored as *none*, *small*, *medium*, or *large amounts*. Amounts for both I&O are automatically calculated to mL, and thus, are not dependent on the metric used for data entry.

The *Journal* page (see Figure 3) includes a place for the date, two sections for “what was noticed” and another for “what was going on or done about it,” and questions/statements to facilitate writing journal entries. The prompts are based on questions used in the previous indwelling catheter study by the

research team (Wilde & Brasch, 2008), with modifications for IC:

- Do you feel less well today than usual?
- Is this an unusual fluid intake or urine output?
- Were your activities different from normal?
- On a new medicine?
- Describe sensations in the bladder area or abdomen on scale of 1 to 10.
- Urine leakage or “accident” and what you could do to prevent it in the future.


Lastly, the Personal Data section includes an Overview page, which is composed of tables and graphs of all cumulative data. These are *intake and output in a bar graph* (see Figure 4) with a blue color for intake and light

yellow for output, showing amounts/day; a table with daily totals of intake and output; and catheterization information with *daily amounts in tables and line graphs* (see Figure 5) showing patterns and trends. These overview visuals show differences among dates and can depict discrepancies between intake and output. In addition, because this overview displays all entries chronologically, the catheter user or study nurse can more readily see patterns between notes in the journal and the entries for I&O. This level of linking detail is believed to facilitate better self-management skills. For instance one might discover reasons for not adhering to their IC planned frequency on

Table 2.
Balance Fluids with Activity: Optimal Fluid Intake

While you need fluids for health, drinking too much can cause over-distention of the bladder, and this can contribute to urinary tract infection (UTI).

Quote: "As long as the urine looks clear and clean, I'm not worried about it."

Paying Attention	Things You Can Do
<p>Notice whether you are getting enough fluids – but not too much – throughout the day.</p> <p>Become aware of whether different types of fluids make you need to cath more frequently or with more urgency.</p> 	<p>If you find you are not drinking enough, by cathing volume, you can try some of the suggestions below to increase your fluids.</p> <p>If you like the water cold, keep several bottles in the fridge and refill them with fresh water every day.</p> <p>To add flavor to water, try 2 ounces of cranberry or apple juice to 8 to 10 ounces of water. You may also try adding a little lime or lemon juice.</p> <p>Keep fresh glasses of water throughout the house.</p> <p>Secure a jug or bottle of water to your wheelchair.</p> <p>Use a rigid straw so you don't have to suck hard.</p> <p>You may want to drink around meal times and before bed.</p> <p>Have a caregiver remind you to drink water.</p>
<p>Notice changes in color of urine every time you catheterize.</p>	<p>Color should remain light yellow to yellow all day. (See the color chart at the end of the booklet.)</p> <p>If color gets dark or urine has foul smell, increase water.</p>
<p>If you are on fluid restriction, make sure you stay within restricted range.</p>	<p>Record fluid intake occasionally to check that you are staying within range.</p>
<p>Be aware of changes in daily activities, such as stress, illness, or travel.</p>	<p>Use a journal to increase awareness of how activity affects fluid intake. If you choose to restrict fluids for a while to prevent leakage, it could take up to 24 hours to balance your intake again. Noticing the color and amount in cathing will tell you when you are back on track.</p>

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weekends by reviewing how their activity and fluid intake varied during the week as compared with the weekend.

Study Nurse Consultations

The study nurse made two phone consultations about a week apart. The first contact was to teach the initial three-day self-monitoring, explaining how to use the online diary formats, including use of the personal database for storing I&O information/graphs and journal notes. The second contact was to discuss the results of the self-monitoring period: reviewing I&O data, graphs, identifying what the person noticed about how intake

affected output, activities, urine leakage, and suggesting self-management activities to prevent problems. While the entire educational booklet was reviewed, special emphasis was on issues related to balancing fluids with activity (see Table 2) and adherence to appropriate IC intervals (see Table 3). Participants were informed that they could email the study nurse with questions. The third consultation phone call was made at three months to identify additional issues and to guide the person in further self-management activities.

Peer-Led Online Forum Discussions

Online forums became avail-

able when three or four people were enrolled. Topics in the Discussion Forum were opened, allowing study participants and peer leaders to start new topics (threads) or post to already developed topics. Peer leaders guided the discussion assisted by the study nurses or principal investigator. A urologist and a urology nurse were available to answer more complex clinical questions, which were then posted by the principal investigator.


Mobile Phone Modification

In addition to our National Institutes of Health funding, we were fortunate to have received a substantial gift for our research

Table 3.
Balance Fluids with Activity: Promote Your Best Intermittent Catheterization (IC) Intervals

IC should be done on the average every four to six hours, and the amount of urine should be less than 500 mL (cc). Cathing too often is irritating to the urethra, but not cathing often enough contributes to a urinary tract infection (UTI).

Quote: "I've met a lot of people who say, 'Oh, I don't want to drink a lot because I'm always worried.' I do the same thing, but I try to find certain times of the day where I can hydrate my body."

Paying Attention	Things You Can Do
Become aware of your own cathing pattern. Pay careful attention to urine color and how you feel. 	Pay attention to cathing intervals (times of day and number of hours in between) and amounts for three days to see what your usual pattern is. If you think you might not be adhering to your best intervals, keep track of it for a few days to be sure you are on track.
Become aware of reasons for urine "accidents" so you can prevent them in the future. (See page on leakage.)	Consider whether you waited too long and your bladder was too full, you drank too much in a short time, or the bathroom was inaccessible. Sometimes more urine is produced during the night related to your position, the legs being up, and that the kidneys function better when lying down. For women, monthly hormone changes can also affect this.
Notice when and what you drink in the evening.	Withhold fluids in the evening to prevent a need to cath at night. However, some people need to wake at night to stay dry. If you avoid caffeine, you are less likely to need to void. (See page on caffeine.)

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from a local donor. The team decided to use these funds to develop a modification in the program for mobile phone use. This decision was based on suggestions from four pretesting study participants who tried out the website in the first six months of the study.

Conclusion

This web-based intervention is the first known of its kind for intermittent catheter users. The intervention included a new and unique web-based interactive urinary diary, which was modified for mobile phone use, three study nurse phone call contacts, and peer-led discussion forums. The intervention will be evaluated for feasibility and usability at the conclusion of the pilot study, which is currently in progress with 30 individuals with SCI. Depending on the feasibility

assessment, further research is likely to test the efficacy of the intervention in a larger sample of people using long-term intermittent urinary catheters, with the eventual goal of wide-spread dissemination in a permanent website. □

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continued on page 138

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Nothing to disclose

† All financial ties (over the last two years) that you may have with any business organization with respect to the subjects mentioned during your presentation

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 **ICS** Education Module

ICS TEACHING MODULE

Urodynamics in children

Part 1. CYSTOMETRY IN CHILDREN

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Peter F.W.M Rosier MD, PhD, Stuart Bauer, MD**

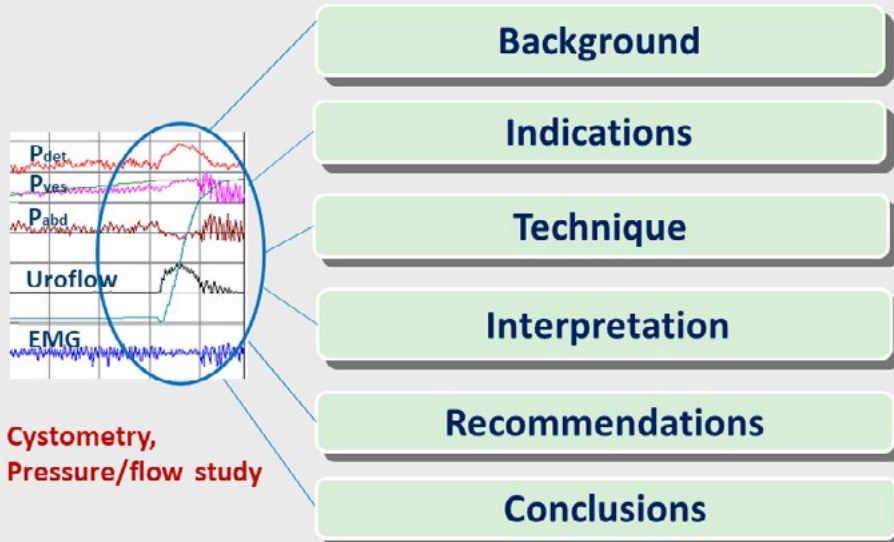
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 **ICS** International Continence Society
Education Module

Cystometry: outline



Background

- Lower urinary tract dysfunction in children is encountered frequently (20-30%) in clinical practice. Some need to be evaluated by urodynamic studies following a careful history & physical examination
- The aim of urodynamic testing is to reproduce symptoms, to identify the underlying causes for symptoms, and to quantify underlying pathophysiological processes
- This section follows the guideline from ICS & ICCS on Good Urodynamic Practice

Oracle – “Pee”
1000-2000 B. C.



<http://www.ics.org/>

Cystometry

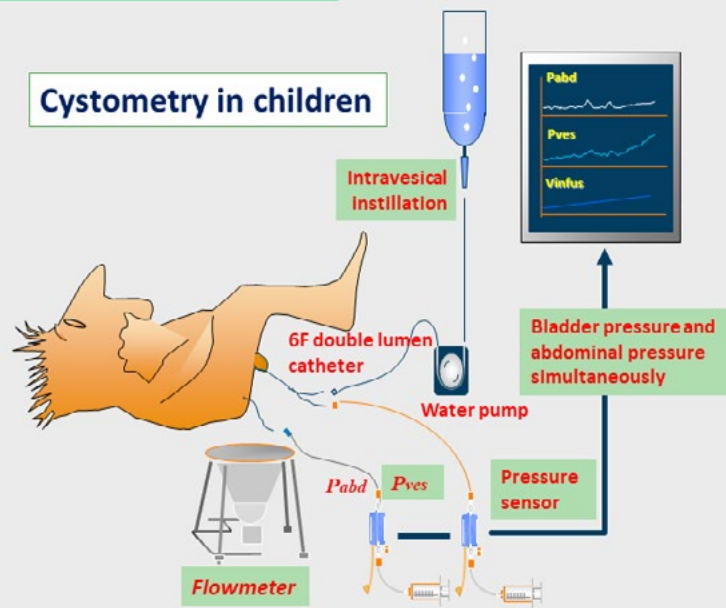
- When undertaken, cystometry is the core evaluation of pediatric urodynamic study (PUDS) in the evaluation of LUTD/LUTS
- It measures the pressure-volume relationship of the bladder during the filling
- In this module, its techniques and recording parameters will be introduced in details
- Pressure flow study & video-urodynamic studies will not be covered in this section



Cystometry in Children

- Indicated from birth and onwards
primarily
- to monitor compliance and thereby avoid potential damage to kidney function

Cystometry: setting



ICS Education Module

Conventional Cystometry


- 1: 6-F transurethral double lumen catheter**
To monitor vesical pressure and for filling
- 2: 8-F (optionally balloon) catheter in rectum**
To register abdominal pressure
- 3: Levelling the transducers both to pubic level**
Filling rate usually 5-10% of expected bladder capacity
- 4: Electronic subtraction of abdominal pressure from vesical pressure = detrusor pressure**

ICS Education Module

Indications

1. Suspicion of, or overt neuropathic voiding dysfunction, LUT obstruction, DSD. etc
2. Profound non-neuropathic detrusor-sphincter dysfunction (ie., dilating ureter(s), high grade vesicoureteral reflux, valve bladder syndrome)
3. Significant PVR with no apparent reason
4. Congenital malformations of the lower urinary tract (ie., exstrophy, epispadias, ureterocele, multiple bladder diverticula)



 ICS Education Module

Indications and preparation


5. The procedure is assumed to effect treatment strategies & for evaluating the treatment response or follow up
6. It is undertaken after history taking, physical examination, voiding diaries & uroflow patch EMG recordings. If these measures do not answer the questions related to causes, nor provide management schemes for LUTD

Preparation

- Empty the rectum. Enema Glycerini is recommended. Severe constipation may need cleaning enema
- Drink sufficient quantities of water in order to have a full bladder for an initial uroflowmetry

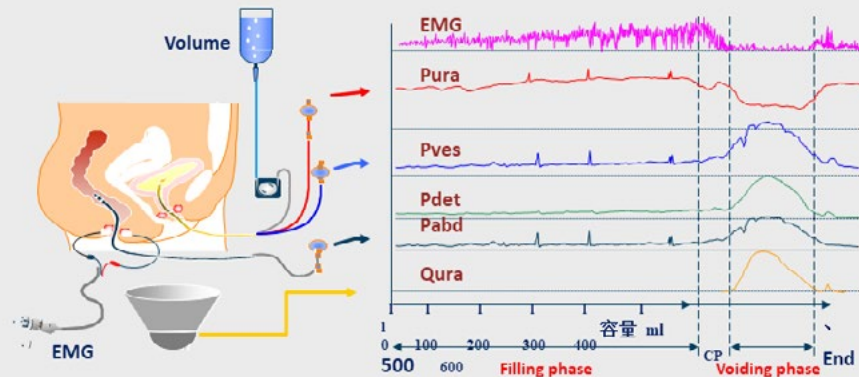


Cleaning enema

 ICS Education Module

Technique: insert catheters

- Double-lumen catheter for Pves, or triple lumen catheter for Pves & Pura recording (3rd channel for filling); rectal balloon catheter for Pabd recording



ICS Education Module

Technique: place surface electrodes

- Surface electrodes are positioned symmetrically left & right from the external anal sphincter, to record the reactivity of pelvic floor muscles



ICS Education Module

Technique: position and zeroing the pressure

Upright or supine position – babies may be held in mother's arm. Before filling the bladder, the vesical pressure channel must be zeroed to the atmosphere with the transducer placed at the level of the pubis

A Credé maneuver or encouraging the child to cough to test the catheter & sensor function

ICS Education Module

Cooperation: during filling

- To build the lab so it looks like a kindergarten, and e.g. animation wall with TV
- Employ dedicated & knowledgeable staff able to give children an explanation of the procedure and aim of the urodynamic study. If possible, engage the infants to cooperate
- Have a well cleansed rectum
- After inserting the catheter in the bladder, if the child is still agitated, engage parents to help to keep him/her calm



Animation wall



To avoid cry



Start until calm

ICS Education Module

Cooperation: during filling

- The urodynamic evaluation approach should start with as minimally tests as possible, ending up with the invasive investigations, if needed
- Toys, eating or drinking, reading, allow mother to be present, during the examination
- Apply 1% lidocaine jelly or other topical anesthetic solution instilled into the urethra to aid in catheter passage
- Administer sedative if necessary but not an anesthetic, & document if child is very fearful



toys



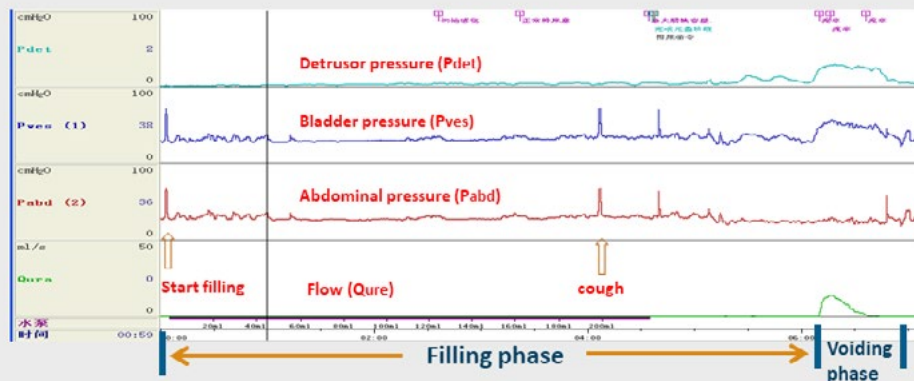
Drinking



Mother with child

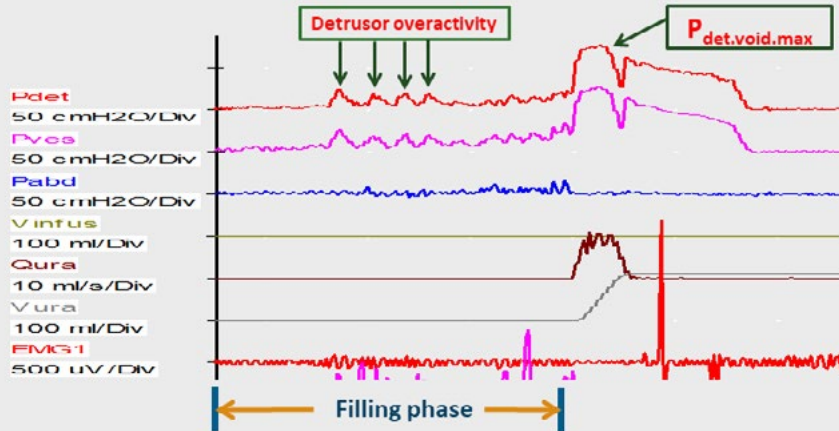
Interpretation: filling pressure

- P_{det} increases initially ($< 5 \text{ cm H}_2\text{O}$) immediately at the start of filling, & incrementally with further filling of the bladder, it reaches a maximum just before the urge to void (normally, $< 15 \text{ cmH}_2\text{O}$).



Interpretation: detrusor overactivity

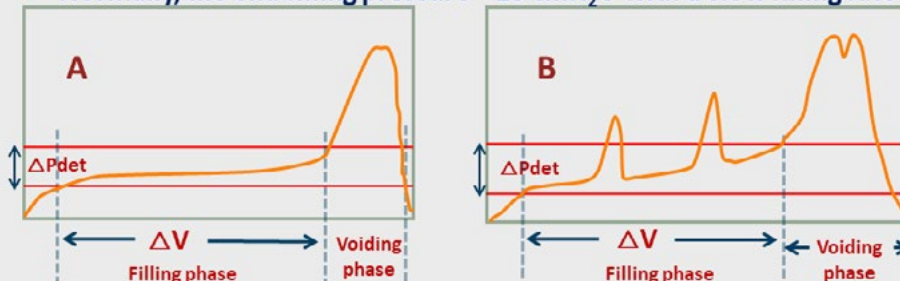
- Detrusor overactivity indicates a detrusor contraction that occurs during the filling phase **before expected bladder capacity is reached** &, which may occur in 10% of normal children. While in children with VUR, it may be seen in more than half of the infants



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Interpretation: detrusor compliance (ΔC)

- $\Delta C = \Delta V / \Delta P_{det}$ – measures the visco-elastic properties of the bladder $\Delta C < 10 \text{ ml/cmH}_2\text{O}$ indicates decreased bladder compliance, which may be due to decreased bladder capacity or increased P_{det} or both
- Normally, the end filling pressure $< 15 \text{ cmH}_2\text{O}$ with a slow filling rate



A: The non-linear portions - the beginning & end of the V/ P_{det} diagram do not contribute to compliance. B: $\Delta V / \Delta P_{det}$ essentially captures the angle of the line describing the incremental increase in resting pressure

ICS Education Module

Interpretation: estimated bladder capacity based on age

Bladder capacity (BC), post-void residual (PVR),
maximum detrusor pressure during voiding (P_{max.det.void}) in the literatures

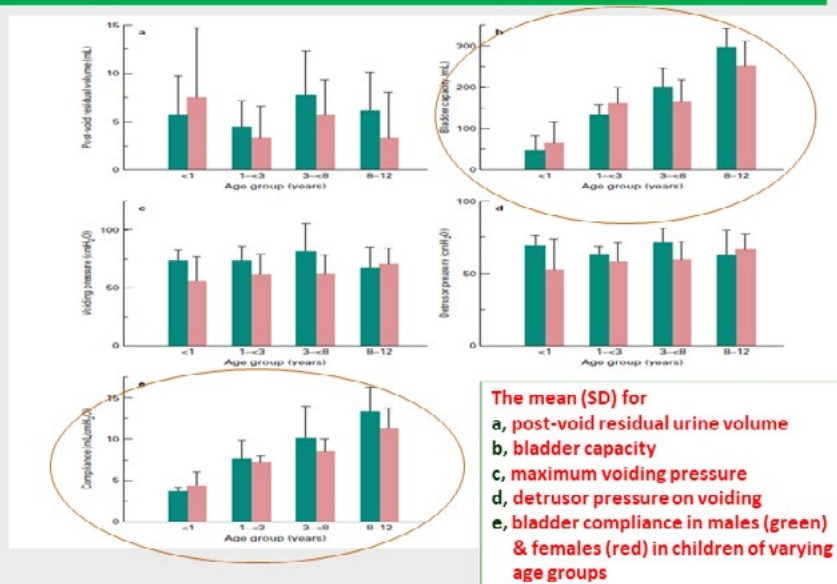
Age	BC (ml)	PVR (ml)	P _{max.det.void} (cmH ₂ O)
Neonatal			
Premature infant (0.5~7w)	13.2 ± 4.9	1.5 ± 1.0	–
(<4w)	22.6 ± 7.8	–	–
Term infant (1w)	24.6 ± 10.9	1.4 ± 1.1	–
(2w)	23.6 ± 8.7	1.2 ± 1.0	–
Infant			
3 month	53 ± 13	5.7 ± 4.5	50~75
12 month	70 ± 30	7.1 ± 6.3	41~66
24 month	79 ± 31	6.6 ± 7.0	38~60
36 month	128 ± 72	3.3 ± 5.3	38~55

Expected capacity (ml) = 30 + (age in years × 30) in a child > 1 year of age;

Expected capacity (ml) = 38 + 2.5 × age (months) for infants < 1 year old

ICS Education Module

Interpretation: bladder capacity, compliance



From Wen, et al. British Journal of Urology 1998 81, 468-73


ICS Education Module

Interpretation: estimate sensation of filling

- Evaluating sensation of filling depends on both verbal or non-verbal signs, such as movement of the feet, awakening from sleep, a sudden cry. Bladder filling should be stopped when the filling pressure exceeds 40 cm H₂O
- In older children, ask them to hold & not void at their first sensation to void, especially if expected or known maximum bladder capacity has not been reached
- For newborn & infants < 1year, it is difficult to identify the sensation of bladder filling; however, it is easy to generate urination during the cystometry in these children

Verbal
communication




 ICS Education Module

Conclusions

- Cystometry with an initial 'free' uroflowmetry is a useful tool to evaluate the LUT function in children
- It should be considered as one procedure, but not the only one, to clarify the diagnosis & to make therapeutic decisions as well as for follow up
- To understand the findings at cystometry, normal voiding parameters as well as following ICS & ICCS recommendations are the basis of successful testing



 ICS Education Module

ICS educational module: Cystometry in children

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Aims: To introduce the standard procedure of cystometry and interpretation of the results in children.

Methods: The literature on cystometry in children in PubMed for the last 20 years was reviewed. The updated knowledge regarding indication, preparation, technique, and interpretation of cystometry in children were summarized.

Results: Filling cystometry is the core content of a paediatric urodynamic study. In this section, the technique for performing cystometry is introduced in details. Emphasis is placed on correctly setting up the equipment according to ICS and ICCS guidelines, using appropriate terminology, providing indications for its performance with specific considerations for children, and proper interpretation of results.

Conclusions: Cystometry can be used in children including newborn to evaluate lower urinary tract dysfunction.

KEY WORDS

children, cystometry, procedure, urodynamics

1 | INTRODUCTION

The International Continence Society (ICS) and International Children Continence Society (ICCS) define filling cystometry as the urodynamic procedure by which the pressure-volume relationship of the bladder is measured. Filling cystometry is done to provide information on storage function (detrusor activity, sensation, compliance, and cystometric capacity). Filling cystometry in children is usually performed in combination with perineal EMG skin electrodes to add information regarding pelvic floor striated muscle activity.¹⁻⁴ On rare occasions needle electrodes are inserted into the pelvic floor musculature to precisely define denervation in patients with neurogenic bladder dysfunction.

The ICS educational module consists of an oral presentation in combination with this manuscript, the latter serving as a scientific background review; the evidence gathered for the ICS PowerPoint presentation is available via <http://www.icsoffice.org>. The presentation explains when and how to do a filling cystometry and how to analyze the results in children.

Filling cystometry is the core content of a paediatric urodynamic study. In this section, the technique for performing cystometry will be discussed in detail. Emphasis will be placed on correctly setting up the equipment according to ICS and ICCS guidelines,²⁻⁴ using appropriate terminology, providing indications for its performance with specific considerations for children, and proper interpretation of results.⁵ Other elements of a urodynamic investigation, for example, pressure flow study or video-urodynamic study will be covered in specific educational modules.

2 | INDICATIONS AND PREPARATION

Filling cystometry is indicated when history and clinical examination raises a suspicion of either anatomic and/or neurologic lower urinary tract dysfunction involving primarily the storage phase, or there is a question that cannot be answered by less invasive testing. Additionally, filling cystometry is relevant when anatomical or functional bladder

outflow obstruction (voiding phase) (eg, valve bladder syndrome, detrusor-sphincter dyssynergia associated with neuropathic bladder), or congenital anomalies of the bladder (exstrophy, ureteroceles, multiple bladder diverticula) may be causing symptoms and signs of dysfunction that may need further delineation.⁶ When a urodynamic investigation is ordered the patient and/or his/her parents should fully understand the reason(s) for the test. It is assumed results of the investigation will define pathophysiology and influence treatment strategies. When constipation exists, it should be managed according to set guidelines before cystometry is undertaken. Having an empty rectum before the urodynamic study is advantageous as this allows for accurate monitoring of abdominal pressure and hence detrusor pressure.

Apart from a comprehensive history and complete physical examination, a voiding (or catheterization) diary, uroflowmetry, and post-void residual volume, as measured by ultrasonography, are to be conducted before ordering this invasive urodynamic study. In children, more than one uroflowmetry is strongly suggested to establish with certainty the necessity of an invasive study.^{1,2} The child is advised to arrive at the urodynamics suite with a full bladder if possible and the examination starts with a free uroflowmetry. This is best accomplished by adequate but not excessive hydration beforehand and/or appropriate timing of a previous void so the bladder is relatively full at the time the child arrives at the urodynamics facility.

The (parents and) child should be instructed that all lower urinary tract modulating medications be taken either at a set time before the study or stopped at a sufficient interval to minimize their effect. Depending on the reason for the study, it should be however decided individually whether to continue or to stop medication (eg, in follow up evaluation). For children who are anxious or fearful beyond consolation, administration of a sedative (not anesthetics) may be considered but its timing and dose should be documented.

3 | TECHNIQUE

Current guidelines recommend multichannel fluid filled pressure recordings for filling cystometry as the standard in children. This educational module combines ICCS and ICS standards, into practical protocol elements to perform cystometry.

As the documents related to the tip-transducer or air-charged catheter used in pediatric urodynamic studies are limited and the pressures measured using air-charged catheters, microtip catheters are not readily comparable with fluid-filled systems, also in pediatric urodynamic studies fluid-filled systems are considered the ICS standard.

Inserting the catheter and placement of surface EMG electrodes

- (1) A transurethral catheter is used to measure the pressure within the bladder. A 6 Fr double-lumen catheter that allows both filling and recording of pressure is recommended. The catheter is inserted after applying lubricating gel. No evidence exists regarding how well this gel acts as an anesthetic in children. In some facilities, a suprapubic double lumen catheter is inserted following administration of a short anesthetic the day before the test.
- (2) The transurethral urodynamic catheter can be used to empty the bladder before starting the cystometry; if a relatively large volume is measured ultrasonographically or expected, it may be helpful to empty the residual by aspirating the bladder via the urodynamic catheter.
- (3) A completely fluid filled open 8-Fr. feeding tube or a small air-free fluid filled balloon catheter is inserted into the rectum to record abdominal pressure.
- (4) Both transurethral and rectal catheters should be secured with tape adjacent to their respective skin openings. After insertion, the catheters are attached, via connecting tubes, to the external pressure transducers and leveled to the height of the pubic symphysis.
- (5) After cleaning the skin two surface EMG electrodes are positioned symmetrically, left, and right from the external anal sphincter, to record reactivity of pelvic floor muscles. No specific evidence regarding skin preparation to reduce impedance or electrode placement is available.² A third reference electrode should be placed at an electrically neutral position; preferably over a bony prominence and not an abdominal or leg muscle.

Position and zeroing the pressure

- (6) Filling cystometry is preferably best performed in a seated position; however, lying supine or an infant held in mother's arm is also acceptable.
- (7) Before filling the bladder, the bladder pressure channel must be zeroed to atmospheric pressure with the transducer situated at the level of the symphysis pubis, irrespective of the position of the child.
- (8) Testing the catheter and sensor: Initial resting pressure should roughly represent the weight of the abdominal contents (below the diaphragm, in centimeter "water"-column) above the pelvic floor, for example, 15-25 cm H₂O. The fluid filled transurethral catheter requires some fluid in the bladder to allow for a degree of "unfolding" in order to obtain an accurate initial resting pressure. Furthermore, when using gel to insert the catheter, it should be flushed away from the pressure measuring side holes. When the child is upright the initial subtracted detrusor pressure should be close to zero. To further test catheter and sensor function in

infants the lower abdomen is gently pressed (Credé) whereas older children are encouraged to cough. The abdominal pressure rise should have a response peak similar to bladder pressure so detrusor pressure remains about zero.

- (9) Even though children usually move and/or talk during the investigation, causing pressure variations that may serve as a quality control measure during the test, regular cough "tests," or Credé maneuvers in infants, should be promoted throughout filling to continuously check the catheters' ability to accurately record pressures.
- (10) In children old enough (and neurologically able) to respond: the sensation of filling should be ascertained according to the ICS standard sequence, as defined by: "first sensation of filling" and subsequently and respectively, "normal desire" and "strong desire to void." These landmarks should be indicated on the urodynamic tracing.

Filling cystometry

- (11) Based on bladder diary notations or estimating capacity based on age ($\text{age [yrs]} + 1 \times 30 = \text{capacity [mL]}$) bladder filling should occur at a rate approximating 5-10% of estimated capacity per minute, using saline, as recommended by the ICCS. Apart from the bladder diary, age related and expected capacities should be kept in mind.^{7,8}
- (12) During filling, intravesical and abdominal pressures are recorded and subtracted simultaneously to obtain true detrusor pressure. During the recording, the flowmeter is kept in position so leakage or incontinence will be shown in the uroflow tracing curve.
- (13) When voiding or leakage occurs, or a strong desire to void is expressed (movement in newborns or infants or curling of toes in older children) these observations may be interpreted as a sign of a full bladder. The filling is stopped and this event marked as the end of filling. It also represents the end of the filling cystometry. Storage function is evaluated until this point.
- (14) Subsequently, as an older child is encouraged to urinate, voiding pressures, and uroflow measurements are recorded simultaneously, thus obtaining a pressure flow study. The pressure flow study will not be discussed further here.
- (15) Directly after voiding an evaluation of the technical quality as well as the clinical representativeness of the study should be undertaken to determine whether a second filling cystometry (and pressure flow study) is necessary. Depending on the specific question being asked or the local protocol, performing a second filling cystometry may be initiated. Often at this time the child

is relaxed enough so that a more accurate tracing of the filling phase is obtained.

End of test

- (16) When the filling cystometry (and pressure flow study) is conclusive, all catheters and the EMG electrodes are removed.
- (17) Children are instructed to carry out their normal activities but advised to drink an additional water after the test to "void away" any urethral irritation as well as to reduce chances of developing a urinary tract infection.
- (18) A clinical evaluation report is completed immediately after the test to be optimally able to integrate urodynamic observations and features with clinical observations during the measurement, while still fresh in the mind of the observer.

Notes:

1. For EMG kinesiological recording, surface electrodes are widely used in children to study pelvic floor activity. Electrophysiologic standards require that the skin should be degreased and desquamated tissue removed before applying a conductive gel and the electrodes. Hooked needle electrodes can be used for kinesiological EMG recording when it is important to determine denervation in neurologically compromised individuals; however, the invasiveness of obtaining this measurement should be weighed against the expected gain from the information. Concentric needle electrodes are useful for motor unit potential analysis during urodynamic testing when it is necessary to know if new onset or progressive sacral spinal cord denervation is present.
2. For retrograde filling, 0.9% saline is recommended. In young children, temperature of the filling solution as well as the medium itself may influence bladder capacity and detrusor activity. It has been established that filling rate and fluid medium have an impact on bladder function.⁹ It is important to use an appropriate rate of filling (5-10% of estimated bladder capacity per minute) in infants.^{1,5}
3. A double lumen catheter has the advantage that it can stay in place (especially during voiding if adequately secured) for a second filling cystometry, if deemed necessary.
4. It is unnecessary to routinely use a warmed infusion solution for urodynamic studies in children; however, for those younger than 2 years, a warmed solution (37°C) is recommended.¹⁰
5. The best position for the child during standard cystometry is in a sitting position, watching a video or DVD surrounded by one or both parents, so as to minimize anxiety. Young children (infants) may be held in their mother's (or caregiver's) arms to achieve a meaningful evaluation. It has not been proven in children that patient position during the procedure has a significant and

- clinically relevant effect on cystometry. However, this has been proven in adults, patient position during the procedure plays a significant and clinically relevant role.¹¹
- The study should not be performed under general anesthesia; intranasal midazolam may be administered in certain situations, as it does not appear to have a significant effect on outcome.¹²

4 | INTERPRETATION

Parameters during the Filling Phase

- The filling detrusor pressure ($P_{\text{det,fill}}$) means the detrusor pressure during filling. The maximum detrusor filling pressure ($P_{\text{det,fill,max}}$) may be reported in the analysis. Detrusor compliance is calculated on the basis of the difference between the initial resting pressure and the detrusor pressure at cystometric capacity. Any phasic pressure increments, interpreted to be caused by detrusor overactivity, should be omitted in the evaluation of the detrusor compliance calculation. It may be advantageous to stop the infusion when reduced compliance is observed to allow the pressure to “equilibrate” for a minute or two in order to uncover artificially reduced compliance, which is sometimes observed as a consequence of too rapid filling rate.
- Phasic detrusor pressure increments of any amplitude, during the filling cystometry (until end of filling and permission to void is given) are defined as detrusor overactivity. Detrusor overactivity may arise spontaneous or be provoked by a cough or Credé. When history and/or clinical examination have confirmed a relevant neurologic abnormality the term neurogenic detrusor overactivity is used.^{1-4,13} Otherwise, idiopathic detrusor overactivity is the preferred term.
- Detrusor compliance (compliance = $\Delta V/\Delta P$) is an important parameter to note during cystometry. It represents detrusor elasticity or volume adaption. A value of $<10 \text{ mL/cm H}_2\text{O}$ indicates low bladder compliance. Assessing the entire pressure curve during filling in this regard may determine when it is best to measure. The ΔP represents the detrusor pressure difference until just before voiding (or pressure at the end of filling); consequently, compliance will represent the overall bladder compliance, from start to a completely full bladder. It has been suggested that quartiles of compliance measurements during filling be considered. The filled volume does not take into account the amount of actual diuresis occurring during the test. To integrate this volume the cystometric capacity and filling phase compliance should be calculated using voiding volume plus PVR measured immediately after voiding or emptying.

- Incontinence is defined when any loss of fluid during the filling phase is detected. In children unable to void willingly, fluid loss occurring before the expected bladder capacity is also called incontinence (as opposed to physiologic—normal but uninhibited—voiding when it occurs at “normal for age” capacity).
- Leak point pressure (LPP) indicates the pressure at which leakage occurs. Detrusor leak point pressure (DLPP) indicates the lowest value of detrusor pressure at which leakage is observed in the absence of increased abdominal pressure or a detrusor contraction. Abdominal leak point pressure (ALPP) refers to measures of the lowest value of intentionally increased intravesical pressure that provokes urinary leakage in the absence of a detrusor contraction. High DLPP (eg, $>40 \text{ cm H}_2\text{O}$) is usually induced by a decrease in bladder compliance and/or detrusor underactivity, is associated with upper urinary tract deterioration.^{1,5} Low DLPP indicated urethral incompetence.^{1,5} Techniques and evaluation are not further standardized in this document describing filling cystometry.
- Bladder filling sensation should be reported, on the basis of observations during the test or, when applicable, on the basis of the child's report. ICCS standard terms in this regard apply also for children.^{1,2,6}

5 | RECOMMENDATIONS

Based on standards and clinical practice guidelines, the results of complete patient history, comprehensive clinical examination, bladder diary, uroflowmetry, and PVR should be available before considering a filling cystometry (and/or other invasive urodynamic tests).

Filling cystometry is preferably done with a 5-6 Fr double lumen catheter and at a filling rate of $\pm 10\%$ per minute of a diary determined maximum or age—expected bladder capacity.

Filling cystometry should be performed in the sitting position. When relevant medication or sedation is used it should be accounted for while evaluating the filling cystometry and be included in the report. In addition, it is important to note the time of last administration of medication in relation to the start of the cystometrogram, in order to determine the influence of any bladder modulating medication. Immediate evaluation of the test (before removing the catheters) should be done to determine technical quality and clinical relevance, as well as the ability to answer the clinical question that prompted the investigation, initially.

6 | CONCLUSION

To understand the characteristics as well as following good urodynamic practice (GUP), recommendations from the ICS

and ICCS are the basis of successful testing. This educational module provides recommendations for good clinical practice to completing filling cystometry in children using these standards. This narrative manuscript is based on expert consensus about the information contained in the existing literature. We hope that this teaching module will also serve as a challenge to improving (evidence-based) practice.

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ICS TEACHING MODULE

Urodynamics in children

Part 2. THE PRESSURE FLOW ANALYSIS IN CHILDREN

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Peter F.W.M Rosier MD, PhD, Stuart Bauer, MD**

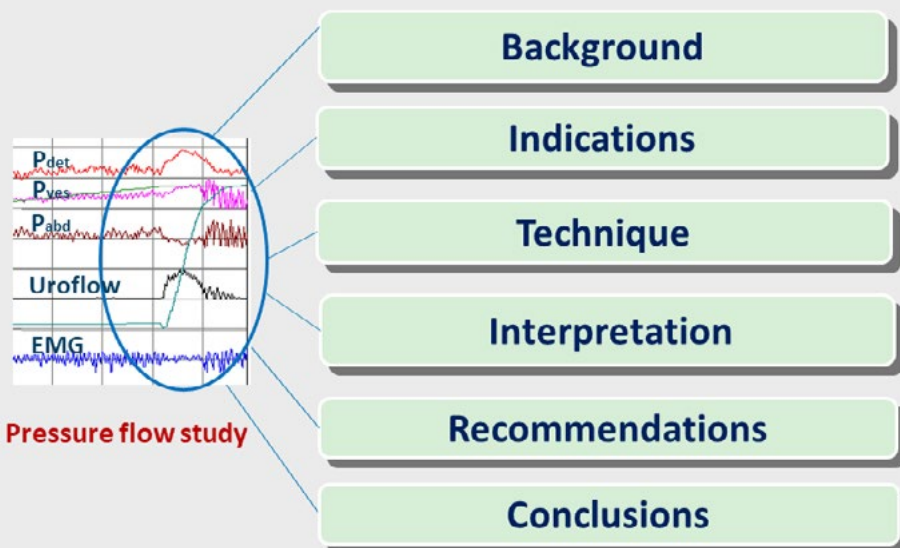
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Pressure flow study: outline



Background

- Pressure flow study (PFS) is an important tool to evaluate the voiding function in children with lower urinary tract dysfunction (LUTD)/lower urinary tract symptoms (LUTS)
- PFS is defined as measuring the detrusor pressure & uroflow during the micturition or voiding phase. It begins when the child & the urodynamicist decide that 'permission to void' has been given or when uncontrollable voiding begins
- This section follows the guideline from ICS & ICCS on Good Urodynamic Practice

<http://www.ics.org/>

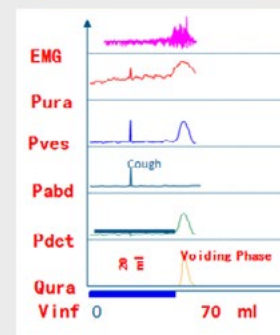
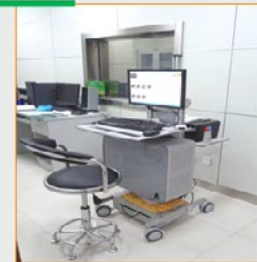
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In China



ICS Education Module

Pressure flow study (PFS)

- PFS has become the gold standard in assessing LUTD/LUTS
- During PFS Q_{max} , voided volume & detrusor pressure are recorded
- During voiding the either detrusor or urethral sphincter may be classified as normal, underactive, or overactive
- PFS can be obtained subsequent to filling cystometry with no specific additional equipment (apart from a flowmeter).

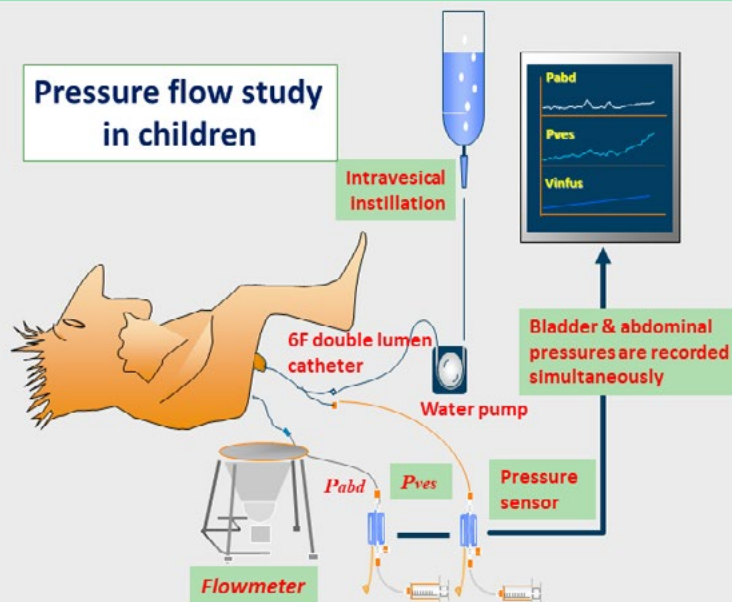


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Indications

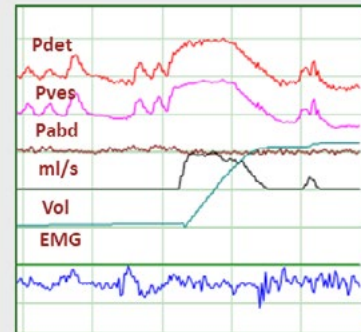
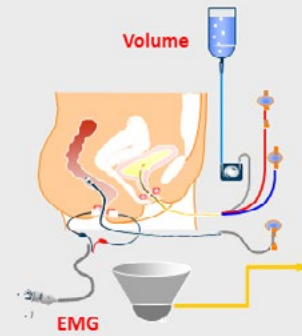
- Congenital malformations of the lower urinary tract (i.e., exstrophy, epispadias ureteroceles, multiple bladder diverticula)
- The procedure must have an impact on treatment strategies
- It is undertaken after history taking, physical examination, voiding diaries & uroflow/patch EMG recordings, if these measures do not answer the questions related to causes, nor provide effective management schemes for LUTD

Technique: the setting is the same as in cystometry



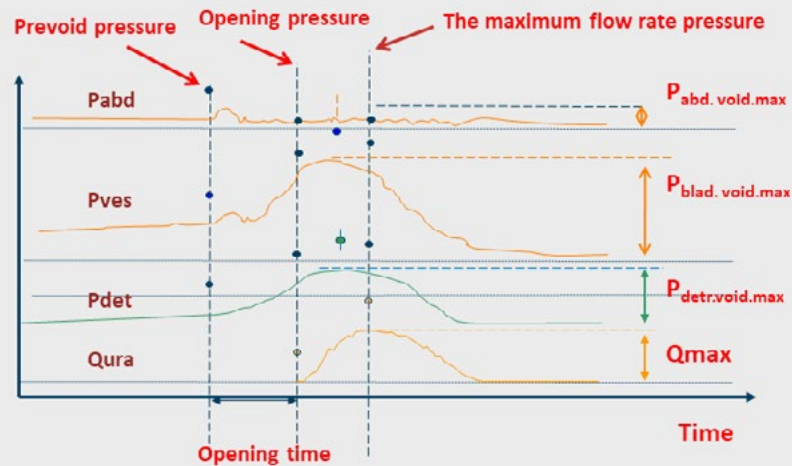
Technique: voiding phase

- The voiding is initiated when the urodynamicist allows, or when uncontrollable voiding begins
- During the recording a flowmeter connected to the urodynamic equipment allows flow rate parameters to be juxtaposed against pressure data & correlated with one another



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Technique: parameters recorded during voiding phase



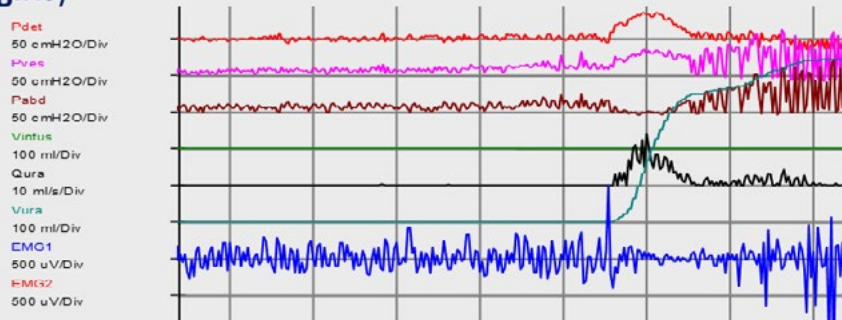
The terminology of voiding phase

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Interpretation: normal voiding detrusor function

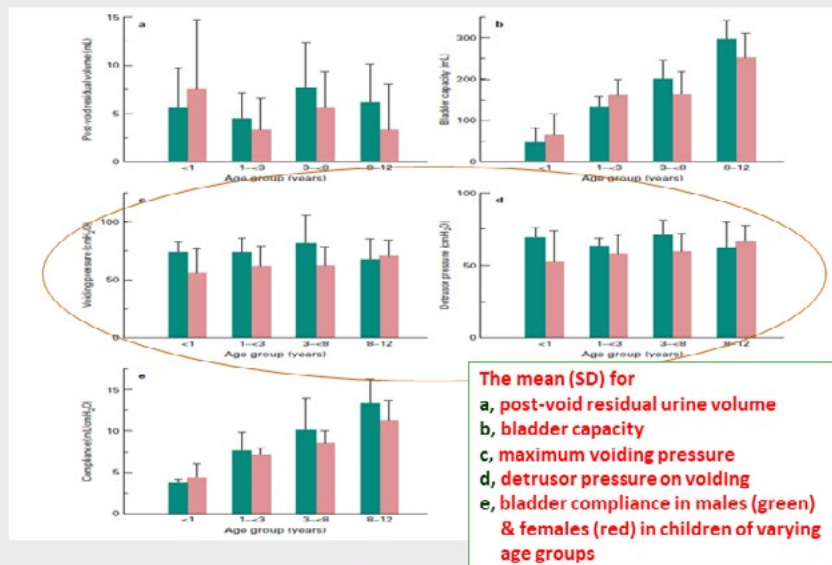
- Normal voiding is achieved by a voluntary, continuous detrusor contraction which leads to complete emptying of the bladder within an acceptable time span
- If the DSD occurred during the voiding, the $P_{\text{detr.void.max}}$ is higher than that of adults (118 - 127 cm H₂O for boys & 72 - 75 cm H₂O for girls)

Normal voiding



ICS Education Module

Interpretation: voiding pressure

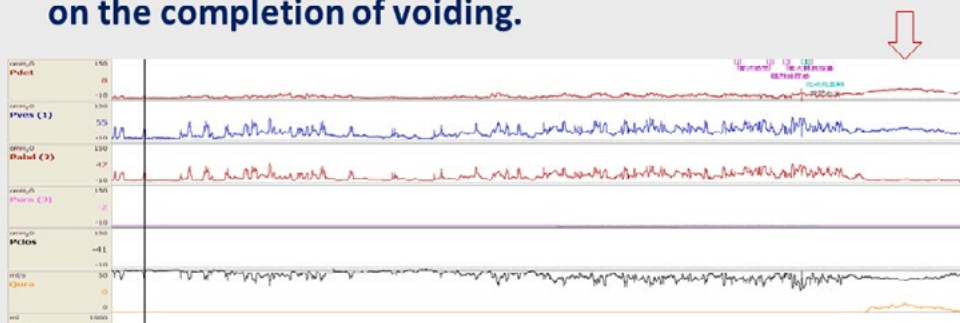


From Wen, et al. British Journal of Urology 1998 81, 468-73

ICS Education Module

Interpretation: detrusor underactivity (DU)

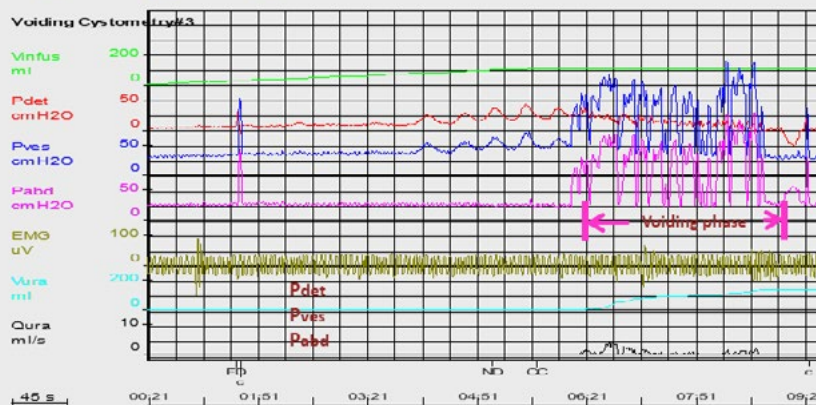
DU is defined as a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within the normal time span. This often results in an increase of PVR on the completion of voiding.



Detrusor underactivity (arrow)

Interpretation: acontractile detrusor

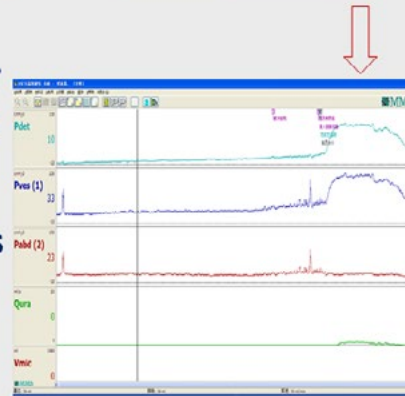
An acontractile detrusor displays decreased contractile activity during urodynamic assessment



Acontractile detrusor in a child with neurogenic bladder; urination achieved by increasing abdominal pressure

Interpretation: voiding phase

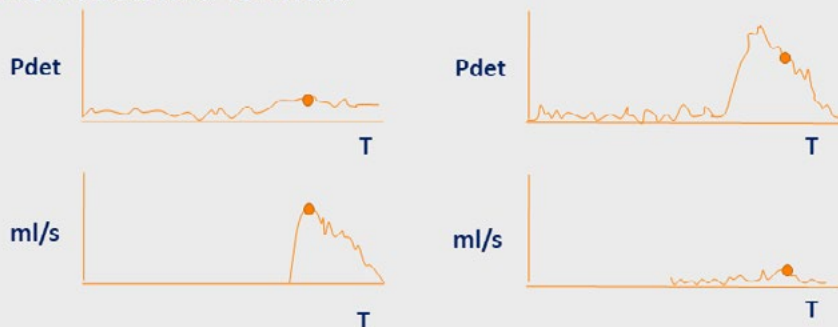
- The voiding efficiency is calculated by functional bladder capacity ($V_{\text{fun.max.cap}}$) / maximum bladder capacity ($V_{\text{max.cap}}$)
- High voiding detrusor pressures which may be induced by significant resistance as is seen in BOO. Conversely, if urethral resistance is low this may be reflected by a low pressure contraction



High voiding detrusor pressure with low Q_{max} (arrow)

Interpretation: voiding phase

Pressure at maximum flow, in combination with corresponding maximum uroflow, give a clinically relevant grading of bladder outlet with obstruction when used in a formula



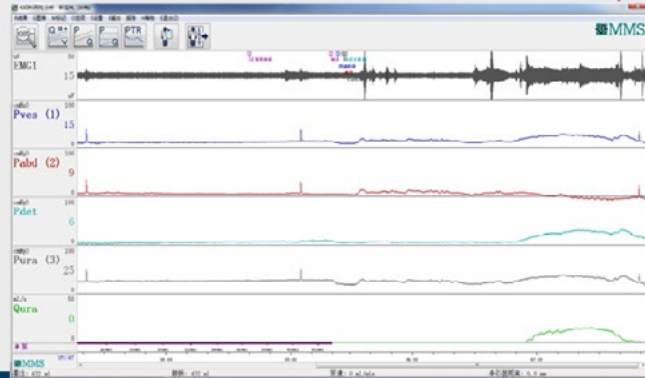
Without obstruction

Obstruction

Interpretation: voiding phase

- DSD during voiding: a sustained or increased response or intermittent changes in urethral sphincter activity during the voiding phase
- DSD is common in infant boys. High $P_{det,void,max}$ in infants or a staccato detrusor pressure curve during voiding indicates the existence of DSD

An increased response in urethral sphincter activity during the voiding phase (Arrow)

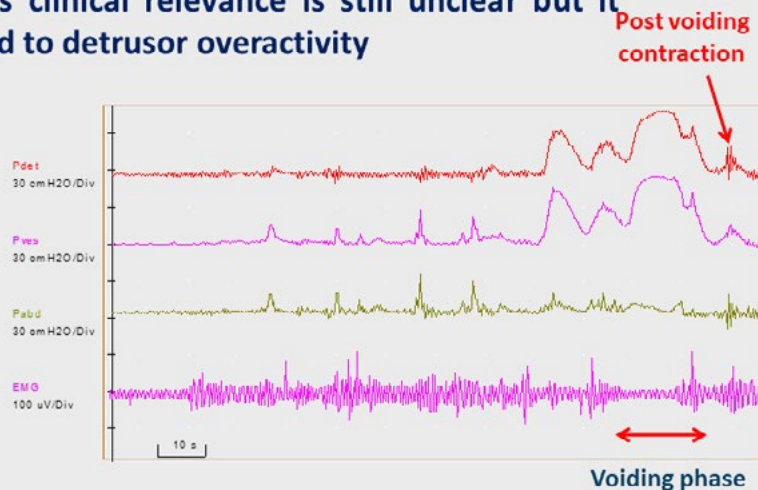


ICS Education Module

Interpretation: voiding phase

A post voiding contraction indicates a detrusor contraction which occurs immediately after micturition has ended. Its clinical relevance is still unclear but it may be related to detrusor overactivity

A 2.5 months old baby with normal voiding



ICS Education Module

Interpretation: how to exclude the artifact

- The parameters of free flow measurement such as the PVR & maximum flow rate are useful tools to be compared with the flow pattern during PFS. If the flow rate & PVR show big difference from that obtained from PFS, it indicates that artifacts may exist.
- For example, the flow rate was lower & the PVR substantially higher significantly compared to these parameters from the free flowmetry (before catheterization), the PFS results may be not representative of **“obstructed”**, or **“underactive”** or **“DSD”** or **“dysfunctional”**.


Conclusions



- PFS is an useful tool to evaluate lower urinary tract function in children
- Investigators must keep in mind that normal bladder capacity increases with increasing age. DSD is common in infant boys so high $P_{detr.void.max}$ is often seen
- To understand the characteristics in PFS, knowing normal voiding parameters as well as following ICS & ICCS recommendations are the basis of successful testing



ICS educational module: Pressure flow study in children

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Aims: To introduce the standard procedure and results interpretation of pressure/flow study (PFS) in children.

Methods: The literature on PFS in children in PubMed for the last 20 years was reviewed. The updated knowledge on PFS in children regarding indication, preparation, technique, and interpretation were summarized.

Results: This educational module explains when and how to do a PFS and how to analyze the results. All requirements and instructions for the PFS in children described in this document follow ICS reports on Good Urodynamic Practice and urodynamic equipment performance as well as guidelines from the ICCS. PFS can be obtained subsequent to filling cystometry with no specific additional equipment (apart from a flowmeter) or patient preparation needed. It requires both vesical and intra-abdominal pressures being recorded. Information from clinical history, physical examination, voiding diaries, and free uroflowmetry with or without perineal patch EMG and pertinent imaging results should be available before undertaking urodynamic testing.

Conclusions: Following ICS and ICCS guidelines, PFS is an easy procedure and a useful tool to provide information on voiding function in children.

KEYWORDS

children, pressure/flow study, procedure, urodynamics

1 | INTRODUCTION

Pressure/flow study (PFS) provides information on voiding function (outflow obstruction, flow pattern, detrusor contractility, and its sustainability as well as intravesical pressure). Combined with filling cystometry, it is the gold standard for evaluating voiding function in children with lower urinary tract dysfunction (LUTD)/lower urinary tract symptoms (LUTS), especially when less invasive studies fail to provide an adequate explanation for the symptoms and/or the signs of dysfunction.^{1–7}

The aim of pressure/flow studies is to reproduce symptoms, to identify the underlying causes for voiding symptoms, and to quantify related pathophysiological processes. It is used to establish as clearly as possible a

baseline, so that changes resulting from treatment and/or growth can be assessed, indicating that the investigation may need to be repeated, and to provide some guidelines for the choice of treatment (although results of urodynamic testing may not necessarily be the deciding factor).

The ICS Urodynamics Committee presents this educational module “Pressure/flow analysis in children” to serve as a standard education module of Good Urodynamic Practice for everyone concerned when prescribing, performing, and analyzing pressure/flow testing in general and especially in children with symptoms and signs of LUTD. The educational module consists of a presentation, in combination with this manuscript. This manuscript serves as a scientific background review; the evidence base, for the ICS PowerPoint presentation; available via <http://www.icsoffice.org/>. The presentation

explains when and how to do a PFS and how to analyze the results. The presentation and this manuscript use expert's opinion where evidence is, especially for the clinical practice aspects, unavailable and is marked with: "eo" (expert's opinion).

Voiding dysfunction is prevalent in pediatric urology practice. The subjective bias by both the child and the clinician and the considerable overlap between symptoms from varying disorders make it difficult to evaluate voiding function without employing some objective parameters. All requirements and instructions for the PFS in children described in this section follow ICS reports on Good Urodynamic Practice^{2,3} and urodynamic equipment performance⁴ as well as guidelines from the ICCS.⁵ Pressure/flow measurements can be obtained subsequent to filling cystometry with no specific additional equipment (apart from a flowmeter) or patient preparation needed. It requires both vesical and intra-abdominal pressures being recorded. Information from clinical history, physical examination, voiding diaries, and free uroflowmetry with or without perineal patch EMG and pertinent imaging results should be available before undertaking urodynamic testing.

2 | INDICATIONS AND PREPARATION

The indications and preparation for PFS are similar to that for cystometry. Whether the child is able to void voluntarily or not, evaluation of the voiding, measured in a continuous fashion after the filling cystometry is complete, can be regarded as standard practice. The child and caregiver should be informed in advance along with an explanation as to why both phases, storage (filling), and voiding are going to be measured. The child's cooperation is explicitly sought whenever possible.

3 | TECHNIQUE

PFS is defined as measuring the detrusor pressure and uroflow during the micturition or voiding phase. The detrusor pressure is equal to the bladder pressure minus the abdominal pressure, thus representing the pressure produced by the detrusor. The voiding phase begins when the child and the urodynamicist decide that "permission to void" has been given, or when involuntary voiding begins.⁶ This occurs when the maximum cystometric capacity (MCC) has been reached in children with no voiding dysfunction.⁷ During this phase the detrusor contracts, producing voiding detrusor pressure as the bladder outlet relaxes. It is not always possible to have very young children follow instructions to void, but in older children it is.

At this phase, the detrusor pressure increases as the pelvic floor relaxes and the urethral pressure decreases resulting in

voiding. The pressures are recorded through the same catheter that is used for cystometry. During the recording, a flowmeter connected to the urodynamic equipment, allows flowrate parameters to be juxtaposed against pressure data and correlated with one another. At the completion of voiding the detrusor relaxes and the urethra/bladder outlet "closes."

During voiding the detrusor may be classified as normal, underactive, or acontractile. Normal voiding is achieved by a voluntarily initiated detrusor contraction; it is sustained and cannot be suppressed easily once it has begun. In the absence of bladder outlet obstruction, a normal contraction will lead to complete emptying.⁶ When the child feels voiding is complete, this phase ends and storage phase begins again. During the voiding phase, a flowmeter connected to the urodynamic equipment, allows flowrate parameters to be juxtaposed against pressure data and correlated with one another.

During PFS Q_{max} and voided volume are recorded. Pressure parameters that can be obtained during the voiding phase are: pre-micturition pressure, opening pressure, opening time, maximum detrusor pressure, detrusor pressure at maximum flow, closing pressure, minimum voiding pressure. The maximum detrusor pressure ($P_{det,max}$) is clinically relevant in determining the presence of bladder outlet obstruction (BOO) or contractile detrusor.

After the PFS, the PVR is measured again through the catheter and confirmed by ultrasound.

3.1 | Cooperation

Cooperation is important for successful cystometry and PFS. The following steps might be valuable for achieving this.

- Bowel or rectum preparation; defecation (at home) before the test whenever possible.
- Dedicated and knowledgeable staff able to provide an explanation about the procedure and the aim of urodynamic studies to the patient is paramount: if applicable, engage the child to increase cooperation.
- Administration of sedatives (not anesthetics), and documenting if the child was very fearful is mandatory.
- Prior application of 1% lidocaine jelly or a liquid solution instilled into the urethra as a topical anesthetic may aid in catheter insertion.
- The approach to urodynamic evaluation should be, start with as minimally invasive tests as possible and proceed with invasive investigations, as necessary, to answer the question.
- If the child is still agitated after inserting the catheter in the bladder, having parents present to help calm their child, is advisable.
- Toys, video games, or movies during the examination are very helpful to distract the child and minimize artifact.

- Two cycles of cystometry and PFS to determine the consistency or representativeness of findings is preferable.

4 | INTERPRETATION

The aim is to analyze accurately, and to critically report results after carefully performing the PFS in children.

1. Normal voiding detrusor function- Normal detrusor function is characterized by an initial (voluntary) relaxation of the external urethral sphincter/pelvic floor followed immediately by a continuous detrusor contraction that leads to complete bladder emptying within a normal time span, in the absence of obstruction.
2. Maximum voiding detrusor pressure ($P_{\text{detr-void.max}}$) should be reported and related to the flowrate to determine diagnosis. The flowrate should be compared to the free flowrate as one means of evaluating the representativeness of the (pressure/flow) voiding.
3. Detrusor-Sphincter Dyssynergia (DSD): describes a detrusor contraction concurrent with an involuntary contraction of the urethral and/or periurethral striated muscle. Occasionally the flow may be prevented altogether
 - .. DSD is usually evaluated by a pressure/flow/EMG study or with simultaneous bladder/urethral pressure recordings. High $P_{\text{detr.void.max}}$ in infants or a staccato detrusor pressure curve during voiding when flowrate reductions are synchronous with detrusor pressure increments indicate the existence of DSD.
4. PVR >20 mL or >15% of bladder capacity (BC) in children age 7-12 years and >30 mL or >21% BC for children 4-6 years on two consecutive uroflows indicates an abnormality.⁸ The uroflow is considered normal if the bladder empties at least once during two uroflow measurements. If a low PVR is demonstrated during free flow uroflowmetry then any raised PVR during the urodynamic assessment can be considered as an artifact due to the artificial circumstances of the test and the presence of an in-situ urethral catheter.
5. Detrusor underactivity is defined as a voiding contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span.⁸ Pressure flow nomograms or calculations are needed to quantify detrusor contractility. Detrusor underactivity may occur with or without an elevated PVR.
6. An acontractile detrusor does not demonstrate any contractile activity during urodynamic assessment. Some children, however, cannot or will not generate a detrusor contraction in a “laboratory” setting. This could be mistaken for a diagnosis. Spending extra time

encouraging the child to void, dripping water on the pubic area, or lower extremity and/or having the mother or caregiver encourage the child to void, helps in the process to induce the child to urinate.

7. A high voiding detrusor pressure (usually >74 cmH₂O in boys, 63 cmH₂O in girls⁷) with a low urine flow indicates BOO; low pressure with a low flow indicates underactive detrusor. A pressure flow plot is useful to evaluate the pressure flow relationship in this regard, although clinical calibration is not yet available for children.
8. High voiding detrusor pressures may be induced by significant resistance as is seen in BOO where the detrusor compensates for BOO. Conversely if urethral resistance is low this may be reflected by a low pressure (high velocity) detrusor contraction.
9. A post voiding contraction indicates a detrusor contraction that occurs immediately after micturition is complete. Its clinical relevance is uncertain, but it may be related to detrusor overactivity and/or a sign of CNS dysfunction as well as collapsing mucosa on catheter pressure channel openings.
10. Bladder voiding efficiency (BVE) = (voided volume/total bladder capacity) × 100%.⁹
11. Cystometry volume parameters can be corrected for any diuresis during the test after pressure flow study by immediately recording the PVR and adding it to the voided volume.

The parameters of free flow measurement such as the PVR and maximum flowrate are useful for determining the accuracy of the flowrate and PVR obtained from PFS. If the flowrate and PVR show substantial differences from those obtained during PFS, it indicates an artifact may exist. For example, if the flowrate is lower and the PVR, significantly higher compared to that obtained from free flowmetry (before catheterization), the PFS results may be not representative.

5 | CONCLUSION

PFS is a useful tool for evaluating lower urinary tract function in children. It should be considered as one procedure, along with a “free” voiding uroflowmetry and filling cystometry, but not the only one, to clarify the diagnosis and to make therapeutic decisions as well as to follow up treatment responses to the voiding dysfunction, when less invasive studies are inconclusive. To understand the characteristics in PFS, normal voiding parameters as well as following GUP recommendations from the ICS and ICCS are the basis of successful testing. We present the evidence background for the PowerPoint presentation, to be used for educational the practice of the test, as is available on the ICS website.

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6. ICS GLOSSARY

Welcome to the ICS Glossary of Terminology. Find the latest terms standardised by ICS.

Please also visit www.ics.org/glossary to browse by glossary section, by letter or search to find the terms and appropriate reference you need to cite in your work.



Bernard Haylen

ICS Glossary Editor & Standardisation Steering Committee Chair

A

Abdominal leak point pressure (ALPP - cm H2O)

Investigation

This is a dynamic test. It is the intentionally increased abdominal pressure that provokes urine leakage in the absence of a detrusor contraction.

Abdominal Leak Point Pressure (female) - ALPP - cm H2O

Investigation

Abdominal leak point pressure (abdominal LPP): This is a dynamic test. It is the lowest value of the intentionally increased intravesical pressure that provokes urinary leakage in the absence of a detrusor contraction.³² The increase in pressure can be induced by a cough (cough LPP) or Valsalva (Valsalva LPP). Multiple estimates at a fixed bladder volume (200–300 ml) are desirable. Catheter size will influence LPP values and should be standardized. LPP values might also be affected by many other factors such as the technique to confirm urine loss, location of catheter, type of pressure sensor, bladder volume, rate of bladder filling, and patient position. A low abdominal LPP is suggestive of poor urethral function.

Abdominal Pressure Catheter for Urodynamics

Investigation

'Flaccid filled' punctured balloon in the rectal ampulla are used to measure abdominal ('perivesical') pressure. vaginal or stoma placement of the abdominal pressure catheter is used alternatively only if rectal catheter placement is impossible.

Abdominal pressure (p abd - female)

Investigation

The pressure surrounding the bladder. It is usually estimated from measuring the rectal pressure, though vaginal and infrequently the pressure through a bowel stoma can be measured as an alternative. The simultaneous measurement of abdominal pressure is essential for interpretation of the intravesical pressure trace. Artefacts on the detrusor pressure trace may be produced by an intrinsic rectal contraction.

Abdominal pressure (Pabd - cm H2O) - male

Investigation

The pressure in the abdominal cavity surrounding the bladder. Usually estimated by measuring the rectal pressure, though pressure through a bowel stoma can be an alternative. The simultaneous measurement of abdominal pressure is essential for interpretation of the intravesical pressure trace. Artefacts on the detrusor pressure trace may be produced by a rectal contraction.

Abdominal signs

Sign

Amongst numerous possible abdominal signs are: (i) Bladder fullness / retention: The bladder may be felt by abdominal palpation or suprapubic percussion; (ii) Other abdominal masses: or distension (e.g. ascites); (iii) Scars: indicating previous relevant surgery or traumas or evidence of previous radiotherapy; (iv) Renal Area: Examination for tenderness, masses.

Abnormal (bladder filling) sensations

Symptom

Complaint of an awareness of sensation in the bladder, urethra or pelvis, described with words like "tingling", "burning" or "electric shock", in the setting of a clinically relevant neurologic disorder (e.g. incomplete spinal cord lesion).

Abnormal sensations - Filling cystometry

Investigation

Awareness of sensation in the bladder, urethra or pelvis described with the words like "tingling", "burning" or "electric shock" in the setting of a clinically relevant neurologic disorder (e.g. incomplete spinal cord lesion).

Abnormal urethral function during voiding - pressure flow studies

Investigation

The urethral sphincter(s) do not relax completely or they are (temporarily) contracted during voiding, resulting in increased detrusor pressure. Bladder emptying may be complete or incomplete (PVR present).

Absent bladder filling sensation

Symptom

Complaint of both the absence of the sensation of bladder filling and a definite desire to void.

Absent bladder sensation - filling cystometry

Investigation

No bladder sensation during filling cystometry, at least to expected capacity of 500 mL.

Absorbent Products

Conservative Management – Female

Absorbent products are those that have been specifically developed to help manage leakage or soiling, such as absorbent pads and pants, absorbent bed sheets and chair covers.

Abstinence (sexual) due to pelvic organ prolapse*Symptom*

Non-engagement in sexual activity due to prolapse or associated symptoms.

Accuracy of Uroflowmeters*Investigation*

The desired clinical accuracy may differ from the technical accuracy of a flow meter. The ICS Technical report recommended the following standards: a range of 0-50 ml/s for Qmax and 0-1,000 ml for voided volume, maximum time constant of 0.75 s ; an accuracy of 5% relative to full scale, although a calibration curve representing the percentage error over the entire range of measurement should be made available.

However, technical specifications from the manufacturers are rare and often not in accordance with ICS recommendations: this situation should be rectified .

Acontractile detrusor - pressure flow studies*Investigation*

The detrusor cannot be observed to contract (i.e. no increase in Pdet) during urodynamic studies resulting in failure to void (CHANGED). Limited voiding may occur by straining. The possibility of "inhibition" of a detrusor voiding contraction must be considered if the man subsequently voids normally post-cystometry. An acontractile detrusor can be of neurogenic or non-neurogenic origin.

Acute on chronic retention*Diagnosis*

An individual with chronic retention goes into acute retention and is unable to void.

Acute Pain*Symptom*

Pain related to acute trauma, infection or other well-defined disease process.

Acute urinary retention*Symptom*

Complaint of a rapid onset, usually painful suprapubic sensation (from a full bladder) due to the inability to void (non-episodic), despite persistent intensive effort.

Acute urinary retention*Diagnosis*

A patient is unable pass any urine despite having full bladder, which on examination is painfully distended and readily palpable or percussible.

Acute urinary tract infection symptoms*Symptom*

Symptoms such as increased bladder sensation, urgency, frequency, dysuria/stranguria, pain in the lower urinary tract with or without urgency urinary incontinence might suggest lower urinary tract infection. Confirmation of a UTI requires evidence of significant microorganisms and pyuria.

Adult*Sign*

Fully grown and physically mature.

Adult neurogenic lower urinary tract dysfunction (ANLUTD)*Diagnosis*

Abnormal or difficult function of the bladder, urethra (and/or prostate in

men) in mature individuals in the context of clinically confirmed relevant neurologic disorder.

Adult neurogenic lower urinary tract dysfunction (ANLUTD) - symptoms*Symptom*

LUTS are classified neurogenic in the presence of a relevant neurological disease ONLY.

Aims of Clinical Urodynamics*Investigation*

The aim of clinical urodynamics is to reproduce symptoms whilst making precise measurements in order to identify the underlying causes for the symptoms, and to quantify the related pathophysiological processes. By doing so, it should be possible to establish objectively the presence of a dysfunction and understand its clinical implications. Thus, we may either confirm a diagnosis or give a new, specifically urodynamic diagnosis. The quantitative measurement may be supplemented by imaging (video-urodynamics).

Aims of filling cystometry*Investigation*

These are to assess bladder sensation, bladder capacity, detrusor activity and bladder compliance as well as to document (the situation of and detrusor pressures during) urine leakage.

Altered libido*Symptom*

Complaint of change in interest in sexual activity

Ambulatory urodynamics*Investigation*

A functional test of the lower urinary tract for which a transurethral catheter is placed in the bladder -performed outside the clinical setting, involving natural bladder filling by drinking and continuous recording of bladder pressure (Pves) for a longer period of time (e.g. 12 hours). It can reproduce bladder function and urine loss during an individual's everyday activities.

Anal Canal - Endoanal ultrasonography (EAUS)*Imaging*

Anal Canal - The anal canal in adults is between 2.5 and 5cm in length and begins as the rectum narrows, passing posteriorly between the levator ani. Three levels of assessment in the axial plane.

- (1) Upper level: the hyperechoic sling of the puborectalis muscle (PR) and the complete ring of the internal anal sphincter (IAS).
- (2) Middle level: corresponds to the superficial part of the EAS (concentric band of mixed echogenicity), the conjoined longitudinal layer, the IAS (concentric hypoechoic ring), and the transverse superficial perineal muscles.
- (3) Lower level: corresponds to the subcutaneous part of the EAS where the IAS is absent.

Anal endosonography (AES) - ultrasound imaging (male)*Imaging*

Anal ultrasound imaging looking for sphincter defects.

Anal fissures*Sign*

Longitudinal split in the skin of the anal canal, exposing the internal anal sphincter muscle. The majority of fissures are found in the mid-line posteriorly and there may be a skin tag associated with them.

Anal incontinence*Symptom*

Complaint of involuntary loss of flatus or feces.

Anal laxity

Symptom

Complaint of the feeling of a reduction in anal tone.

Anal Manometry

Investigation

Anal manometry is a test to assess the mechanical strength of the anal sphincters. A range of methods is available, including water perfused, solid state, and micro-balloon systems. The length of the canal is measured either by station pull-through or continuous pull-through. Station pull-through involves inserting the catheter to 6cm from the anal verge, withdrawing the catheter at 5–10mm intervals and measuring for 1–5min at each “station”. Continuous pull-through involves withdrawing the catheter at a set speed by hand or by a mechanical puller. As normal values can differ substantially between laboratories according to the style of catheter used, each unit is encouraged to generate its own normal data. In patients with fecal incontinence the value of manometry is: (a) To define functional weakness of one or both sphincter muscles (as a compliment to anal endosonography). (b) To support findings of other tests and to monitor outcome and predict response to biofeedback training. (c) In cases where anal endosonography is not available, vector manometry may help identify anatomic defects of the anal sphincter complex. In constipated patients the value of manometry is: (a) To exclude Hirschsprung’s disease. (b) To identify and predict responses to biofeedback training (pelvic floor dyssynergia = failure to expel a water-filled balloon).

Anal Manometry - Balloon expulsion pressure

Investigation

The balloon expulsion pressure is the anal canal pressure during straining with a filled balloon in the rectum. Balloon expulsion can be performed on patients with evacuatory difficulty. An inappropriate increase in sphincter pressure on attempted voiding evacuation is usually reported as a present or absent response, rather than numerically. Such increased pressure is referred to as “anismus” or “paradoxical sphincter contraction.”

Anal Manometry - Endurance Squeeze Pressure

Investigation

The endurance squeeze pressure is the length of time the individual is able to maintain the pressure during a voluntary contraction. To assess the endurance squeeze pressure, measurements are taken during a 5–10sec squeeze (normal 5sec). Incontinent patients typically have fatigue rate of greater than two-thirds of initial pressure at the end of the sustained squeeze. By calculating fatigability, the fatigue rate (using linear regression on the mean pressure over one second periods throughout the endurance squeeze) can be derived.

Anal Manometry - Involuntary Maximum Squeeze Pressure

Investigation

A common maneuver is a maximal cough to measure this involuntary increment, usually reported as a present or absent response, rather than numerically.

Anal Manometry - Maximum resting pressure

Investigation

The maximum resting pressure is the maximum resting pressure generated in the anal canal at rest. Strictly speaking, it is defined as the difference between the intrarectal pressure and the highest recorded rectal pressure at rest. However, rectal contents may affect the accuracy of rectal pressure measurements. The internal anal sphincter (IAS) exhibits continuous tonic activity and is responsible for 55–85% of the resting anal canal pressure. Its

contribution to resting tone is variable along the length of the anal canal with the proximal two thirds being more reliant on IAS tone to maintain adequate resting pressures. The range of maximal resting pressure is typically between 60 and 120cm H₂O. The EAS has constant tonic activity contributing to the resting anal canal pressure.

Anal Manometry - Maximum Squeeze Pressure

Investigation

The maximum squeeze pressure is the maximum pressure generated in the anal canal during a voluntary contraction. Although the EAS contributes to the resting pressure the specific function of the EAS can be assessed during the squeeze and cough maneuvers. The pressure increment above resting pressures during these maneuvers is a direct representation of EAS function. The normal range, as stated above, varies according to measurement modality in each laboratory, but is approximately above 60 cm H₂O. Typically, higher values are obtained by automated pull-through rather than station withdrawal methodologies.

Anal Manometry - Rectoanal Inhibitory Reflex (RAIR)

Investigation

The recto-anal inhibitory reflex (RAIR) a relaxation response in the IAS following rectal distension. A drop of at least 25% of resting pressure has to occur with subsequent restoration to at least two thirds of resting pressure for it to be deemed present. It is elicited by rapid insufflation and disinflation of 50mls of air into a balloon positioned in the distal rectum during anal manometry at the level of the proximal high pressure zone. This reflex is absent in Hirschsprung’s disease: of greater physiological meaning, this reflex is thought to underlie the sampling response that allows rectal content to be sensed by the anal mucosa, thus ensuring continence of flatus and stool.

Anal Manometry (Advanced) - High Resolution Manometry

Investigation

In this technique, a catheter with a large number of pressure sensors spaced less than 0.5mm apart along the length of the catheter. This allows complete definition of the intra-anal pressure environment. The resulting data is displayed on a topographical three dimensional plot to allow easier pattern recognition. It is a measurement with the variables of pressure (displayed as the color), distance into the anal canal (y-axis) and time (x-axis). Normal ranges are slightly higher than measured with standard manometry, but the readings agree well with each other.

Anal Manometry (Advanced) - Vector Manometry

Investigation

Vector manometry is a quantitative measure of radial symmetry and volume of the anal sphincter. It involves withdrawing (commonly using a mechanical puller) a radially arranged multi-channel anorectal manometry catheter through the length of the anal canal. The following parameters are identified: Radial asymmetry index (RAI) is a quantitative measure of the radial symmetry and can be calculated at any level in the anal canal but most commonly refers to the level at which the highest resting pressure is generated. The principle is that an asymmetrical sphincter is more likely to have a sphincter defect. The vector volume is the volume of the 3D shape generated and provides a value which reflects the overall length and symmetry of the sphincter.

Anal Plugs

Conservative Management – Female

Anal plugs are containment devices aimed at blocking the loss of stool to control fecal incontinence. Plugs come in different designs, sizes, and compositions, such as polyurethane and polyvinyl-alcohol.

Anal sexual practices with body parts*Symptom*

Stimulation of the anus and/or rectum with bodily parts other than the penis (e.g., finger, fist) for sexual purposes by the recipient and/or a partner.

Anal Sexual practices with non-living objects*Symptom*

Stimulation of the anus and/or rectum with non-living objects (e.g., dildo) for sexual purposes by the recipient and/or a partner.

Anejaculation*Symptom*

Complaint of the absence of seminal fluid emission. May be associated with the absence of the sensation of orgasm or anorgasmia.

Anodyspareunia*Symptom*

Complaint of pain or discomfort associated with attempted or complete anal penetration.

Anorectal examination - female position*Sign*

The patient lies in the left lateral position with hips flexed and ankles away from the examiner. Dorsal lithotomy position could also be used.

Anorectal examination (female) - perianal sensation/ reflex*Sign*

In patients with possible neurogenic pelvic floor dysfunction there should be particular note of those neurological signs related to S2-4 but these should be complimented by a more general neurological examination as indicated. Specific to ano-rectal dysfunction, assessment of anal reflex, and perianal sensation should be performed.

Anorectal incontinence*Symptom*

Complaint of involuntary loss of flatus or feces.

Anorectal Manometry - Ambulatory*Investigation*

Using solid-state catheters, prolonged ano-rectal motor events have been recorded, including in ambulant subjects. The clinical applicability of these techniques has not been established.

Anorectal Neurophysiology - Pudendal Nerve Terminal Motor Latencies (PNTML)*Investigation*

The PNTML is a measurement of the delay between the electrical stimulation of the pudendal nerve and the EMG activity of the EAS. The pudendal nerve is stimulated as it passes over the ischial spine using a specially designed electrode attached to the index finger of the assessor in the rectum. The surface EMG recording electrode which sits on the base of the assessor's index finger and measures external sphincter activity. The test does not reliably reflect the pudendal nerve damage. This may be because PNTMLs measure the speed of nerve conduction, which involves the fastest nerve fibers that are least susceptible to damage. The latencies are reported as normal if below 2.2msec, but are also very operator dependent, with poor reproducibility and hence not recommended for general clinical use.

Anorectal neurophysiology - Surface EMG*Investigation*

Electrodes placed on the skin of the perineum or inside the vagina or rectum. Surface recordings from the sphincter show increased activity with

body actions and decreased activity in sleep. Needle EMG however is regarded as superior. Some centers use surface EMG as an indicator of anal sphincter activity to provide feedback for patients undergoing behavioral biofeedback training for fecal incontinence or constipation.

Anorectal Neurophysiology (female) - Concentric fibre EMG*Investigation*

Concentric needle EMG can be used to record activity in the external sphincter and puborectalis. The responses of these muscles to voluntary contraction, coughing and straining can be displayed. The data are qualitative and compared to appearances in these muscles at rest. The muscles can also be studied at several sites to define areas of functioning muscle and identify sites of muscle injury (sphincter mapping) although this is has now been superseded by anal endosonography.

Anorectal neurophysiology (female) - single fibre EMG*Investigation*

A single fiber needle EMG technique is used to measure the muscle fiber density in the external sphincter and puborectalis. A raised fiber density indicates re-innervation in the muscles, which may occur following partial denervation. Calculating EAS fiber density is another method of assessing denervation and re-innervation of the EAS. It is used almost exclusively as a research tool. Conventional EMG can be used to quantify the re-innervation of the EAS by detecting prolongation in the duration of the motor unit potential.

Anorectal pain symptoms*Symptom*

Complaint of pain, pressure or discomfort particularly during defecation or straining to defecate, but can occur at any time.

Pain during defecation or straining to defecate.

Inflammatory: characterized by burning or stinging

Non-inflammatory: blunted anorectal or muscular-spasm type pain

Anorectal Pain Syndromes (Female)*Diagnosis*

1: Levator ani syndrome: Episodic rectal pain caused by spasm of the levator ani muscle. Proctalgia fugax (fleeting pain in the rectum) and coccydynia (pain in the coccygeal region) are variants of levator ani syndrome. 2: Proctalgia fugax definition: Proctalgia fugax (or Levator syndrome) is a severe, episodic, rectal and sacrococcygeal pain. It can be caused by cramp of the pubococcygeus or levator ani muscles 3: Pudendal neuralgia Pudendal Neuralgia (PN) is a painful condition that is caused by inflammation of the pudendal nerve involving it's dermatome. It can affect both men and women.

Anorectal prolapse*Symptom*

Complaint of external protrusion (bulge) of the anus or rectum (differentiation on subsequent examination between rectal mucosal prolapse and full thickness rectal wall prolapse which includes muscle and serosal layers).

Anorectal prolapse (female)*Symptom*

Complaint of a "bulge" or "something coming down" towards or through the anus/rectum. The woman may state she can either feel the bulge by direct palpation or see it aided with a mirror

Anorectal prolapse (female)*Sign*

Full thickness eversion of the lower part of the rectum and anal canal. The exposed mucosa is red with circumferential folds around the central pit,

which is the lumen of the rectum. Look for associated utero-vaginal prolapse, fistulas, sepsis, and ulcers.

Anorectal sensory measurements (female) - Assessment of rectal sensation to distension

Investigation

Rectal sensation to distension is most commonly assessed by manually inflating an intrarectal domestic balloon at a rate of approximately 5ml/second. The following are elicited: Volume which elicits the first sensation of balloon expansion (threshold) [typical normal range 12–25ml], Volume to get an urge to defecate (typical normal range 35–65ml), Maximal tolerated volume (typical normal range 120–300ml) - [normal ranges for the latter two sensations are highly variable due to lack of consensus on measurement technique especially of the nature and speed of inflation of the balloon]. The pressure required to elicit these sensations can also be measured using an electro-mechanical barostat and may be more reproducible. The barostat measures the volume and the pressure required to elicit these volumes sensations. Typically distension thresholds with a barostat are higher, with larger volumes being required to elicit the same sensation. However, again, the published ranges vary widely between units: typically distension volumes 1.5 to 3 times are published for thresholds with a barostat compared to manual balloon inflation. Distension sensitivity testing is of proven value in: (a) Patients with fecal incontinence to help with biofeedback training by normalization of the initial sensation sensory thresholds. (b) Identifying visceral hypersensitivity, poor rectal compliance, or rectal irritability if maximal tolerated volumes are low. There is no evidence to support use of the sensory thresholds for diagnosis and biofeedback training of patients with constipation. Compliance testing has also not proven valuable in identifying candidates for specific therapies.

Anorectal sensory measurements (female) - Mucosal Electrosensitivity

Investigation

This is test to measure anal and rectal sensory thresholds. Mucosal electrical stimulation is performed using a probe with two ring electrodes between which a small electrical potential is applied generating an alternating square wave with a variable frequency. Normal ranges have been established as anal electrosensation <10mA, and rectal as <30mA. In general, prolonged anal electrosensation is suggestive of damage to the sensory fibers of pudendal nerve, and prolonged rectal electrosensation is suggestive of autonomic neuropathy.

Anorectal Sepsis

Diagnosis

1: Abscess Infection in a (non Crohn's) anal gland, located at the base of the dentate line, that initially forms an abscess, which can be located in one of the potential spaces surrounding the anus and rectum. 2: Ano-rectal/vaginal/perineal fistula: Rectovaginal fistula is a communication from the rectum to the vagina and rarely the perineal area. An anovaginal/perineal fistula is an abnormal communication from the anal canal to the vagina or perineal area.

Anorectal/vaginal/perineal fistula

Sign

Is an abnormal communication from the anal canal to the vagina or perineal area.

Ano-rectal/vaginal/perineal fistula

Sign

Is an abnormal communication from the anal canal to the vagina or perineal area.

Anorgasmia or difficulty in achieving orgasm (female)

Symptom

Complaint of lack of orgasm; the persistent or recurrent difficulty, delay in or absence of attaining orgasm following sufficient sexual stimulation and arousal, which causes personal distress.

Anorgasmic intercourse

Symptom

Complaint of lack of orgasm; the persistent or recurrent difficulty, delay in or absence of attaining orgasm following sufficient sexual stimulation and arousal, which causes personal distress.

Anoscopy of proctoscopy

Investigation

This is the inspection of the anal canal to identify anal fissure, fistula, or hemorrhoids as a cause of anal symptoms.

Anterior enterocele

Sign

Hernia of peritoneum and possibly abdominal contents into the anterior vaginal vault, most commonly after prior reconstructive surgery.

Anterior vaginal repair - colporrhaphy - native tissue

Surgery – Female

Repair the vaginal by excision and suturing of the edges of any defect, most commonly by midline fascial plication.

Anterior vaginal repair (colporrhaphy) - mesh or graft re-inforcement

Surgery – Female

A structural addition or inclusion used to give additional strength in function. It should be noted whether the graft is biologic, absorbable synthetic or permanent synthetic.

Anterior vaginal wall (compartment) prolapse

Sign

Observation of descent of the anterior vaginal wall (compartment). Most commonly this might represent bladder prolapse (cystocele). Higher stage anterior vaginal wall prolapse will generally involve descent of uterus or vaginal vault (if uterus is absent). Occasionally there might be an anterior enterocele (hernia of peritoneum and possibly abdominal contents), most commonly after prior reconstructive surgery.

Anterior vaginal wall (compartment) prolapse

Imaging

Diagnosis by symptoms and clinical examination, assisted at times by any relevant imaging (i.e. clinically evident) descent of the anterior vaginal wall (compartment).

Anterior vaginal wall (compartment) prolapse

Diagnosis

Clinically evident (symptoms, signs or any relevant imaging) descent of the anterior vaginal wall (compartment).

Anteverted uterus

Sign

The axis of the uterus is directed forwards overlying the bladder. Cervix is noted in/ towards the posterior fornix with fundus perhaps palpable anteriorly on bimanual palpation.

Aseptic intermittent catheterization

Conservative Management – General

This implies genital antiseptic preparation and the use of sterile (single-use) catheters and instruments/gloves in a designated clean area.

Associated POP-related Radiology (female)

Imaging

Defecography demonstrates normal anatomy of the anorectum as well as disorders of rectal evacuation. With barium paste inserted rectally prior to defecation, measurement of the anorectal angle is allowed with evidence of the presence, size or emptying of any rectocele. Enteroceles, rectal intussusception and mucosal prolapse might be diagnosed as well as a spastic pelvic floor (anismus).

Atrophic

Sign

Decrease from previous normal size of the body or a part, cell, organ, or tissue. An organ or body part's cells may be reduced in number, size or both. Atrophy of some cells and organs is normal at certain points in the life cycle. Other causes include malnutrition, disease, disuse, injury, and hormone over- or underproduction

Autonomic dysreflexia

Diagnosis

B

Balanitis xerotica obliterans (BXO - syn lichen sclerosis et atrophicus)

Symptom

Depigmentation of the penile skin, scrotum or glans.

Balanoposthitis

Sign

Inflammation of the foreskin and glans penis.

Behavioral and Cognitive Therapies

Conservative Management – Female

The way someone behaves, especially toward other people, and behavioral science is the study of human behavior.

1. Behavior therapy: a type of psychotherapy that attempts to modify observable maladjusted patterns of behavior by substituting a new response or set of responses to a given stimulus. The treatment techniques involve the methods, concepts, and procedures derived from experimental psychology; they include assertiveness training, aversion therapy, contingency management, flooding, modeling, operant conditioning, and systematic desensitization. It is also called behavior modification. 2. Cognitive therapy: any of the various methods of treating mental and emotional disorders that help a person to change their attitudes, perceptions, and patterns of thinking, from rational to realistic thoughts about the self and situations. The technique is often used in association with behavior therapy principles. 3. Cognitive behavior therapy (CBT): Cognitive techniques are often used in association with behavior therapy principles; this is called cognitive behavior therapy (CBT).

Bladder abnormalities - ultrasound imaging (male)

Imaging

Tumor, foreign body, overdistension, stones, diverticulum.

Bladder compliance - factors affecting (female)

Investigation

(i) Bladder filling: Faster filling is more provocative. An artifact may be produced which settles when filling is interrupted; (ii) Contractile / relaxant

This is a syndrome resulting from upper thoracic or cervical spinal cord injury above T6, elicited by a stimulus in the field of distribution of the autonomous sympathetic nucleus, characterized by unregulated sympathetic function below the lesion and compensatory autonomic responses. Can be asymptomatic if there is an increase in blood pressure without any other symptoms.

Average (urine) flow rate (AUFR - mL/s) - Qave

Investigation

Voided volume divided by the flow time.

Average voided volume

Sign

Summation of volumes voided divided by the number of voided during an assessment period of frequency-volume chart (FVC).

properties of the detrusor: e.g. post-radiation changes of the detrusor wall; (iii) Starting point for compliance calculations: Usually the detrusor pressure at the start of bladder filling and the corresponding bladder volume (usually zero); (iv) End point for compliance calculations: The detrusor pressure (and corresponding bladder volume) at cystometric capacity or immediately before the start of any detrusor contraction that causes significant leakage (and therefore causes the bladder volume to decrease, affecting compliance calculations). Both points are measured excluding any detrusor contraction.

Bladder (detrusor) compliance - filling cystometry (mL/cmH2O)

Investigation

Relationship between the change in bladder volume and change in detrusor pressure as a measure for the distensibility of the bladder. Compliance = Change Vol/ change Pdet. Compliance reflects the amount of fluid in the bladder to increase the bladder pressure by 1cm H2O (mL per cm H2O)

Bladder diary

Sign

Adds to the Frequency Volume Chart (FVC), the fluid intake, pad usage, incontinence episodes, the degree of incontinence and the circumstances at the time of the leakage.

Episodes of urgency and sensation might also be recorded, as might be the activities performed during or immediately preceding the involuntary loss of urine. Additional information obtained from the bladder diary involves: severity of incontinence in terms of leakage episodes and pad usage.

Bladder expression

Conservative Management – General

This refers to various compression manoeuvres aimed at increasing intravesical pressure to facilitate bladder emptying with or without obvious sensation from the bladder.

Bladder filling (sensory) symptoms

Symptom

Abnormal sensations experienced during bladder filling.

Bladder outlet obstruction (BOO - male)*Diagnosis*

A diagnosis based on urodynamic investigations (pressure-flow studies +/- imaging +/- EMG), generally (but not always) with relevant symptoms and signs, manifest by an abnormally slow urine flow rate, with evidence of abnormally high detrusor voiding pressures and abnormally slow urine flow during pressure-flow studies, with or without a high PVR.

BOO can be functional (bladder neck obstruction, detrusor sphincter dysfunctions or pelvic floor overactivity) or mechanical (prostatic enlargement, sphincter sclerosis, urethral stricture, meatal stenosis).

Bladder outlet obstruction (BOO) - pressure flow studies (male +/- VCU, EMG)*Investigation*

This is the generic term for obstruction during voiding. It is a reduced urine flow rate with a simultaneously increased detrusor pressure. PVR may be present.

Bladder outlet obstruction (female)*Investigation*

This is the generic term for obstruction during voiding. It is a reduced urine flow rate and/or presence of a raised PVR and an increased detrusor pressure. It is usually diagnosed by studying the synchronous values of urine flow rate and detrusor pressure and any PVR measurements. A urethral stricture or obstruction due to higher degrees of uterovaginal prolapse or obstructed voiding after stress incontinence procedures are amongst possible causes.

Bladder oversensitivity - filling cystometry*Investigation*

Increased sensation during bladder filling with: early first desire to void; early strong desire to void, which occurs at low bladder volume; lower cystometric bladder capacity; no abnormal increases in detrusor pressure.

Bladder Oversensitivity (BO)*Diagnosis*

Increased perceived bladder sensation during bladder filling with specific cystometric findings of early first desire to void; early strong desire to void, which occurs at low bladder volume; low maximum cystometric bladder capacity; no abnormal increases in detrusor pressure.

Bladder pain*Symptom*

Complaint of suprapubic or retropubic pain, pressure or discomfort related to the bladder, and usually associated with bladder filling. It may persist or be relieved after voiding.

Bladder Pain Syndrome (BPS - Chronic)*Symptom*

Persistent or recurrent chronic pelvic pain, pressure or discomfort perceived to be related to the urinary bladder accompanied by at least one other urinary symptom such as an urgent need to void or urinary frequency.

Bladder wall thickness (BWT) - ultrasound imaging (male)*Investigation*

Distance from the outer border of the mucosa to the outer border of the adventitia on the anterior bladder wall with a linear 7,5MHz linear array in a bladder filled to over 250ml.

Bowel diary*Sign*

It is a recording of bowel actions. Bowel diaries have been widely used in diagnostic and intervention studies. Patient recall is less accurate than a diary. Patients tend to underestimate symptom frequency, in one study by over 50 %. However, there are few published examples and no consensus on what should be included. Elements that might be included: (i) urgency; (ii) fecal incontinence (amount, consistency); (iii) flatus incontinence; (iv) passive staining/soiling (tends not be discrete episodes); (v) pads (changes, degree of soiling); (vi) straining/difficulty/time in the toilet; (vii) unsuccessful attempts to defecate; (viii) assistive measures (e.g. digital stimulation, manual evacuation, irrigation); (ix) laxative or rectal evacuant use; (x) diet and fluids (type and/or timing). Patients often need careful and detailed instructions on how to complete a diary, and still many are poorly completed. An incomplete diary is difficult to interpret and is liable to misinterpretation as a low bowel/event frequency.

Bulbospongiosus reflex (BSR)*Sign*

A reflex contraction of the striated muscle of the pelvic floor (anal sphincter) and the bulbo-spongiosus muscle that occurs in response to various stimuli in the perineum or genitalia.

Burch colposuspension - open, laparoscopic, robotic*Surgery – Female*

Elevation or attachment of the upper paraurethral tissue adjacent to the bladder neck region to the iliopsoic ligament bilaterally. Although a recognized treatment for stress incontinence, this procedure will often correct associated anterior wall prolapse.

C**Catheterization***Conservative Management – General*

This is a technique for bladder emptying employing a catheter to drain the bladder or a urinary reservoir.

Catheterization - aseptic intermittent*Conservative Management – General*

This implies genital antiseptic preparation and the use of sterile (single-use) catheters and instruments/gloves in a designated clean area.

Catheterization - clean intermittent (CIC)*Conservative Management – General*

This is the use of a clean technique. This implies ordinary hand and genitals washing techniques and use of disposable or cleansed reusable catheters.

Catheterization - indwelling*Conservative Management – General*

An indwelling catheter remains in the bladder, urinary reservoir or urinary conduit for a period longer than one emptying.

Catheterization - intermittent (IC)*Conservative Management – General*

Drainage of the bladder or a urinary reservoir with subsequent removal of the catheter mostly at regular intervals

Catheterization - no-touch technique intermittent

Conservative Management – General

This was introduced as an easier way for the patient to perform self-intermittent catheterization with a ready-to-use catheter (pre-lubricated catheter, usually a hydrophilic catheter). A pull-in aid or special packages are used to handle the catheter without directly touching the sliding surface of the hydrophilic catheter.

Catheterization - sterile intermittent

Conservative Management – General

Complete sterile setting, including genital skin antisepsis, sterile gloves, forceps, gown and mask.

Central sensitization*Symptom*

Nociceptor sensitization results in synaptic strengthening by incoming afferent volleys (sensitization) and is expressed as hyperalgesia (a form of non-associative learning characterized by an increase in responsiveness upon repeated exposure to a stimulus)

Centrally generated pain/ Deafferentiation pain*Symptom*

Pain which may result from injury to either the peripheral or central nervous system, leading to burning pain below the level of the lesion. It can be sympathetic-nervous system maintained pain, which may result in chronic regional pain syndrome (CRPS). There is increased responsiveness of nociceptive neurons in the central nervous system to normal or sub-threshold afferent input.

Chronic Bladder Pain Syndrome - Cystoscopic evaluation*Investigation*

Cystoscopic findings by hydrodistension are important in subclassification of Bladder Pain Syndrome (BPS) / Interstitial Cystitis (IC).

i. Glomerulation during cystoscopy with hydrodistension, glomerulations, with or without waterfall lesions (blood trickling downwards), may often be observed ii. Hunner Lesion.

A Hunner lesion is not an ulcer, but an inflammatory infiltrate. Morphologic findings in Hunner Lesion

1. Inflammatory infiltrate on examination of biopsy taken with electro-resection or by cold cup biopsy. 2. Lymphocyte-like cells dominate in the infiltrate, but neutrophilic and eosinophilic granulocytes as well as plasma cells and mast cells are also found. 3. Perineural and perivascular arrangement of lymphocyte-like cell infiltrates. Granulation tissue.

Chronic Intra-abdominal Female Genital Pain Syndrome - Evaluation*Investigation*

1. Questionnaires

i. Visual Analog Scale for pain.

2. Laboratory Testing

i. Culture. ii. Complete blood count.

3. Laparoscopy (with or without biopsy) 4. Ultrasound (US) 5. MRI 6. Venography (to rule out Pelvic Congestive Syndrome)

Chronic Musculoskeletal Pain Syndromes - Evaluation*Investigation*

1. Questionnaires i. McGill Pain Questionnaire. ii. Pelvic Floor Distress Inventory (PFDI). iii. Female Sexual Function Index (FSFI). iv. Female Sexual Distress Scale (FSDS). 2. Pain Location Drawing (Pain Mapping) i. Pain Chart body map. 3. Evaluation of Muscle Tension There is no single tool which is able to measure all components of muscle tone. Some tools may be able to measure aspects of tone such as contractility, stiffness or elasticity. Instrumented methods may have a role in the valid and reliable evaluation

of muscle tone, for example, surface electromyography, dynamometry, real-time ultrasound, elastometry, myo-tonometry. i. Pressure manometry is the measurement of resting pressure or pressure rise generated during contraction of the pelvic floor muscles using a pressure device (a manometer) inserted into the urethra, vagina or anus. ii. Surface electromyography (sEMG) refers to the bioelectrical activity generated by muscle fibres. iii. Dynamometry is the measurement of pelvic floor muscle resting and contractile forces using strain gauges mounted on a speculum (a dynamometer), which is inserted into the vagina. iv. Real-time ultrasound measures pelvic floor muscle morphology and function via a non-invasive (trans-abdominal or trans-perineal) probe. v. Elastometry measures the elasticity of a tissue. 4. Trigger point injection or needling has been used as a diagnostic test to identify pain generators. 5. *Imaging*
i. X-Ray. ii. Ultrasound. iii. MRI.

Chronic Neuropathic Pain Syndromes - Evaluation*Investigation*

A. Neuropathic Pain Questionnaires 1. VAS Pain Score. 2. Pain DETECT (Validated for CPPS evaluation). 3. Leeds Assessment for neuropathic symptoms and signs (not validated for chronic pelvic pain). 4. Douleur Neuropathique 4 Questionnaire. B. Quantitative Sensory Testing

1. 1Q-tip touch sensitivity. 2. Sensory pain mapping. 3. Reflex evaluation. 4. Electromyography.

C. Nerve Blocks 1. May/may not be done under Computed Tomography, Ultrasound or EMG guidance.

D. Imaging

1. Ultrasound 2. Magnetic resonance Imaging (MRI)

Chronic Pain*Symptom*

Persistent or continuous/recurrent pain for at least 6 months. If non-acute and central sensitization pain mechanisms are well documented, then the pain may be regarded as chronic, irrespective of the time period.

Chronic Pain and Fatigue Syndromes*Diagnosis*

Chronic pain and fatigue syndromes are characterized by pain, often widespread; fatigue; sleep disturbances; and disability. The symptoms are usually medically unexplained, have no known pathophysiology or organic basis and show no abnormal laboratory or imaging investigations. The literature suggests that many of these conditions share demographic characteristics, clinical course and psychosocial profiles. Examples are:

1. Fibromyalgia: symptoms are widespread musculoskeletal pain, fatigue, non-restorative sleep, psychological distress, and regions of localized tenderness. 2. Temporomandibular Joint Disorders: symptoms consist of complaints of facial, jaw, neck, or shoulder pain. The pain is experienced in or around the ear with chewing, speaking, or opening the mouth, with or without migraine. 3. Chronic Fatigue Syndrome: is defined as clinically evaluated, unexplained, persistent or relapsing fatigue plus four or more specifically defined associated symptoms (self-reported impairment in short term memory or concentration; sore throat; tender cervical or axillary nodes; muscle pain; pain in multiple joints without redness or swelling; headaches of a new pattern or severity; unrefreshing sleep).

Chronic Pelvic Floor Muscle Pain Syndrome*Investigation*

1. Questionnaires. i. Visual Analog Scale for pain. ii. Pelvic Floor Distress Inventory (PFDI). iii. Prolapse and Incontinence Sexual Questionnaire (PISQ). 111

2. Laboratory Testing

i. Wet Mount, Culture. ii. Biopsy.

3. Imaging References

- i. Ultrasound (4D if available for visualization of mesh, where applicable). ii. MRI (with or without defecography). iii. Defecography.

Chronic Pelvic Joint, Ligament or Bone Pain Syndrome

Diagnosis

1. Joint pain:
 - i. Sacroiliac or pubic symphysis joint.
2. Ligament pain:
 - i. Sacro-spinous or Sacro-tuberous ligament.
3. Bony pain:
 - i. Pain described in or along the margins of the pubic ramus, ilium, ischial spine or ischial tuberosity.

Chronic Pelvic Pain

Diagnosis

Chronic pelvic pain is characterized by persistent pain lasting longer than 6 months or recurrent episodes of abdominal/pelvic pain, hypersensitivity or discomfort often associated with elimination changes, and sexual dysfunction often in the absence of organic etiology.

Chronic Pelvic Pain - Characteristics

Symptom

a: Duration of pain: Six months or more of persistent pain. b. Location of pain: Pelvis, lower abdomen, low back, medial aspect of thigh, inguinal area, perineum. c. Perception of pain: Patients may describe the pain as sharp, burning, aching, shooting, stabbing, pressure or discomfort, sexual pain (dyspareunia). d. Modality of pain: Persistent and/or continuous, recurrent and/or episodic and/or cyclic (related to menstrual cycle).

Chronic (persistent or recurrent) Anorectal Pain Syndrome

Diagnosis

1. Chronic Proctalgia—rectal pain, more than 20min of duration per episode, for at least 3 months with symptom onset at least 6 months prior to diagnosis.
 - i. Persistent or recurrent rectal pain. ii. Rectal pressure or aching episodes. iii. In the absence of other causes of rectal pain.
2. Levator Ani Syndrome(the term may refer to the same syndrome as “pelvic floor muscle pain syndrome”/ “tension myalgia of the PFM”).
 - i. Pain with sitting. ii. Pain with defecation.
3. Proctalgia Fugax
 - i. Severe recurrent episodic pain localized in the anus or lower rectum. ii. Duration seconds to minutes. iii. No pain between episodes.

Chronic (persistent or recurrent) Epididymal Pain Syndrome

Diagnosis

Pain is specific/localized to the epididymis.

- i. Persistent or recurrent episodic pain. ii. Spontaneous, or reproduced by digital pressure and physical activities. iii. Lower urinary tract symptoms or sexual dysfunction.

Chronic (persistent or recurrent) Pelvic Muscle Pain Syndrome

Diagnosis

1. Pelvic Floor Muscle Pain (Pelvic Floor Myalgia):
 - i. Pain in the muscles of the pelvic floor (perineal or levator ani).
2. Intra-pelvic Muscle Pain:
 - i. Pain in the pelvic side wall muscles (obturator internus, piriformis, coccygeus).
3. Anterior Pelvic/Lower Abdominal Muscle Pain:
 - i. Pain in the rectus abdominus, oblique or transverse abdominus muscles, described below the umbilicus.
4. Posterior Pelvic/Buttock Muscle Pain:
 - i. Pain in the gluteal muscles.

Chronic (persistent or recurrent) penile pain syndrome

Diagnosis

Pain within the penis that is not primarily in the urethra and may be:

- i. Persistent or recurrent. ii. Spontaneous, or reproduced by digital pressure and physical activities. iii. Lower urinary tract symptoms or sexual dysfunction.

Chronic (persistent or recurrent) Prostate Pain Syndrome

Diagnosis

Persistent or recurrent prostate pain, associated with symptoms suggestive of urinary tract and/or sexual dysfunction. No proven infection or other obvious pathology is present to account for the symptoms. Bladder, perineal, testicular, penile and/or groin pain.

- i. Perception of pain: variable. ii. Persistent or recurrent. iii. Dyspareunia or erectile dysfunction. iv. Voiding and post micturition symptoms (for example: hesitancy, intermittency, feeling of incomplete emptying).

Chronic (persistent or recurrent) Scrotal Pain Syndrome

Diagnosis

Chronic scrotal pain (generic term used when site of pain is not clearly in the testis or epididymis).

- i. Persistent or recurrent episodic pain, unilateral or bilateral. ii. Spontaneous, or reproduced by digital pressure and physical activities. iii. Pain is not in the skin of the scrotum but perceived within its contents. iv. Lower urinary tract symptoms or sexual dysfunction.

Chronic (persistent or recurrent) testicular pain syndrome

Diagnosis

i. Persistent or recurrent episodic pain. ii. Spontaneous, or reproduced by digital pressure and physical activities. iii. Lower urinary tract symptoms or sexual dysfunction.

Chronic Prostatic Pain Syndrome - Evaluation

Investigation

1. Quantitative assessments. i. Bladder diary. ii. CPSI (Chronic Prostatitis Symptom Index). iii. Visual Analog Scale for Pain (VAS).
2. Laboratory Testing
 - i. Urinalysis (including post prostate massage). ii. Urine Culture post prostate massage. iii. Semen Culture.
3. Uroflowmetry, Post voiding residual volume, pressure flow study 4. Cystoscopy 5. Ultrasonography, with or without biopsy

Chronic retention of urine (female)

Diagnosis

This is defined as a nonpainful bladder, where there is a chronic high PVR.

Chronic Scrotal, Epididymal, Testicular and Penile Pain Syndrome - Evaluation

Investigation

1. Quantitative assessments i. VAS for Pain. 2. Ultrasonography

Chronic Sexual Pain Disorder

Diagnosis

Dyspareunia

i. Female sexual pain: Burning, ripping, tearing, or aching sensation associated with penetration. The pain can be at the vaginal opening, deep in the pelvis, or anywhere between. It may also be felt throughout the entire pelvic area and the sexual organs and may occur only with deep thrusting. ii. Male sexual pain: Sexual activity may induce a central sensitization process characterized by hypersensitivity or hyperalgesia. History should include duration of symptoms, identification of disorder, impact on quality of life, and partner relationship. Partner interviews may be very helpful as erectile

dysfunction, delayed or premature ejaculation in males with hypoactive sexual desire disorder result in a 4–30 times increased risk of female partner desire, arousal or orgasmic disorder.

Chronic Sexual Pain Syndrome

Diagnosis

i. Penile

1. Prior to penetration (example: pain with erection). 2. With penetration. 3. Post coital.

ii. Perineal

1. During intercourse. 2. After intercourse.

iii. Orgasmic Pain (during ejaculation)

1. Penile. 2. Anorectal. 3. Pelvic.

Chronic Urethral Pain Syndrome - Evaluation

Investigation

1. Quantitative assessments

i. Bladder diary. ii. VAS for Pain.

2. Laboratory Testing

i. Urinalysis (including post prostate massage, Ureaplasma/Chlamydia as appropriate).

3. Urethroscopy/Urethrography 4. Ultrasonography

Chronic urinary retention

Symptom

Complaint of chronic or repeated inability to empty the bladder, despite the ability to pass some urine. This may result in the frequent passage of small amounts of urine or urinary incontinence and a distended bladder.

Chronic (urinary) retention

Diagnosis

This defined as a generally (but not always) painless and palpable or percussible bladder, where there is a chronic high PVR where the patient experiences slow flow and incomplete bladder emptying. Overflow incontinence can occur. Some individuals with retention present with impaired renal function and/or hydronephrosis.

Chronic Vulvar, Vestibular and Clitoral Pain Syndromes - Evaluation

Investigation

1. Questionnaires i. Visual Analog Scale for pain. ii. Female Sexual Function Index (FSFI). iii. Female Sexual Distress Scale (FSDS).

2. Laboratory Testing

i. Culture. ii. Biopsy.

3. Diagnostic Testing

i. Vulvoscopy, with or without biopsy. ii. Quantitative Sensory Testing (Q-tip touch sensitivity test).

Chyluria (albiduria)

Symptom

Complaint of the passage of chyle (pale or white, milky cloudy) urine.

Classification

Surgery – Complication related

A systematic arrangement into classes or groups based on perceived common characteristics.

Clean intermittent catheterization (CIC)

Conservative Management – General

This is the use of a clean technique. This implies ordinary hand and genital washing techniques and use of disposable or cleansed reusable catheters.

Climacturia

Symptom

Complaint of involuntary loss of urine at the time of orgasm.

Closing pressure

Investigation

Pressure recorded at the end of measured flow.

Closure of the Enterocele Sac - Open, Laparoscopic, Robotic

Surgery – Female

(a) Moschowitz procedure - Concentric purse-string suture(s) are placed around the cul-de-sac to include the posterior vaginal wall, pelvic side-walls and serosa of the sigmoid. (b) Halban procedure- Obliteration of the cul-de-sac by using successive sutures placed sagittally between the uterosacral ligaments. (c) Uterosacral ligament plication – transverse plication of the uterosacral ligaments to obliterate the cul-de-sac. Successive sutures are placed into the medial portion of one ligament, into the back wall of the vagina and into the medial border of the opposing ligament. Variations in technique for all abdominal mesh/graft procedures

Coccygeal pain (coccydynia)

Symptom

Complaint of pain, pressure or discomfort felt in the coccygeal region

Coccyx Pain Syndrome

Diagnosis

Complaint of chronic or recurrent pain in the coccyx or sacro-coccygeal joint.

Coital fecal (flatal) incontinence (female)

Symptom

Fecal (flatal) incontinence occurring with vaginal intercourse.

Coital fecal incontinence

Symptom

Complaint of involuntary loss of stool occurring with intercourse.

Coital fecal urgency (female)

Symptom

Feeling of impending bowel action during vaginal intercourse.

Coital urinary incontinence

Symptom

Urinary incontinence occurring during or after vaginal intercourse.

Coital urinary incontinence (female)

Symptom

Complaint of involuntary urine loss during or after coitus. This symptom might be further divided into that occurring with penetration and that occurring at orgasm.

Coital urinary urgency (female)

Symptom

Feeling of urgency to void during vaginal intercourse.

Colonoscopy

Investigation

Colonoscopy examines the entire colon following a full oral preparation to clear the bowel to allow this.

Colonoscopy

Investigation

The entire colon is examined following a full oral preparation to clear the bowel to allow this.

Colpocleisis

Surgery – Female

Operation for obliterating the lumen of the vagina.

Colporecto-cystourethrography (colpo-cystodefecography)

Imaging

This involves the instillation of radio-opaque media into bladder, vagina, and rectum simultaneously for pelvic floor evaluation with images obtained during rest and straining

Colporecto-cystourethrography: (Colpo-cystodefecography)

Imaging

This involves the instillation of radio-opaque media into bladder, vagina and rectum simultaneously for pelvic floor evaluation with images obtained during rest and straining.

Combination therapy (also known as polytherapy, multimodal therapy or combined modality therapy)

Conservative Management – Female

Combination therapy is the use of more than one intervention concurrently to treat a single condition with one or multiple symptoms, for example, a combination of medication with PFM training (PFMT).

1. Adjunctive therapies: any treatment or modality used to augment or assist the main treatment. In conservative treatments, adjunctive therapies often refer to equipment or a secondary therapy used to supplement the effect of the primary therapy, e.g., biofeedback-assisted PFMT or neuromuscular electrical stimulation to augment PFMT.

Complaint

Symptom

The description of the symptom.

Complex Regional Pain Syndrome (CRPS)

Diagnosis

Sympathetic, centrally generated pain. 1. CRPS 1- Triggered by tissue injury with no underlying nerve injury. 2. CRPS 2- Associated with nerve injury.

i. Burning pain. ii. Increased skin sensitivity. iii. Changes in skin temperature, color, and/or texture.

Compliance - bladder (female)

Investigation

This describes the relationship between a change in bladder volume and change in detrusor pressure. Compliance is calculated by dividing the volume change (Change V) by the change in detrusor pressure (Change Pdet) during that change in bladder volume (Compliance = Change V/Change Pdet). Compliance is expressed as ml per cm H2O.

Complication

Surgery – Complication related

A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery.

Compromise

Surgery – Complication related

Bring into danger.

Computerized tomography (CT) - male

Imaging

(1) CT Urogram (CT-U): CT study of the urinary tract system using injected

contrast, used to clarify diagnoses such as (i) tumors; (ii) renal disease; (iii) abnormal fluid collections/abscesses (iv) bladder pathology.

(2) CT Kidneys, ureter, bladder (CT- KUB): Non-contrast study aimed primarily at identifying stones but may identify other pathology. Aka "stone protocol".

Computerized tomography (CT) of the pelvic floor

Imaging

Computed tomography (CT) is not routinely recommended for imaging the pelvic floor mainly due to irradiation and poor soft tissue contrast. However multiplanar spiral CT may offer an accurate visualization of the pelvic floor soft and bony structures by reconstruction of axial images using 1 mm thick slices without gaps thus increasing the diagnostic accuracy of pelvic floor anatomical disorders (ie. LAM trauma).

Conditions for cystometry - female

Investigation

(i) Pressures: All systems are zeroed at atmospheric pressure; (ii) External pressure transducers: Reference point is the superior edge of the pubic symphysis; (iii) Catheter mounted transducers: Reference point is the transducer itself; (iv) Initial bladder volume: Bladder should be empty;(v) Fluid medium: Usually water or saline (or contrast if radiology involved); (vi) Temperature of fluid: Should ideally be warmed to body temperature; (vii) Position of patient: Sitting position is more provocative for abnormal detrusor activity than the supine position. At some point in the test, filling might desirably take place with the patient standing; (viii) Filling rate: The filling rate, including any changes during testing, should be noted on the urodynamic report.

Constipation (General)

Symptom

Complaint that bowels motions are infrequent and/or incomplete and/or there is a need for frequent straining or manual assistance to defecate (Rome IV criteria)

Constipation (obstructed defecation)

Symptom

Complaint of difficulty in evacuation due to a mechanical obstruction.

Constipation (slow transit)

Symptom

Infrequent bowel motions due to a delay in transit of bowel contents to reach rectum.

Continuous urinary incontinence

Symptom

Complaint of continuous involuntary loss of urine

Contraction

Surgery – Complication related

Shrinkage or reduction in size.

Contraction pressure at maximum flow

Investigation

This is the difference between pressure at maximum flow and the pre-micturition pressure.

Cough-Associated Detrusor Overactivity

Investigation

Cough associated DO is reported when the onset of the DO (with or without leakage) occurs immediately following the cough pressure peak. No precise definition of cough associated detrusor activity is available. 'Cough induced DO' is sometimes reported, although the precise (patho-)physiology remains speculative and only the association in time can be observed. The ICS

WG presents a descriptive definition and does not discuss the consequences for management.

Counseling in Pelvic Floor Dysfunction

Conservative Management – Female

Counseling is the provision of professional assistance and guidance in resolving personal or psychological problems and may be part of any clinician's management.

1. Patient education: providing patients with knowledge and understanding of their condition, thereby empowering them to play an active role in its management. 2. Motivational interviewing: a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence. Compared with nondirective counseling, it is more focused and goal-directed. The examination and resolution of ambivalence is its central purpose, and the counselor/clinician is intentionally directive in pursuing this goal. 3. Coping strategies: intervention aimed at helping patients to live with the condition in the best way possible under the circumstances, to regain a feeling of being in control, to adjust their lifestyle where necessary, and to take a positive rather than a negative approach. 4. Self-care: the set of activities that comprise daily living, such as bed mobility, transfers, ambulation, dressing, grooming, bathing, eating, and toileting. 5. Self-help: various methods by which individuals attempt to remedy their difficulties without making use of formal care providers. 6. Self-efficacy: an individual's belief that he or she is capable of successfully performing a certain set of behaviors.

Cremasteric reflex

Sign

Contraction of the ipsilateral cremaster muscle, drawing the testis upwards, when the upper inner aspect of the thigh is stroked longitudinally.

CTS Complication code

Surgery – Complication related

The category (C), time (T) and site (S) classes and divisions have a sensitivity that should encompass all conceivable scenarios for describing insertion complications and healing abnormalities. The CTS code for each complication, involving three (or four) letters and three numerals is likely to be very suitable for any surgical audit or registry, particularly one that is procedure-specific.

Cyclical (menstrual) pelvic pain

Symptom

Cyclical pelvic pain related to menses that raises the possibility of a gynecological cause.

Cystic dilatations of epididymal tubules

Sign

Cystic dilatations of epididymal tubules (epididymal cysts or spermatocele) and hydroceles (fluid collections between the visceral tunica albuginea and parietal layer of the testicular peritoneum)- usually benign. The examination of these structures would be generally non-tender and without pain.

Cystometric capacity - filling cystometry

Investigation

Bladder volume at the end of filling cystometry, when a "permission to void" is usually given by the urodynamicist.

Cystometric capacity - filling cystometry (mL)

Investigation

Bladder volume at the end of filling cystometry, when a "permission to void" is usually given by the urodynamicist.

Cystometrogram

Investigation

Graphical recording of the bladder pressure(s) and volume(s) over time.

Cystometry

Investigation

Measurement of the pressure-volume relationship of the bladder during filling.

Cystometry - Aftercontraction

Investigation

An after-contraction, is a continued or new detrusor pressure rise immediately after flow ended. It is important to note if this occurs with the complete emptying of the bladder.

Cystometry - Catheter flush

Investigation

When one of the catheters is flushed during the test a steep pressure rise is observed in that pressure line for one or two seconds followed by an immediate fall to resting pressure.

Cystometry - conditions (female)

Investigation

(i) Pressures: All systems are zeroed at atmospheric pressure; (ii) External pressure transducers: Reference point is the superior edge of the pubic symphysis; (iii) Catheter mounted transducers: Reference point is the transducer itself; (iv) Initial bladder volume: Bladder should be empty; (v) Fluid medium: Usually water or saline (or contrast if radiology involved); (vi) Temperature of fluid: Should ideally be warmed to body temperature; (vii) Position of patient: Sitting position is more provocative for abnormal detrusor activity than the supine position. At some point in the test, filling might desirably take place with the patient standing; (viii) Filling rate: The filling rate, including any changes during testing, should be noted on the urodynamic report.

Cystometry - Cough Pressure Peak

Investigation

A cough pressure peak is recognizable during post-test evaluation as a phasic positive pressure change observed in pves and in pabd.

Cystometry - Dead Signal

Investigation

A signal that is not showing small pressure fluctuations and is not adequately responding on straining, patient movements or coughing is reported as a dead signal.

Cystometry - Expelled Catheter

Investigation

When a catheter is expelled, this is observed as a sudden drop in either pves or pabd, usually below zero.

Cystometry - Poor Pressure Transmission

Investigation

Poor pressure transmission has occurred when the cough/effort pressure peak signals on pves and pabd are not nearly equal.

Cystometry - Position Change

Investigation

A change in patient position, either active or passive (e.g. tilting), is visible on the cystometry trace by a lasting change of equal magnitude in both pves and pabd. Note: A position change should be (is readily) noted during the test and followed by readjustment of the external pressure sensors height to the standard so that the physiological pves and pabd are observed

again. A position change should not affect pdet. The position change pattern should be recognized during post-test evaluation of the cystometry.

Cystometry - Pressure Drift

Investigation

Continuous slow fall or rise in (one of either) pressure, that is physiologically inexplicable.

Cystometry - Pump Vibrations

Investigation

Pump vibrations are visible as stable frequency oscillations of small but constant amplitude if the filling tube touches the pressure connecting tube (when a two catheter system is used) and the pump is switched on (switching of the pump can ascertain the situation).

Note: ICS standard is double lumen catheter, and despite the channels being side by side, with the usual filling rate and measuring scale, oscillations are not typically observable.

Cystometry - Rectal Contractions

Investigation

Rectal Contractions are temporary phasic increases in pabd without synchronous change in pves resulting in negative deflections of pdet.

Cystometry - Straining

Investigation

Straining is observable as a temporary increase in both pves and pabd pressure. Straining may be associated with (patient -active) position change (such as repositioning from leaning backwards to upright).

Cystometry - Tube Knock

Investigation

Tube Knock is observable as high frequency, short duration spikes visible in pves, pabd, or both, and with spikes also usually visible in pdet .

Cystometry - Urodynamic Stress Test

Investigation

The urodynamic stress test is used for any physical effort of the person tested, to elevate abdominal pressure, during cystometry with the aim of testing for (urodynamic) stress urinary incontinence.

ICS has defined urodynamic stress incontinence. Evidence is lacking (or conflicting) with regard to the preferred technique of stress testing. Note: The provocation method, the pressure measuring catheter(size) and method, the leak detection method as well as the absolute or relative (percentage of cystometric capacity) intravesical volume(s) while testing may be reported.

Cystometry Position

Investigation

ICS standard cystometry is done in the vertical position (standing or normally seated) whenever physically possible. A pressure-flow study is done comfortably seated (women, some men) or standing if that is preferred position (men).

D

Daytime

Sign

The period between waking up with the intention of rising until going to bed with the intention of sleeping (awake hours - ideally recorded on chart or diary)

Daytime (urinary) frequency

Sign

Number of micturitions during daytime (awake hours, including first void after waking up from sleep and last void before sleep).

De novo (postoperative) dyspareunia

Symptom

Dyspareunia first reported after surgery or other interventions

De novo (postoperative) sexual dysfunction symptoms

Symptom

New onset sexual dysfunction symptoms (not previously reported before surgery)

Decreased arousal (female)

Symptom

Persistent or recurrent inability to achieve or maintain sexual excitement. This may be expressed as lack of excitement, lack of lubrication, lack of vaginal and clitoral engorgement, or lack of expression of other somatic responses.

Decreased libido (male)

Symptom

Complaint of a decreased interest in sexual activity in comparison with previous experience

Decreased libido or sexual desire (female)

Symptom

Absent or diminished feelings of sexual interest or desire, absent sexual thoughts or fantasies, and a lack of responsive desire. Motivations (here defined as reasons/incentives) for attempting to become sexually aroused are scarce or absent. The lack of interest is considered to be beyond the normative lessening with lifecycle and relationship duration.

Decreased libido or sexual desire (female)

Symptom

Absent or diminished feelings of sexual interest or desire, absent sexual thoughts or fantasies, and a lack of responsive desire. Motivations (here defined as reasons/incentives) for attempting to become sexually aroused are scarce or absent. The lack of interest is considered to be beyond the normative lessening with lifecycle and relationship duration.

Decreased (low) semen volume

Symptom

Complaint of smaller amount of seminal fluid than normal or previously experienced.

Deep dyspareunia

Symptom

Complaint of pain or discomfort on deeper penetration (mid or upper vagina)

Defecatory dysfunction (female)*Diagnosis*

A diagnosis by clinical history and examination, assisted, at times, by the results of diagnostic tests involving the confirmation of abnormal or difficult function in the initiation, passage or completion of defecation.

Defecatory/Post-defecatory symptoms*Symptom*

Symptoms experienced during or following the act of defecation.

Defecography (female)*Imaging*

This demonstrates normal anatomy of the anorectum as well as disorders of rectal evacuation. Barium paste is inserted rectally prior to defecation over a translucent commode. Measurement of the anorectal angle is allowed with evidence of the presence, size or emptying of any rectocele. Enteroceles, rectal intussusception and mucosal prolapse might be diagnosed as well as a spastic pelvic floor (anismus).

Defecography (male)*Imaging*

This demonstrates the anatomy of the anorectum as well as disorders of rectal evacuation. Barium paste is inserted rectally prior to defecation over a translucent commode.

Deficient perineum / cloacal-like defect*Sign*

A spectrum of tissue loss from the perineal body and rectovaginal septum with variable appearance. There can be a common cavity made up of the anterior vagina and posterior rectal walls or just an extremely thin septum between the anorectum and vagina.

Dehiscence*Surgery – Complication related*

A bursting open, splitting or gaping along natural or sutured lines.

Delayed ejaculation*Symptom*

Complaint of an increase in the time taken for ejaculation to occur.

Detrusor acontractility (male)*Diagnosis*

A diagnosis by urodynamic investigation, generally (but not always) with relevant signs and symptoms, manifest by the absence of an observed detrusor contraction during pressure-flow studies resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span. Voiding is usually achieved by straining or manual pressure on the bladder resulting generally in an abnormally slow urine flow rate and/or an abnormally high postvoid residual.

Subtypes:

- (I) Neurogenic
- (II) Non-neurogenic

Detrusor leak point pressure (DLPP - cm H2O)*Investigation*

This is a static test. The pressure is the lowest value of the detrusor pressure at which leakage is observed in the absence of either a detrusor contraction or increased abdominal pressure.

Detrusor Leak Point Pressure (female) - DLPP - cm H2O*Investigation*

This is a static test. The pressure is the lowest value of the detrusor pressure at

which leakage is observed in the absence of increased abdominal pressure or a detrusor contraction. High detrusor LPP (e.g., over 40 cm H2O) may put patients at risk for upper urinary tract deterioration, or secondary damage to the bladder in the cases of known underlying neurological disorders such as paraplegia or MS. There are no data on any correlation between detrusor LPP and upper tract damage in nonneurogenic patients.

Detrusor leak point volume (DLPV)*Investigation*

The bladder volume at which urine leakage first occurs, either with detrusor overactivity or low compliance.

Detrusor opening pressure (cm H2O) - pressure flow studies*Investigation*

Detrusor pressure recorded immediately before the initial isovolumetric contraction.

Detrusor overactivity - filling cystometry*Investigation*

The occurrence of detrusor contraction(s) during filling cystometry. These contractions, which may be spontaneous or provoked, produce a waveform on the cystogram, of variable duration and amplitude. Symptoms, e.g. urgency and/or urgency incontinence or perception of contraction may or may not occur.

Detrusor overactivity - Subtypes*Diagnosis*

- (i) Idiopathic (primary) detrusor overactivity: No identifiable cause for the involuntary detrusor contraction(s).
- (ii) Neurogenic (secondary) detrusor overactivity: There is detrusor overactivity and evidence (history; visible or measurable deficit) of a relevant neurological disorder.
- (iii) Non-neurogenic (secondary) detrusor overactivity: An identifiable possible non-neurological cause exists for involuntary detrusor contraction(s) during bladder filling. e.g. functional (obstruction); stone, tumor (e.g. carcinoma in situ), UTI.

Detrusor Overactivity (DO)*Diagnosis*

In men and women with LUT/PF symptoms when detrusor muscle contractions occur during filling cystometry.

Detrusor overactivity (DO) - filling cystometry*Investigation*

The occurrence of detrusor contraction(s) during filling cystometry. These contractions, which may be spontaneous or provoked, produce a wave form on the cystometrogram, of variable duration and amplitude. The contractions may be phasic or terminal. They may be suppressed by the patient, or uncontrollable. Symptoms, e.g. urgency and/or urgency incontinence or perception of the contraction may (note if present) or may not occur.

Detrusor Overactivity (female)*Diagnosis*

This diagnosis by symptoms and urodynamic investigations is made in women with lower urinary tract symptoms (more commonly OAB-type symptoms)—when involuntary detrusor muscle contractions occur during filling cystometry

Detrusor overactivity leak point pressure (DOLPP)*Investigation*

Lowest detrusor pressure rise with detrusor overactivity at which urine

leakage first occurs in the absence of a voluntary detrusor contraction or increased abdominal pressure.

Detrusor pressure at end of flow (Pdet-ef – unit: cm H₂O) - pressure flow studies

Investigation

Detrusor pressure recorded at the end of urine flow.

Detrusor pressure at maximum flow (Pdet-Qmax – unit: cm H₂O)

Investigation

Detrusor pressure recorded at maximum urinary flow rate.

Detrusor pressure (Pdet - cm H₂O)

Investigation

The component of intravesical pressure that is created by forces in the bladder wall (passive and active). It is calculated by subtracting abdominal pressure from intravesical pressure (Pdet = Pves - Pabd).

Detrusor sphincter dyssynergia (DSD) - female

Investigation

This is incoordination between detrusor and sphincter during voiding due to a neurological abnormality (i.e. detrusor contraction synchronous with contraction of the urethral and/or periurethral striated muscle). This is a feature of neurological voiding disorders. Neurological features should be sought. Videocystourethrography (VCU) is generally valuable to conclude this diagnosis.

Detrusor sphincter dyssynergia (DSD) - pressure flow studies (male +/- VCU, EMG)

Investigation

Dyscoordination between detrusor and smooth or striated sphincter function during voiding due to a neurological abnormality (i.e. detrusor contraction synchronous with contraction of the urethral and/or periurethral striated muscle). This is a feature of neurological voiding disorders.

Detrusor underactivity (DU)

Diagnosis

A diagnosis based on urodynamic investigations, generally (but not always) with relevant symptoms and signs, manifest by low detrusor pressure or short detrusor contraction in combination with a low urine flow rate resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span (a high postvoid residual may be present).

Detrusor underactivity (DU) - pressure flow studies.

Investigation

Low detrusor pressure or short detrusor contraction time, usually in combination with a low urine flow rate resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span.

Detrusor wall thickness (DWT) or Bladder wall thickness (BWT)

Imaging

Transabdominal visualization of the anterior bladder wall with a (linear) high frequency ultrasound scanner for the detection of BOO if DWT is ≥ 2 mm in bladders filled with ≥ 250 ml (or BWT is ≥ 5 mm in bladders filled with 150 ml).

Diagnosis

Diagnosis

The determination of the nature of a disease; clinical: made from a study

of the symptoms and signs of a disease; laboratory: investigative options/procedures to be mentioned.

Digital rectal examination (DRE - female)

Sign

The gloved finger should be placed in the center of the anus with the finger parallel to the skin of the perineum in the midline. The finger should then be pressed gently into the anal canal but at the same time pressed backwards against the skin of the posterior wall of the anal canal and underlying sling of the puborectalis muscle. This overcomes most of the tone of anal sphincter and allows the finger to straighten and slip into the rectum. This will allow assessment of: (a) Resting anal tone, voluntary squeeze of the anal sphincter as well as the levator muscles, sustained squeeze over 5 sec and involuntary contraction elicited during a cough; (b) Obvious hemorrhoids can be palpated but grade II and grade III. Hemorrhoids are better assessed by proctoscopy. Painful examination may be associated with fistula in ano, fissure in ano, infection or pilonidal abscess; (c) Palpable anal sphincter gap. An assessment can be made of a palpable anal sphincter gap to assess if there has been previous obstetric or surgical damage. The perineal body can be assessed for deficiency; (d) Rectal contents. The contents of the rectum can be assessed. The feces may be hard or soft, the rectum may be empty or collapsed and sometimes ballooned out. This allows assessment of fecal impaction; (e) Confirmation of presence of rectocele, enterocele, or perineocele. Use of POP-Q for staging of prolapse; (f) Bidigital examination may be carried out with the patient supine in a gynecological examining position. By inserting the index finger in the vagina and the middle finger in the rectum, the rectovaginal septum and any intervening small bowel loops can be palpated to differentiate a rectocele from an enterocele, during a Valsalva maneuver; (g) Rectal lesions such as carcinoma, intussusception or recto-vaginal fistula. If a mass is felt on a fingertip, the patient should be asked to strain, and this will often move the mass down to bring it within reach; (h) An assessment can be made of the rectovesico/rectouterine pouch to look for extra rectal masses.

Digital Recto-vaginal examination

Sign

While the patient is straining and the prolapse is maximally developed. The aim is to try to differentiate between a high rectocele and an enterocele.

Digitation (female)

Symptom

Use of fingers in rectum or vagina to manually assist in evacuation of stool contents.

Diminished rectal sensation (rectal hyposensitivity)

Symptom

Complaint of diminished or absent sensation of filling in the rectum.

Direct electrical neurostimulation

Conservative Management – General

This is a direct stimulation of the nerves or neural tissue to effect function of the end organ. It is done through electrodes implanted directly or near the nerve or neural tissue.

Directly

Surgery – Complication related

Without an intermediary or intervening factor.

Disability associated urinary incontinence

Symptom

Complaint of urinary incontinence in the presence of a functional inability

to reach a toilet/urinal in time because of a physical impairment, (e.g. orthopedic, neurological) and/or mental impairment.

Discharge (female)

Sign

Perianal or vaginal bloody or mucus discharge.

Diurnal polyuria

Symptom

Complaint that daytime urine excretion volume is noticeably larger than the previous experience.

Division

Surgery – Complication related

A separation into two or more parts.

Double incontinence

Symptom

Complaint of both anal incontinence and urinary incontinence.

Dysfunction

Diagnosis

Difficult or abnormal function

Dysfunctional voiding - pressure flow studies (male +/- VCU, EMG)

Investigation

This is characterized by an intermittent and/or fluctuating flow due to inadequate or variable relaxation generally of the external sphincter during voiding in neurologically normal men (i.e. no historical, visible or measurable evidence of neurological disease).

Dysfunctional voiding (female)

Investigation

This is characterized by an intermittent and/or fluctuating flow rate due to

involuntary intermittent contractions of the peri-urethral striated or levator muscles during voiding in neurologically normal women. This type of voiding may also be the result of an acontractile detrusor (abdominal voiding) with electromyography (EMG) or video-urodynamics required to distinguish between the two entities.

Dyspareunia

Symptom

Complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration.

Dyspareunia - deep

Symptom

Complaint of pain or discomfort on deeper penetration (mid or upper vagina).

Dyspareunia - superficial (introital)

Symptom

Complaint of pain or discomfort on vaginal entry or at the vaginal introitus.

Dyspareunia with penile vaginal movement

Symptom

Pain that is caused by and is dependent on penile movement.

Dysuria

Symptom

Complaint of pain, burning or other discomfort during voiding. Discomfort may be intrinsic to the lower urinary tract (e.g. bladder or urethra), external or referred from other adjacent similarly innervated structures e.g. lower ureter.

E

Ejaculatory dysfunction

Symptom

Complaint of alteration of the emission of seminal fluids during ejaculation.

Ejaculatory pain

Symptom

Complaint of pain, pressure or discomfort felt in the perineum, suprapubic region and/or penis during ejaculation but may continue for a time afterwards.

Electrical Currents Used in Pelvic Floor Therapies

Conservative Management – Female

a) Faradic current: an alternating and interrupted low frequency current capable of stimulating (depolarizing) nerve fibers through the skin using surface-stimulating electrodes. It is used to stimulate innervated muscles, causing them to contract. b) TENS: an alternating and interrupted low-frequency current capable of stimulating (depolarizing) nerve fibers through the skin using surface-stimulating electrodes for pain modulation or pain relief. c) Interferential current: a medium frequency, amplitude modulated electrical current that results from the interference (hence the word interferential) caused by crossing two or more medium-frequency alternating sine wave currents with different carrier frequencies. The carrier frequency

of these medium, alternating sine wave currents ranges between 2,000 and 5,000 cycles per second.

Electrical neuromodulation

Conservative Management – General

This is the stimulation of the nerves or neural tissue to modulate function and induce therapeutic response of the LUT.

Electrical Therapies - Mode of Application

Conservative Management – Female

1. Surface electrodes: non-invasive placement of electrodes, including intravaginal and intra-anal electrodes, in contrast to electrodes that pierce the skin, i.e., needle stimulation. a) Non-invasive electrical nerve stimulation or transcutaneous electrical nerve stimulation (TENS): the application of electrical energy to stimulate cutaneous nerve and peripheral motor nerves, via suprapubic, perineal or sacral placement of electrodes, or other external sites, or intravaginal or intra-anal plug electrodes. Tibial nerve stimulation (TNS) is a form of peripheral neuromodulation targeting symptom relief of overactive bladder (OAB) and urinary urge incontinence. Indirect access to the sacral plexus is achieved by intermittent, electrical stimulation of the tibial nerve, which lies behind the medial malleolus, using skin surface electrodes applied to the medial malleolar area (transcutaneous TNS). There are two main types of electrical stimulation with surface electrodes: i) Long-term or chronic electrical stimulation: is delivered below the sensory thresh-

old. It is aimed at inhibiting detrusor activity by afferent pudendal nerve stimulation. The device is used 6–12h per day for several months. ii) Maximal neuromuscular electrical stimulation: applies a high-intensity stimulus, set just below the pain threshold. It is aimed at improving urethral closure, via striated muscle recruitment. Detrusor inhibition by afferent pudendal nerve stimulation has also been suggested as a mechanism of effect. Maximal electrical stimulation (35–70Hz) is applied over short period (15 to 30min), is used several times per week (and up to 1–2 times daily), and may be provided via in-clinic application or via portable devices at home).

Electrical Therapy

Conservative Management – Female

Electrical therapy is the use of electric potential or currents to elicit therapeutic responses. Current may be directed at motor or sensory functions. It is not within the scope of this document to define all electrical stimulation terms. Electrical muscle stimulation (also known as neuromuscular electrical stimulation or electromyostimulation). Electrical muscle stimulation (EMS) is the application of electric impulses directly to striated PFM (end-plate) to facilitate contraction. EMS is often referred to as “pelvic floor muscle electrical stimulation” (PFES) or “functional electrical stimulation.” PFES is the application of electrical current to the PFM. All of these stimulations may (indirectly) cause inhibition of the detrusor contraction.

Electromyography

Investigation

Electromyography (EMG) is the recording of electrical potentials generated by the depolarization of muscle fibers. Electromyographic diagnosis is made by evaluating the state of the muscle (muscle pathology) by recording and analyzing the electrical activity generated by the muscle. 1. Intramuscular EMG: insertion of a wire or needle electrode into the muscle to record motor unit action potentials. 2. Surface electromyography: electrodes placed on the skin of the perineum or inside the urethra, vaginal or rectum.

Electrophysiological Parameters

Conservative Management – Female

1. Electrical current: the flow (current) of electrons (electricity) from an electron source (stimulator) the wires and electrodes used to deliver such an electrical current to soft tissues. There are three types of current: direct, alternating, and pulsed. – a) Direct: the continuous, unidirectional flow of charged particles for 1s or longer, the direction of which is determined by the polarity selected. Polarity refers to two oppositely charged poles, one positive and one negative. Polarity determines the direction in which current flows. b) Alternating: the continuous, bidirectional flow of charged particles, for 1s or longer, relative to the isoelectric baseline. c) Pulsed: the noncontinuous, interrupted, and periodic flow of direct (DC) or alternating (AC) currents.

Electrostimulation - direct electrical neurostimulation

Conservative Management – General

This is a direct stimulation of the nerves or neural tissue to effect function of the end organ. It is done through electrodes implanted directly or near the nerve or neural tissue.

Electrostimulation - electrical neuromodulation

Conservative Management – General

This is the stimulation of the nerves or neural tissue to modulate function and induce therapeutic response of the LUT.

Electrostimulation - pelvic electrical stimulation

Conservative Management – General

This is the application of electrical current to stimulate the pelvic viscera or their nerve supply.

Electrostimulation - transcutaneous electrical nerve stimulation (TENS)

Conservative Management – General

This is electrical stimulation of the nerves through intact skin to modulate function and induce therapeutic response of the LUT.

Endoanal Ultrasonography (EAUS) or Anal Endosonography (AES)

Imaging

Ultrasound of the anal canal performed with a pole-like ultrasound probe placed in the anal canal giving a 360 degree image of the anal canal. It is usually performed with the patient placed in the lithotomy, prone position or sometime left lateral. Two dimensional AES; three dimensional AES – three-dimensional reconstruction of the anal canal is performed using either axial or sagittal images.

Enterocoele

Sign

Bulge of upper wall of the vagina associated with herniation of the peritoneal sac and loops of small bowel.

Enterocoele

Sign

Hernia of peritoneum and possibly abdominal contents into the vault.

Enuresis

Symptom

Complaint of intermittent incontinence that occurs during periods of sleep. If it occurs during the main sleep period, then it could be qualified by the adjective “nocturnal”. The patient has to be asleep when enuresis happens and is usually unaware of it.

Enuresis

Sign

“Wetting” while asleep

Enuresis - acquired

Symptom

Complaint of intermittent incontinence that occurs during periods of sleep that has developed in adulthood.

Enuresis - primary

Symptom

Complaint of intermittent incontinence that occurs during periods of sleep that has been present lifelong.

Episodic inability to void

Symptom

Complaint of inability to initiate voiding despite relaxation and/or intensive effort (by abdominal straining, Valsalva or suprapubic pressure).

Epispadias

Sign

Urethral meatus sited on dorsal surface of the penis, either congenital or acquired, proximal to its normal position on the tip of the glans.

Erectile dysfunction (male)

Symptom

Complaint of inability to achieve and sustain an erection firm enough for satisfactory sexual performance.

Excoriation

Sign

Perianal excoriation, skin rashes.

Exercise and Exercise Training

Conservative Management – Female

Exercise is a form of leisure time activity that is usually performed on a repeated basis over an extended period of time (exercise training) with specific external objectives, such as improvement of fitness, physical performance, or health. Exercise training includes: endurance training, strength training, flexibility training, and motor control (including balance), all of which may apply to the PFM.

Therapeutic exercise/exercise therapy: consists of interventions directed toward maximizing functional capabilities. It includes a broad range of activities intended to improve strength, range of motion (including muscle length), cardiovascular fitness, flexibility, or to otherwise increase a person's functional capacity.

1. Rehabilitation/re-education: help individuals to regain skills and abilities that have been lost as a result of illness, injury or disease, or incarceration, restoring a disabled individual to maximum independence commensurate with his or her limitations. Mode of exercise training: is not only the type of activity to be performed (for instance, fast walking, jogging, or swimming, strength training), but also the temporal pattern of activity that is recommended (that is, continuous or intermittent activity), with a detailed specification of the duration of exercise and rest periods in the case of intermittent activity bouts. Authors are encouraged to specifically describe all components of the mode of exercise and the dose provided.

Explant

Surgery – Female

F

Fecal (flatal) urgency incontinence.

Symptom

Complaint of an involuntary loss of feces (flatus) associated with fecal urgency.

Fecal incontinence

Symptom

Complaint of involuntary loss of feces.

- when feces is solid and/or
- when feces is liquid

Fecal Incontinence (Female)

Diagnosis

Fecal incontinence: involuntary loss of solid or liquid stool and could be due to: 1: Anal sphincter disruption is due to discontinuity of the external anal sphincter, internal anal sphincter or both; 2: Hypocontractile/acontractile sphincter is due to neuropathy or atrophy; 3: Combined anal sphincter disruption and hypocontractile/acontractile sphincter. 4: Rectal overactivity due to exaggerated smooth muscle contraction of the rectum could also be associated with hypersensitivity; 5: Overflow incontinence seepage of stool due to fecal impaction.

Fecal (rectal) urgency

Symptom

Complaint of a sudden compelling desire to defecate that is difficult to defer.

Fecal urgency warning time

Symptom

Time from first sensation of urgency to voluntary defecation or fecal incontinence.

A surgically excised prosthesis or graft.

Exposure

Surgery – Complication related

A condition of displaying, revealing, exhibiting or making accessible e.g. vaginal mesh exposure. (NB: "erosion" is not an ICS definition).

Extra-pelvic Muscle Activity

Conservative Management – General

Is the contraction of muscles other than those that comprise the pelvic floor, for example the abdominal, gluteal and adductor muscles. Extra-pelvic muscle activity is needed for maximal pelvic floor muscle effort.

Extra-urethral incontinence

Sign

Observation of urine leakage through channels other than the urethral meatus, e.g. fistula.

Extrusion

Surgery – Complication related

Passage gradually out of a body structure or tissue, e.g. a loop of tape protruding into the vaginal cavity. (NB "Erosion" is not an ICS definition)

Fecaluria

Symptom

Complaint of passage of feces (per urethram) in the urine.

Feeling of incomplete (bladder) emptying

Symptom

Complaint that the bladder does not feel empty after voiding has ceased.

Feeling of incomplete bowel evacuation

Symptom

Complaint that the rectum does not feel empty after defecation. May be accompanied by the desire to defecate again.

Female Anorectal Dysfunction - Assessment of Pelvic Floor Muscle Function

Sign

Pelvic floor muscle function can be qualitatively defined by the tone at rest and the strength of a voluntary or reflex contraction as strong, normal, weak, or absent or by a validated grading symptom. Voluntary pelvic floor muscle contraction and relaxation may be assessed by visual inspection, by digital palpation (vaginal or anorectal) (circumferentially), electromyography, dynamometry, manometry, or ultrasound. Factors to be assessed include muscle strength (static and dynamic) (graded as strong, normal, weak or absent), voluntary muscle relaxation (graded as absent, partial, complete, delayed), muscular endurance (ability to sustain maximal or near maximal force), repeatability (the number of times a contraction to maximal or near maximal force can be performed), duration, co-ordination, and displacement. Assessment can be made of each side of the pelvic floor separately to allow for any unilateral defects and asymmetry. Assessment of displacement (perineal elevation or descent) of the pelvic floor can be made during cough or Valsalva. Normally, there is some downward movement of the pelvic floor muscles or there is a ventral movement (perineal elevation, inward (cephalad) and upward movement of vulva, perineum, and anus). Rectal examination obser-

vations can include: (a) Anal sphincter tone and strength: given the absence of a formal quantitative assessment via the rectal route, assessment of anal tone and strength on digital examination, can be graded using the same convention used when grading transvaginally—as strong, normal, weak, or absent or by a validated grading symptom. (b) Anal sphincter tear: may be recognized as a clear “gap” in the anal sphincter on digital examination.

Female Anorectal Dysfunction - Clinical Applications of Defecating Proctography

Imaging

Assuming that posterior wall prolapse and rectocele can be considered the same anatomic entity, clinical examination is not accurate in diagnosing anatomical defects of posterior vaginal wall and enteroceles compared to defecography as reference standard. Clinical examination overestimates the presence of the posterior wall defects (large false positive rates) but misses enterocele in patients with primary POP (large false negative rates). The major function of proctography is not merely to document evacuatory abnormalities, but also to classify those abnormalities into those potentially surgically relevant, those likely to benefit from behavioral biofeedback therapy alone, or indeed those which are incidental. 1: Pelvic floor descent: Pelvic floor descent, defined as the distance moved by the ARJ or ARA at rest to the point of anal canal opening, is considered abnormal if it exceeds 3cm. 2: Intussusception and prolapse Intussusception refers to infolding of the rectal wall into the rectal lumen. It may be described as intra-rectal, intra-anal or external to form a complete rectal prolapse. 3: Rectocele: Rectocele diagnosis on evacuation proctography is defined as any anterior rectal bulge. The depth of a rectocele is measured from the anterior border of the anal canal to the anterior border of the rectocele. A distance of <2cm is classified as small, 2–4cm as moderate and >4cm as large. Of more relevance however is barium trapping at the end of evacuation (defined as retention of >10% of the area, and this itself is related to the size of the rectocele. 4: Enterocele: An enterocele is diagnosed when small bowel loops enter the peritoneal space between the rectum and vagina. Diagnosis of an enterocele on proctography is only really possible if oral contrast has been administered before the examination. Herniation of the sigmoid into the rectogenital space (sigmoidocele) is significantly less common than an enterocele. 5: Dyssynergic defecation Various proctographic abnormalities have been described including prominent puborectal impression, a narrow anal canal and acute anorectal angulation. However these observations may be found in normal controls and are in themselves unreliable distinguishing features.

Female Anorectal Dysfunction - Clinical Applications of MRI in the Posterior Compartment

Imaging

1: Fecal incontinence Endoanal ultrasound and endoanal magnetic resonance imaging (MRI) have been demonstrated to be comparable in the detection of external sphincter defects. External phased array coil MRI can replace endoluminal MRI with comparable results. 2: Levator ani injuries Abnormalities of the LA are identified on MRI as present or absent. Defect severity is further scored in each muscle from 0 (no defect) to 3 (complete loss). A summed score for the two sides (0–6) is assigned and grouped as minor (0–3) or major (4–6). 3: Obstructed defecation During maximal Valsalva maneuver, dynamic MRI may be used to demonstrate: • Rectocele: measured as the depth of wall protrusion beyond the expected margin of the normal anorectal wall. Based on sagittal MR-sections through mid of pelvis, rectoceles are graded as small (<2cm), moderate (from 2 to 4cm), and large (>4cm). • Rectal intussusception: the infolding of the rectal mucosa occurring during defecation. Depending on the location, an intrarectal intussusception, limited to the rectum, is distinguished from an intra-anal intussusception extending into the anal canal. The location of the intussusception may be anteriorly, posteriorly, or circumferentially. The intussusception either involves only the mucosa or the full thickness of the rectal wall. • Enter-

ocele: defined as a herniation of the peritoneal sac, which contains omental fat (peritoneocele), small bowel (enterocele) or sigmoid (sigmoidocele), into the rectovaginal or rectovesical space below the PCL. The largest distance between the PCL and the most inferior point of the enterocele is measured with a perpendicular line. Depending on this distance, small (<3cm), moderate (3–6cm), and large (>6cm) enteroceles are distinguished. • Dyssynergic defecation: different structural imaging findings can be seen on dynamic pelvic MRI, including prominent impression of the puborectal sling, narrow anal canal, prolonged evacuation, a lack of descent of the pelvic floor and thus a failure to increase the ARA. In comparison with clinical examination (POP-Q), dynamic MRI has no additional value in the prediction of symptoms with increasing degree of POP. 4: Perianal abscesses and fistulas.

Female Anorectal Dysfunction - Defecating Proctography

Imaging

Evaluates in real time the morphology of rectum and anal canal in correlation with pelvic bony components both statically and dynamically by injection of a thick barium paste into the rectum and its subsequent evacuation. Contrast administration into the bladder and vagina provides a more comprehensive assessment of the pelvic organs and has been labelled “dynamic cystoproctography.” At rest, the anal canal is closed and rectum assumes its normal upright configuration. The position of the pelvic floor is inferred by reference to the PCL (inferior margin of pubic symphysis to the sacro-coccygeal junction). Perineal descent is measured from this line to the ARJ, and may be up to 1.8cm at rest. Some pelvic floor descent during evacuation is considered normal and a descent of up to 3cm from the rest position to anal canal opening is acceptable. The ARA is defined as the angle between the anal canal axis and the posterior rectal wall, and on average is around 90 degrees. The puborectalis length (PRL) can be estimated by measuring the distance between the ARA and symphysis pubis. A normal emptying phase at the proctogram is described by five elements: • Increase in the ARA by around 20–30 degrees; • Obliteration of the puborectalis impression and the PRL should increase by around 3–4cm; • Wide opening of the anal canal within a couple of seconds; • Evacuation of rectal contents proceeding promptly and to completion; • Lack of significant pelvic floor descent. After evacuation is complete, the anal canal should close, the ARA recover and the pelvic floor return to its normal baseline position. Post toilet imaging may be required, particularly in those suspected of retained barium within rectoceles.

Female Anorectal Dysfunction - Endoanal ultrasonography (EAUS)

Imaging

The majority of current systems provide 2D & 3D Imaging which give a 360 degree axial view of the anal canal and of the rectal wall. Endoanal ultrasound can be performed with the patient placed in the dorsal lithotomy, left lateral or prone position. Irrespective of the position, the probe should be rotated so that the anterior aspect of the anal canal is superior (12 o'clock) and left lateral is right (3 o'clock) on the screen. The anal canal is divided into three levels of assessment in the axial plane referring to the following anatomical structures: • Upper level: the hyperechoic sling of the puborectalis muscle (PR) and the complete ring of the internal anal sphincter (IAS) are visualized • Middle level: corresponds to the superficial part of the EAS (concentric band of mixed echogenicity), the conjoined longitudinal layer, the IAS (concentric hypoechoic ring), and the transverse superficial perineal muscles; • Lower level: corresponds to the subcutaneous part of the EAS where the IAS is absent. The acquisition of a three-dimensional data volume (3D ultrasound) and the underlying techniques vary. Acquisition may be “free-hand” (low resolution 3D) or “automatic computer-controlled” (high resolution 3D).

Female Anorectal Dysfunction - Squeeze pressure

Sign

Measurement of squeeze pressure involves the exertion of pressure, compressing the assessor's finger during digital palpation or using a mechanical device. The patient is asked to squeeze the PFM as hard as possible (maximum strength), to sustain the squeeze contraction (endurance), or to repeat squeeze contractions (repetitions). The measurement can be done in the anorectum using manual muscle testing with digital rectal palpation or pressure manometry in the vagina using manual muscle testing with digital vaginal palpation or pressure manometry, or dynamometry. So far, not all quantitative assessments and scales of pelvic floor squeeze pressure have the same methodological qualities, like validity, reproducibility, and responsiveness. Pelvic floor muscle spasm was defined as persistent contraction of striated pelvic floor muscle that cannot be released voluntarily. If the contraction is painful, this is usually described as a cramp. Spasm over days or weeks may lead to a contracture. Pelvic floor muscle tenderness: sensation of discomfort with or without pain; discomfort of pelvic floor muscle elicited through palpation. Tenderness can be scored during a digital rectal (or vaginal) examination of levator ani, piriformis and internal obturator muscles bilaterally, according to each subject's reactions: 0, no pain; 1, painful discomfort; 2, intense pain; with a maximum total score of 12. Although not universally accepted, pelvic floor muscle traction is the use of a pulling force to examine or treat pelvic floor muscles, postulated to end pelvic muscle spasm or relieve pain.

Female Anorectal Dysfunction - Transperineal ultrasonography (TPUS)

Imaging

Conventional convex transducers (frequencies between 3 and 6MHz and field of view at least 70 degrees) provide 2D imaging of the pelvic floor. Transperineal ultrasound is performed with the patient placed in the dorsal lithotomy position, with the hips flexed and abducted. If necessary, the patient can be examined standing, to maximise descent of pelvic organs, especially if the patient finds it difficult to produce an effective Valsalva maneuver. No rectal or vaginal contrast is used. Perineal ultrasound provides sagittal, coronal and oblique sectional imaging, with the mid-sagittal plane being the most commonly used as this gives an overall assessment of all anatomical structures (bladder, urethra, vaginal walls, anal canal, and rectum) between the posterior surface of the symphysis pubis (SP) and the posterior part of the levator ani (LA). The imaging is usually performed at rest, on maximal Valsalva maneuver and on pelvic floor muscle contraction (PFMC). The access to the mid-sagittal plane allows the following evaluations: • Integrity of the perineal body: appearing as a triangular shaped, slightly hyperechoic structure anterior to the anal sphincter, • Measurement of the anorectal angle (ARA): formed by the longitudinal axis of the anal canal and the posterior rectal wall, • Dynamic assessment of the posterior compartment. During Valsalva it is possible to visualize descent of an enterocele, to assess the movement of the anterior rectal wall to detect a rectocele, and to evaluate movement of the PR and ARA to diagnose pelvic floor dyssynergy. 3D TPUS may be performed with volumetric probes (electronic curved array of 4–8MHz). An advantage of this technique is the opportunity to obtain tomographic or multi-slice imaging, for example, in the axial plane, in order to assess the entire PR and its attachment to the pubic rami. It is also possible to measure the diameter and area of the levator hiatus (LH) and determine the degree of hiatal distension on Valsalva. Four dimensional (4D) imaging indicates real-time acquisition of volume ultrasound data.

Female Anorectal Dysfunction - Transvaginal Ultrasound (TVUS)

Imaging

Transvaginal ultrasound is performed with the patient placed in the dorsal lithotomy position. Currently, the transducers used for pelvic floor 3D TVUS are high multi-frequency (9–16MHz), 360 degree rotational mechanical probe or radial electronic probe. The pelvic floor is divided into four levels of assessment in the axial plane referring to the following anatomical structures (not to be confused with Delancey's description of vaginal Levels of

supports). • Level I: at the highest level the bladder base is visualized on the screen at 12 o'clock position and the inferior third of the rectum at 6 o'clock position. • Level II: corresponds to the bladder neck, the intramural region of the urethra and to the anorectal junction. At this level the subdivisions of the LA (pubovaginalis, puboperinealis, puboanalis, puborectalis, and iliococcygeus) may be identified. • Level III: corresponds to the midurethra and to the upper third of the anal canal. At this level, the LA is visualized as a multilayer hyperechoic sling coursing lateral to the vagina and posteriorly to the anal canal and attaching to the inferior pubic ramus. In the axial plane of minimal hiatal dimensions, identified as the minimal distance between the inferior edge of the SP and the anterior border of the LA at the ARA, the biometric indices (anteroposterior and transverse diameters, area) of the LH can be determined. • Level IV: at the outer level, the perineal muscles (bulbospongiosus, ischiocavernosus, and superficial transverse perineii muscles), the perineal body, the distal urethra and the middle and inferior third of the anal canal are visualized. The anterior-posterior diameter of the urogenital hiatus (UGH), corresponding to the SP-perineal body distance, can be determined. Transvaginal ultrasound may be also performed with electronic probes with linear array, which provide mid-sagittal image of the posterior compartment. The main advantage of this technique is the dynamic assessment of the anorectal region, during Valsalva and pelvic floor muscle contraction (PFMC).

Female Anorectal Dysfunction - Ultrasonography to Assess Fecal Incontinence

Imaging

Anal inspection and digital rectal examination can give information about internal and external anal sphincter function but are inaccurate for determining external anal sphincter defects < 90 degrees and internal sphincter defects. Therefore, a sufficient diagnostic work-up should comprise at least rectal examination, anal inspection and endoanal ultrasonography. EAUS has become the gold standard for morphological assessment of the anal canal. The International Consultation on Incontinence (ICI) has recommended EAUS as the first line imaging investigation for fecal incontinence to differentiate between those with intact anal sphincters and those with sphincter lesions (defects, scarring, thinning, thickening, and atrophy). Routine use of transperineal, transvaginal and translabial ultrasonography to image the anal sphincter complex are not recommended, although research is ongoing. The operator should identify if there is a combined or isolated lesion of the IAS and EAS and report the number of defects, as well as the extent of the defect circumferentially (radial angle in degrees or in hours of the clock) and longitudinally (proximal, distal or full length). Using 3D EAUS, two scoring systems have been proposed to define the severity of anal sphincter damage. EAUS has an important role in detecting undiagnosed anal sphincter injuries following vaginal delivery and can be useful in the management of subsequent pregnancies following OASIS. It is also useful to evaluate the results of treatment (anterior sphincter repair, bulking agent injections).

Female Anorectal Dysfunction - Ultrasound Imaging (General)

Imaging

Ultrasound is increasingly being incorporated as an investigation of posterior compartment disorders. An integrated multi-compartmental pelvic floor ultrasonography with a combination of different modalities has been described to assess pelvic floor dysfunction for a global and multi-compartmental perspective. Modalities in current routine clinical use: (a) Endoanal: intra-anal 360 degree sector scanning using rotational mechanical probe or radial electronic probe. (b) Transperineal: curved array probe applied in the perineum between the mons pubis and the anal margin. This term incorporates trans-labial ultrasound. Introital ultrasound is usually assumed to imply the placement of transducer with smaller footprints (such as end-firing endo-vaginal probe) within the introitus. (c) Transvaginal: intra-vaginal curvilinear, linear array, or 360 degree sector scanning.

Female Anorectal Dysfunction - Ultrasound in the Assessment of Levator Ani Injuries

Imaging

Levator avulsion is the disconnection of the muscle from its insertion on the inferior pubic ramus and the pelvic sidewall, whereas tears may occur in any part of the muscle. Avulsion is a common consequence of overstretching of the levator ani during the second stage of labor and it is detectable by 3D TVUS and 3D TPUS imaging as the lateral attachments of the pubic bone are clearly visualized. Defects are usually visualized most clearly on maximal PFMC. Tomographic ultrasound imaging is particularly useful. Levator ani injuries affect the size of the levator hiatus, with a hiatal enlargement to over 25sq cm on Valsalva maneuver defined as "ballooning," and are related to symptoms and signs of prolapse.

Female Anorectal Dysfunction - Ultrasound in the Assessment of Obstructed Defecation Syndrome (ODS)

Imaging

The term obstructed defecation syndrome (synonym: "outlet obstruction") encompasses all pelvic floor dysfunctions, which are responsible for an incomplete evacuation of fecal contents from the rectum, straining at stool and vaginal digitations. During maximal Valsalva maneuver, dynamic TPUS and TVUS may be used to demonstrate. • Rectocele: herniation of a depth of over 10mm of the anterior rectal wall; • Rectal intussusception: invagination of the rectal wall into the rectal lumen, into the anal canal or exteriorized beyond the anal canal (rectal prolapse); • Enterocele: herniation of bowel loops into the vagina. It can be graded as small, when the most distal part descends into the upper third of the vagina, moderate, when it descends into the middle third of the vagina, or large, when it descends into the lower third of the vagina; • Dyssynergic defecation: the ARA becomes narrower, the LH is shortened in the anteroposterior dimension, and the PR muscle thickens as a result of contraction.

Female Anorectal Dysfunction - Use of a Contrast Enema

Imaging

Contrast enema is used to identify colon pathology (benign and malignant lesions, diverticular disease, inflammatory conditions, congenital anomalies, intrinsic and extrinsic abnormalities). 1: Single-contrast barium enema: Using an appropriate catheter, a barium-water mixture or a water-soluble solution of diatrizoate sodium (Gastrografin) is inserted into the colon with the patient in the prone position until the column of barium reaches the splenic flexure. 2: Double-contrast or air-contrast barium enema: This procedure has become the routine study for evaluation of the bowel. With the double-contrast examination, the colon is coated with a thin layer of contrast material and the bowel is distended with air so that the entire mucosal circumference is visualized.

Female Anorectal Dysfunction - Use of Dynamic Magnetic Resonance Imaging (MRI)

Imaging

With the development of fast multi-slice sequences MR imaging has gained increasing acceptance for dynamic imaging of the pelvic floor. Because the posterior compartment is traditionally in the focus of interest, dynamic MR imaging of the pelvic floor is often called "MR defecography." Dynamic pelvic imaging may be performed in an open-configuration MR system in the sitting position, or in a closed configuration MR-system in the supine position. Both techniques are equally effective in identifying most of the clinically relevant abnormalities of the pelvic floor. For evaluation of the posterior compartment of the pelvic floor, the rectum should be filled with a contrast agent (ultrasound gel or mashed potatoes, gadolinium-based MR contrast agent) to study the actual act of defecation. The use of reference lines for image evaluation is helpful. The most used reference line is the pubococcygeal line (PCL), which is defined on mid-sagittal images as the line joining

the inferior border of the symphysis pubis to the last or second last coccygeal joint. The anorectal junction (ARJ) is defined as the cross point between a line along the posterior wall of the distal part of the rectum and a line along the central axis of the anal canal. To determine pathologic pelvic floor descent, the measurements are made on the images, which show maximal organ descent, usually during maximal straining or during evacuation. The anorectal angle (ARA) is defined as the angle between the posterior wall of the distal part of the rectum and the central axis of the anal canal and can be measured at rest, squeezing and straining. The extent of rectoceles and enteroceles are measured. The degree of pelvic floor relaxation is measured with two reference lines: the H line which represents hiatal widening and extends from the inferior aspect of the symphysis pubis to the posterior wall of the rectum at the level of the ARJ and the M line which represents hiatal descent and extends perpendicularly from the PCL to the posterior end of the H line. Lesions of the pelvic musculofascial support result in widening of the hiatus and descent of the levator plate. Thus, the H and M lines tend to elongate with pelvic floor relaxation, widening the levator plate descent. Abnormal pelvic floor relaxation is present, when the H line exceeds 6cm, and when the M line exceeds 2cm in length.

Female Anorectal Dysfunction - Use of Nuclear Colonic Transit Study

Imaging

Colon scintigraphy is performed at 6, 24, and 48 hr in ventral and dorsal projection after oral administration of methacrylate-coated capsule of non-sorbable ¹¹¹Indium-labeled polystyrene (¹¹¹In-DTPA) micropellets. The geometric center, as the sum of products of colon segment activity and colon segment number (1 - ascending colon, 2 - transverse colon, 3 - descending colon, 4 - rectosigmoid, and 5 - evacuated feces) dividing by the total counts is used to determine the velocity of colonic transit. Meals normally reach the cecum at 6 hr and are evacuated in 30 to 58 hr. Retention of radioactivity in the proximal colon at 48hr, indicates slow colonic transit while retention in the rectum indicates anorectal dysfunction.

Female Anorectal Dysfunction - Use of Radiological Colonic Transit Studies

Imaging

Segmental and total colonic transit time is assessed with the use of radio-opaque markers and sequential abdominal X-rays. There are different protocols. Most frequently used, utilizes a capsule containing 24 markers of 1 x 4.5mm. Patient takes one capsule on day 0 by mouth and X-ray is performed on day 5. Patients who expel at least 80% markers on day 5 have normal colonic transit. Patients who retain 6 or more markers may have follow-up abdominal X-rays within several days. If remaining markers are scattered about the colon, the condition is slow transit or colonic inertia. If the remaining markers are accumulated in the rectum or rectosigmoid, this suggests functional outlet obstruction.

Female Anorectal Dysfunction - Use of Static Magnetic Resonance Imaging (MRI)

Imaging

Static MRI provides detailed information of the pelvic floor anatomy. Current state-of-the-art MR imaging of the pelvic floor includes imaging at a magnetic field strength of 1.5 Tesla (T), using pelvic or phased-array coils and T2-weighted fast-spin echo (FSE) sequences. The spatial resolution can be enhanced by using endoluminal (endorectal, endovaginal) coils. In combination with T2-weighted FSE sequences, endoluminal coils provide improved signal-to-noise ratio (SNR) and high resolution images. Based on T2-weighted turbo spin-echo sequences, muscles are relative hypointense, ligaments and fascia hypointense while fat and smooth muscle are hyperintense. The prominent pelvic floor structures of the posterior compartment visualized at MRI are: • Perineal body and superficial perineal muscles; • Anal sphincters: the IAS is easily recognized as a circular hyperintense structure. It is approximately 2.9mm thick on endoluminal MRI. The inter-sphincteric

space is seen as a bright line on T2-weighted MRI. The EAS has a thickness of 4.1mm on endoluminal imaging; • Puborectalis muscle and levator ani; • Superficial perineal muscles; • Rectum and rectal support.

Female Orgasmic Disorder

Diagnosis

Presence of either of the following on all or almost all (75% - 100%) occasions of sexual activity: (i) Marked delay in, marked infrequency of, or absence of orgasm; (ii) Markedly reduced intensity of orgasmic sensations

Female Sexual Dysfunction

Symptom

Complaint of dyspareunia or impairment of sexual desire, arousal, or orgasm.

Female Sexual Dysfunction - Conservative treatments - Lifestyle modification

Conservative Management – Female

Alterations of certain behaviors may improve sexual function. These include weight loss, appropriate sleep, adequate physical fitness, and management of mood disorders. Vulvo-vaginal pain may be treated by dietary changes and perineal hygiene (avoiding irritant soaps, detergents, and douches), although data are conflicting. Dietary modifications may be disorder specific including low oxalate diet as reduction in dietary levels of oxalate may improve symptoms of vulvodynia, or a bladder friendly diet with reductions in acidic foods and bladder irritants may treat bladder pain and associated sexual pain.

Female Sexual Dysfunction - Conservative Treatments - Topical Therapies

Conservative Management – Female

Lubricants and moisturizers - Application of vaginal lubricant during sexual activity or vaginal moisturizers as maintenance may assist with atrophic symptoms and dyspareunia. Examples of some lubricants are described below, although no one lubricant or moisturizer has been adequately studied to recommend it over others. Additionally, not all products are available in all countries.

1: Essential arousal oil: Feminine massage oil applied to vulva prior to activity. Some evidence to support efficacy in treatment of sexual dysfunction, including arousal and orgasm, compared with placebo. 2: Vulvar soothing cream: Non-hormonal cream containing cutaneous lysate, to be applied twice daily. Study shows improvement in vulvar pain with use compared to placebo. 3: Prostaglandin E1 analogue, may help increase genital vasodilation. Ongoing trials to determine efficacy in arousal or orgasmic dysfunction.

Female Sexual Dysfunction - Non-pharmacological treatments - Clitoral suction devices

Conservative Management – Female

This is a battery-operated hand held device, designed to be placed over the clitoris. It provides a gentle adjustable vacuum suction with low-level vibratory sensation. Intended to be used three or more times a week for approximately 5min at a time. This therapy has been shown to increase blood flow to the clitoral area as well as to the vagina and pelvis. Small non-blinded studies have shown it may significantly improve arousal, orgasm, and overall satisfaction in patients with sexual arousal disorder.

Female Sexual Dysfunction - Non-pharmacological treatments - Fractional CO2 Laser

Conservative Management – Female

Use of thermoablative laser to vaginal mucosa may improve microscopic structure of epithelium. This results in increased thickness, vascularity, and connective tissue remodeling, which can improve climacteric symptoms.

Although long term data are lacking, some studies have shown significant improvements in subject symptoms of vaginal dryness, burning, itching, and dyspareunia as well as quality of life.

Female Sexual Dysfunction - Non-pharmacological treatments - Vaginal dilators

Conservative Management – Female

Vaginal forms or inserts, dilators are medical devices of progressively increasing lengths or girths designed to reduce vaginal adhesions after pelvic malignancy treatments or in treatment of vulvar/vaginal pain. Can be useful for perineal pain or introital narrowing following pelvic reconstructive repairs. However, routine use after surgery not supported. Dilators can also be used for pelvic floor muscle stretching (ie, Thiele massage) and was found helpful in women with interstitial cystitis and high-tone pelvic floor dysfunctions.

Female Sexual Dysfunction - Non-pharmacological treatments - Vaginal exercising devices

Conservative Management – Female

Pelvic muscle strengthening tools in form of balls, inserts or biofeedback monitors. May improve pelvic floor muscle tone and coordination by improving ability to contract and relax. Studies are lacking assessing their use without concurrent physical therapy.

Female sexual dysfunction - Non-pharmacological treatments - Vaginal vibrators

Conservative Management – Female

Vaginal vibrators, external and internal: May be associated with improved sexual function, data controversial. Possibility that use of vibrators for self-stimulation may negatively impact sexual function with partner related activity.

Female Sexual Dysfunction - Physical therapy

Conservative Management – Female

Manual therapy: Techniques that include stretching, myofascial release, pressure, proprioceptive neuromuscular facilitation, and massage applied externally on the perineum and internally to increase flexibility, release muscle tensions and trigger points in the pelvic floor muscles. It was found to be effective to improve sexual function in women with pelvic floor disorders in recent meta-analysis and systematic review. These therapies have also been found helpful in women with genito-pelvic pain.

1: Pelvic muscle exercises with or without biofeedback: May improve sexual function in women with pelvic floor disorders or pain. 2: Dry needling: Placement of needles without injection in myofascial trigger points. 3: Trigger point injections i. Anesthetic: Injection of local anesthetics, often Lidocaine, directed by trigger point palpation, can be external or transvaginal. ii. Botox: Injection of Botulinum toxin type A, a potent muscle relaxant, into refractory myofascial trigger points to reduce pelvic pain.

Female sexual dysfunction - Prescription treatments - Hormonal

Conservative Management – Female

1: Estrogen: Available via prescription for both systemic use (oral or transdermal preparations); or locally use (creams, rings ,or tablets). May assist with overall well-being, sexual desire, arousal and dyspareunia. Role for topical use in treatment of post-surgical atrophy or mesh extrusion. 2: Ospemifene: Selective estrogen receptor modulator for treatment of moderate to severe dyspareunia related to vulvar and vaginal atrophy, in postmenopausal women. Acts as an estrogen agonist/antagonist with tissue selective effects in the endometrium. 3: Testosterone: Not approved for use in women in

the USA or UK, may be available in other countries. Variety of preparations including transdermal, oral, or pellet administration. Long term safety unknown, studies suggest improvements in satisfying sexual events, sexual desire, pleasure, arousal, orgasm and decreased distress. 4: Tibolone: Synthetic steroid with estrogenic, progestogenic and androgenic properties. It is not currently available in the USA. Studies have suggested a positive effect on sexual function with use. 5: Prasterone: dehydroepiandrosterone suppository available as a vaginal insert. It has been shown to be efficacious when compared to placebo in decreasing vulvovaginal atrophy.

Female Sexual Dysfunction - Prescription treatments - non-hormonal

Conservative Management – Female

1: Bremelanotide; formerly PT-141- Melanocortin agonist, initially developed as a sunless tanning agent, utilizes a subcutaneous drug delivery system. Treatment significantly increased sexual arousal, sexual desire and the number of sexually satisfying events with associated decreased distress in premenopausal women with FSD. 2: Serotonin receptor agonist/antagonist; Flibanserin-5-hydroxytryptamine (HT)1A receptor agonist and 5-HT2A receptor antagonist, initially developed as antidepressant. Challenges in FDA applications, due to possible long term risks. Studies show improved sexual desire, satisfying sexual events, and reduced distress. 3: Dual control model in differential drug treatments for hypoactive sexual desire disorder and female sexual arousal disorder: i. Testosterone in conjunction with phosphodiesterase type 5 inhibitor (PDE-5); ii. Testosterone in conjunction with a 5-HT1A agonist. May be able to target physiologic and subjective measures of sexual functioning in a more specific manner. Premise of two types of HASDD subjects: low sensitivity to sexual cues, or prone to sexual inhibition. Tailoring on demand therapeutics to different underlying etiologies may be useful to treat common symptoms in women with lack of sexual interest and provide the appropriate therapy. Testosterone is supplied as a short acting agent 4 h prior to sexual event to lessen the side effect/risk profile. 4: Apomorphine: Nonselective dopamine agonist that may enhance response to stimuli. 5: Antidepressants and Neuropathics: Include tricyclic antidepressant and anticonvulsants, may be useful in treating sexual pain, and vulvar pain. 6: Bupropion: Mild dopamine and norepinephrine reuptake inhibitor and acetylcholine receptor antagonist, it may improve desire and decrease distress or modulate Selective Serotonin Reuptake Inhibitor (SSRI) induced FSD.

Female Sexual Dysfunction - Psychological intervention

Conservative Management – Female

Counseling and therapy are widely practiced treatments for female sexual dysfunction. Even when a sexual problem's etiology and treatment is primarily urogenital, once a problem has developed there are typically psychological, sexual, relationship, and body image consequences and it may be tremendously validating and helpful for these women to be referred to counselors or therapists with expertise in sexual problems. Psychological interventions include cognitive behavioral therapy (CBT), sex therapy, and mindfulness training. While there is insufficient evidence with regard to controlled trials studying the efficacy of psychological treatment in women with sexual dysfunction, the available evidence suggests significant improvements in sexual function after intervention with traditional sex therapy and/ or cognitive behavioral therapy. Specific techniques include: 1: Sex therapy: Traditional treatment approach with aim to improve individual or couple's sexual experiences and reduce anxiety related to sexual activity; 2: Cognitive-behavioral therapy: Incorporates sex therapy components but with larger emphasis on modification of thought patterns that may interfere with sexual pleasure; 3: Mindfulness: An ancient eastern practice with Buddhist roots. The practice of "relaxed wakefulness," and "being in the moment," has been found to be an effective component of psychological treatments for sexual dysfunction.

Female sexual dysfunction - the effect of pelvic reconstructive surgery for prolapse and incontinence on sexual health

Surgery – Female

Women with pelvic floor dysfunction commonly report impaired sexual function, which may be associated with the underlying pelvic floor disorder. Treatment of the underlying disorders may or may not impact sexual function. While both urinary incontinence and pelvic organ prolapse affect sexual function, prolapse is more likely than urinary incontinence to result in sexual inactivity. Prolapse is also more likely to be perceived by women as affecting sexual relations and overall sexual satisfaction. This perception is independent of diagnosis or therapy for urinary incontinence or prolapse. Very little is known about the impact of fecal incontinence on sexual function. The effect of pelvic reconstructive surgery on sexual function has increased but there is need for more focused research. Overall, randomized trials are lacking, varied outcome measures are used among studies. There is a lack of reporting per DSM-IV/DSM 5 categories and a lack of long-term follow-up. Level of Evidence (LOE) is poor in many studies and sexual dysfunction is usually reported as a secondary outcome measure. While any surgery can impact sexual function postoperatively, most commonly performed pelvic floor surgeries were not designed with the intent to improve sexual function. In general, successful surgical treatment of incontinence or prolapse may improve sexual symptoms associated with the underlying disorder. For example, coital incontinence improves after sling surgery, but whether it impacts other aspects of sexual function such as orgasm, desire, or arousal is unclear. Surgery for prolapse may improve underlying symptoms of laxity or embarrassment from bulge, which in turn may improve sexual function, but does not seem to have a direct impact on other aspects of sexual function. A small but significant number of patients will develop pain or other sexual disorders following surgery. These pain disorders spring from a variety of causes including those caused by the use of grafts. Prediction of who will develop these pain disorders is challenging. A recent paper which evaluated the effect of vaginal surgery on sexual function reported that women overall reported improved function, decrease in dyspareunia rates, and that de novo dyspareunia rates were low at 5% at 12 months and 10% at 24 months. Nonetheless, assessment of sexual activity and partner status and function prior to and following surgical treatment is essential in the evaluation of surgical outcomes. Because of the negative impact of pain on sexual function, assessment of sexual pain prior to and following procedures should also be undertaken.

Female Sexual Dysfunction Diagnoses - Female Orgasmic Disorder (American Psychiatric Association)

Diagnosis

Presence of either of the following on all or almost all (75-100%) occasions of sexual activity: 1: Marked delay in, marked infrequency of, or absence of orgasm; 2: Markedly reduced intensity of orgasmic sensations

Female sexual dysfunction diagnoses - Female Sexual Interest/Arousal Disorder (American Psychiatric Association)

Diagnosis

Lack of, or significantly reduced, sexual interest/arousal as manifested by 3 of the following: 1: Absent/reduced interest in sexual activity; 2: Absent/reduced sexual/erotic thoughts or fantasies; 3: No/reduced initiation of sexual activity and unresponsive to partner's attempts to initiate; 4: Absent/reduced sexual excitement/pleasure during sexual activity in almost all or all (75-100%) sexual encounters; 5: Absent/reduced sexual interest/arousal in response to any internal or external sexual/ erotic cues (written, verbal, visual) 6: Absent/reduced genital or non-genital sensations during sexual activity in almost all or all (75-100%) sexual encounters.

Female Sexual Dysfunction Diagnoses - General comments

Diagnosis

The Diagnostic and Statistical Manual of Mental Disorders fifth edition (DSM-5), the International Classification of Diseases 10th edition (ICD-10), and the Joint Terminology from the fourth International Consultation of Sexual Medicine (ICSM) all have proposed diagnoses for sexual disorders in women. Many of the diagnoses from the various societies overlap; ICS have chosen the diagnoses from the DSM 5, as well as the diagnosis of genitourinary syndrome of menopause as these diagnoses seem most relevant to the population of women with pelvic floor dysfunction. The DSM 5 has combined disorders that overlap in presentation and reduced the number of disorders from six to three. Hypoactive sexual desire disorder (HSDD) and female sexual arousal disorders (FSAD) have been combined into one disorder, now called Female Sexual Interest/Arousal Disorder (FSIAD), based on data suggesting that sexual response is not always a linear, uniform process, and that the distinction between certain phases, particularly desire and arousal, may be artificial. Although this revised classification has not been validated clinically and is controversial, it is the new adopted standardization. One reason offered for the new diagnostic name and criteria were clinical and experimental observations that sexual arousal and desire disorders typically co-occur in women and that women may therefore experience difficulties in both. The DSM-IV categories of vaginismus and dyspareunia have been combined to create "genito-pelvic pain/penetration disorder" (GPPPD). Female Orgasmic Disorder remains its own diagnosis. The DSM 5 has also changed the relevant specifiers of these disorders with the goal of increasing objectivity and precision and to avoid over-diagnosis of transient sexual difficulties. In particular, all diagnoses now require a minimum duration of approximately 6 months and are further specified by severity. Genitourinary syndrome of menopause (GSM) is a new term introduced by the International Society of Sexual Medicine to describe a variety of symptoms which may be associated with sexual health. Although not validated, this diagnosis was introduced in an effort to improve communication between providers and patients regarding symptoms which may be difficult to discuss. While not a sexual dysfunction diagnosis, given the age of women who typically develop pelvic floor dysfunction, symptoms associated with GSM may be relevant to the assessment of the sexual health of women with pelvic floor dysfunction. For each of the DSM-5 diagnoses, providers should indicate whether or not the condition is lifelong or acquired, generalized or situational, and rate the severity as mild, moderate or severe in terms of the distress it causes. All of the diagnoses, except for the pain diagnoses, need to meet the criterion that it has been present for 6 months, causes significant distress, and are not a consequence of non-sexual mental disorder, severe or primarily attributable to a medication or underlying illness. For genitourinary syndrome of menopause, not all signs and symptoms need be present, but the symptoms must be bothersome and not better accounted for by another diagnosis.

Female Sexual Dysfunction Diagnoses - Genito-Pelvic Pain/Penetration Disorder (American Psychiatric Association)

Diagnosis

Persistent or recurrent difficulties with 1 or more of the following: 1: Vaginal penetration during intercourse; 2: Marked vulvovaginal or pelvic pain during intercourse or penetration attempts; 3: Marked fear or anxiety about vulvovaginal or pelvic pain in anticipation of, during, or as a result of vaginal penetration; 4: Marked tensing or tightening of the pelvic floor muscles during attempted vaginal penetration.

Female Sexual Dysfunction Diagnoses - Genitourinary syndrome of menopause

Diagnosis

The genitourinary signs and symptoms of menopause that arise from decreasing level of estrogens and other steroids. This includes burning and irritation of reproductive organs and structures, dryness, pain with intercourse and urinary urgency, dysuria and recurrent infections.

Female Sexual Interest/Arousal disorder

Diagnosis

Lack of, or significantly reduced, sexual interest/arousal as manifested by 3 of the following: (i) Absent/reduced interest in sexual activity; (ii) Absent/reduced sexual/erotic thoughts or fantasies; (iii) No/reduced initiation of sexual activity and unresponsive to partner's attempts to initiate; (iv) Absent/reduced sexual excitement/pleasure during sexual activity in almost all or all (75% - 100%) sexual encounters; (v) Absent/reduced sexual interest/arousal in response to any internal or external sexual/erotic cues (written, verbal, visual); (vi) Absent/reduced genital or non-genital sensations during sexual activity in almost all or all (75% - 100%) sexual encounters.

Female Sexual Interest/Arousal Disorder (FSIAD)

Diagnosis

Hypoactive sexual desire disorder (HSDD and female sexual arousal disorders (FSAD)) have been combined into one disorder, now called Female Sexual Interest/Arousal Disorder (FSIAD), based on data suggesting that sexual response is not always a linear, uniform process and that the distinction between certain phases, particularly desire and arousal, may be artificial.

Filling cystometry

Investigation

Pressure-volume relationship of the bladder during bladder filling. It begins with the commencement of filling and ends when a "permission to void" is given by the urodynamicist or with incontinence (involuntary loss) of the bladder content.

Filling cystometry - intrinsic sphincter deficiency (ISD)

Investigation

Very weakened urethral closure mechanism.

Filling cystometry - abnormal sensations

Investigation

Awareness of sensation in the bladder, urethra or pelvis described with the words like "tingling", "burning" or "electric shock" in the setting of a clinically relevant neurologic disorder (e.g. incomplete spinal cord lesion).

Filling cystometry - absent bladder sensation.

Investigation

No bladder sensation during bladder filling, at least to an expected capacity of 500mLs.

Filling cystometry - aims

Investigation

These are to assess bladder sensation, bladder capacity, detrusor activity and bladder compliance as well as to document (the situation of and detrusor pressures during) urine leakage.

Filling cystometry - bladder (detrusor) compliance (mL/cm H2O)

Investigation

Relationship between the change in bladder volume (Vol) and change in detrusor pressure (pdet) as a measure of the distensibility of the bladder. Compliance = Change Vol / change Pdet. Compliance reflects the amount of fluid in the bladder to increase the bladder pressure by 1 cm H2O (mL per cm H2O)

Filling cystometry - bladder oversensitivity

Investigation

Increased sensation during bladder filling with: early first desire to void; early strong desire to void, which occurs at low bladder volume; lower cystometric bladder capacity; no abnormal increases in detrusor pressure.

Filling cystometry - bladder sensation*Investigation*

Usually assessed by questioning the individual in relation to the fullness of the bladder during cystometry.

Filling cystometry - cystometric capacity*Investigation*

Bladder volume at the end of filling cystometry, when "permission to void" is usually given by the urodynamicist. This endpoint and the level of the woman's bladder sensation at that time, for example, "normal desire to void", should be noted.

Filling cystometry - cystometric capacity (mL)*Investigation*

Bladder volume at the end of filling cystometry, when a "permission to void" is usually given by the urodynamicist.

Filling cystometry - detrusor overactivity*Investigation*

The occurrence of detrusor contraction(s) during filling cystometry. These contractions, which may be spontaneous or provoked, produce a waveform on the cystogram, of variable duration and amplitude. Symptoms, e.g. urgency and/or urgency incontinence or perception of contraction may or may not occur.

Filling cystometry - filling rate (male)*Investigation*

The filling rate, including any changes during testing, should be noted on the urodynamic report. A medium fill rate (25-50 mL/min) should be applicable in most routine studies. Much slower filling rates (under 25 mL/min) are appropriate in men where there are concerns for poor compliance or with a bladder diary showing low bladder capacity or those with neuropathic bladder. A higher filling rate is greater than 50mL/min.

Filling cystometry - first desire to void*Investigation*

The first feeling that the individual may wish to pass urine. The volume at which this occurs should be noted.

Filling cystometry - first sensation of bladder filling*Investigation*

The feeling when the individual first becomes aware of bladder filling.

Filling Cystometry - First sensation of bladder filling*Investigation***Filling cystometry - Idiopathic (primary) detrusor overactivity***Investigation*

No identifiable cause for the involuntary detrusor contraction(s)

Filling cystometry - incompetent urethral closure mechanism*Investigation*

Leakage occurs during activities which might raise intra-abdominal pressure in the absence of a detrusor contraction.

Filling cystometry - Initial bladder volume*Investigation*

Bladder should be empty.

Filling cystometry - maximum cystometric capacity (mL)*Investigation*

In an individual with normal sensation, this is the volume during filling cystometry when voiding can no longer be delayed.

Filling cystometry - Neurogenic (secondary) detrusor overactivity*Investigation*

Detrusor overactivity and evidence (history; visible or measurable deficit) of a relevant neurological disorder.

Filling cystometry - non-specific bladder awareness*Investigation*

Perception of bladder filling as abdominal fullness, vegetative symptoms (nausea, vomiting, faintness), spasticity or other "non-bladder" awareness, in the setting of a clinically relevant neurologic disorder (e.g. incomplete spinal cord lesion).

Filling cystometry - normal detrusor activity/function.*Investigation*

There is little or no change in detrusor pressure with filling or any provocative activities.

Filling cystometry - normal urethral closure mechanism.*Investigation*

A positive urethral closure pressure is maintained during bladder filling, even in the presence of increased abdominal pressure, although it may be overcome by detrusor overactivity.

Filling cystometry - pain*Investigation*

The complaint of pain during filling cystometry is abnormal. Its site, character and duration should be noted.

Filling cystometry - Position of female patient*Investigation*

Sitting position is more provocative for abnormal detrusor activity than the supine position. At some point in the test, filling might desirably take place with the woman standing.

Filling cystometry - position of male patient*Investigation*

Sitting (standing) position is more provocative for abnormal detrusor activity (i.e. overactivity) than the supine position. At some point in the test, filling might desirably take place with the patient standing (in those patients able to do so). Many men will void standing.

Filling cystometry - reduced bladder sensation.*Investigation*

Bladder sensation perceived to be diminished during filling cystometry.

Filling cystometry - temperature of fluid*Investigation*

Fluid at room temperature is mostly used. It can be warmed to body temperature but without evidence that this influences results.

Filling cystometry - urgency.*Investigation*

Sudden, compelling desire to void which is difficult to defer.

Filling cystometry - urodynamic stress incontinence (USI)*Investigation*

Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

Filling cystometry: first sensation of bladder filling.*Investigation*

The feeling when the individual first becomes aware of bladder filling. Filling volume when this occurs can be noted/recorded.

Filling cystometry: normal desire to void.*Investigation*

The feeling that leads the individual to void at the next convenient moment, but voiding can be delayed if necessary

Filling cystometry: strong desire to void.*Investigation*

The persistent desire to void without the fear of leakage.

First desire to void - filling cystometry*Investigation*

The first feeling that an individual may wish to void. Volume when this occurs may be noted/recorded.

First morning void*Sign*

The first void after waking with the intention of rising.

First sensation of bladder filling - filling cystometry*Investigation*

The feeling when the individual first becomes aware of bladder filling.

First sensation of bladder filling - Filling cystometry*Investigation*

The feeling when the individual first becomes aware of bladder filling. Filling volume when this occurs can be noted/recorded.

Fistula in ano*Sign*

An anal fistula is an abnormal connection between the anal canal epithelium (or rarely rectal epithelium) and the skin epithelium. Patients may complain of pain, swelling, intermittent discharge of blood or pus from the fistula and recurrent abscesses formation.

Flatal incontinence.*Symptom*

Complaint of involuntary loss of flatus (gas).

Flaturia*Symptom*

Complaint of passage of gas per urethra.

G**Generalised Vulvar Pain Syndrome***Symptom*

i. Diffuse vulvar pain perceived to be in the vestibule or beyond. ii. Dyspareunia. iii. Provocation of pain with touch, pressure or friction.

Genital hiatus*Sign*

This is measured from the middle of the external urethral meatus to the posterior margin of the hymen.

Flexible sigmoidoscopy*Investigation*

This refers to the inspection of the distal colonic mucosa, typically up to the splenic flexure, with a 60 cm flexible endoscope following enema preparation.

Flow delay (unit: s) - pressure flow studies*Investigation*

The time elapsed from initial rise in pressure to the onset of flow. This is the initial isovolumetric contraction period of micturition. It reflects the time necessary for the fluid to pass from the point of pressure measurement to the uroflow transducer.

Flow time (FT - unit: s)*Investigation*

Time over which measurable flow actually occurs.

Frequency-volume chart (FVC)*Sign*

Frequency-volume chart (FVC): The recording of the time of each micturition together with the volume voided for at least 24 hours. Ideally a minimum of three days of recording (not necessarily consecutive) will generally provide more useful clinical data. It is relevant to discriminate daytime and night-time micturition.

Functional Anal Length - Anal Manometry*Investigation*

Functional anal canal length is defined as the length of the anal canal over which resting pressure exceeds that of the rectum by greater than 5mmHg or, alternatively, as the length of the anal canal over which pressures are greater than half of the maximal pressure at rest.

Functional profile length - Urethral pressure profile - female*Investigation*

The length of the urethra along which the urethral pressure exceeds intravesical pressure in women.

Functional profile length (on stress) - urethral pressure profile (female)*Investigation*

The length over which the urethral pressure exceeds the intravesical pressure on stress.

Genital skin signs*Sign*

Excoriation, redness, irritation secondary to urinary incontinence and the effect of pads or diapers. (ii) Mycotic infections (balanoposthitis, intertrigo, or scrotal): moist, red pruritic skin usually in men with urinary or fecal incontinence, immune suppression or poorly controlled diabetes mellitus; (iii) Skin pigmentation: balanitis xerotica obliterans (BXO – syn. lichen sclerosus) and vitiligo may cause depigmentation (penile skin, scrotum, glans); (iv) Cutaneous manifestations of sexually transmitted diseases: vesicles, ulcers.

Genito-Pelvic Pain/Penetration Disorder

Diagnosis

Persistent or recurrent difficulties with 1 or more of the following: (i) vaginal penetration during intercourse; (ii) marked vulvovaginal or pelvic pain during intercourse or penetration attempts; (iii) marked fear or anxiety about vulvovaginal or pelvic pain in anticipation of, during, or as a result of vaginal penetration; (iv) marked tensing or tightening of the pelvic floor muscles during attempted vaginal penetration.

Genito-pelvic pain/penetration disorder" (GPPPD)

Diagnosis

The categories of vaginismus and dyspareunia have been combined to create "genito-pelvic pain/penetration disorder" (GPPPD)

Genitourinary syndrome of menopause (urogenital aging)

Sign

(i) Pallor/erythema: Pale genital mucosa; (ii) Loss of vaginal rugae: vaginal rugae flush with the skin; (iii) Tissue fragility/fissures: genital mucosa that is easily broken or damaged; (iv) Vaginal petechiae: a petechia, plural petechiae, is a small (1–2 mm) red or purple spot on the skin, caused by a minor bleed (from broken capillary blood vessels); (v) Urethral eversion: urethral epithelium turned outside the lumen; (vi) Urethral prolapse: complaint of a lump at the external urethral meatus; (vii) Loss of hymenal remnants: absence of hymenal remnants; (viii) Prominence of urethral meatus vaginal canal shortening and narrowing: Introital retraction.

H

Halban procedure

Surgery – Female

Obliteration of the cul-de-sac by using successive sutures placed sagittally between the uterosacral ligaments.

Hemospermia

Symptom

Complaint of the appearance of visible blood in the seminal fluid. Colour of the seminal fluid may be red or brown.

Hematuria

Symptom

Complaint of passage of visible blood mixed with urine. This may be initial (at the beginning), terminal (at the end) or total (throughout bladder emptying).

Hemorrhoids

Sign

Abnormality of the normal cushion of specialized, highly vascular tissue in the anal canal in the submucosal space. Hemorrhoids can be divided into those originating above the dentate line which are termed internal and those originating below the dentate line which are termed external. Internal hemorrhoids are graded as follows: (I) Grade I bleeding without prolapse; (II) Grade II prolapse with spontaneous reduction; (III) Grade III prolapse with manual reduction; (IV) Grade IV incarcerated, irreducible prolapse. Grade II and Grade III hemorrhoids will become evident on asking the patient to bear down and grade IV hemorrhoids are obvious at the time of the examination. A proctoscopy is essential in examining for hemorrhoids unless they are completely prolapsed.

Good Urodynamic Practice - Key Elements

Investigation

A Good Urodynamic Practice comprises three main elements: . A clear indication for and appropriate selection of relevant test measurements and procedures; Precise measurement with data quality control and complete documentation; Accurate analysis and critical reporting of results.

Graft

Surgery – Female

Any tissue or organ for transplantation. This term would be used to refer to biological materials inserted. (i) Autologous grafts: From patient's own tissues e.g. rectus sheath or fascia lata. (ii) Allografts: From post-mortem tissue banks. (iii) Xenografts: From other species e.g. modified porcine dermis, porcine small intestine and bovine pericardium. Terminology for grafts has not been separated into the different applications for POP and continence surgery.

Granulation

Surgery – Complication related

Fleshy connective tissue projections on the surface of a wound, ulcer or inflamed tissue surface.

Hesitancy

Symptom

Complaint of a delay in initiating voiding (when the individual is ready to pass urine).

Hispareunia

Symptom

Male partner pain with intercourse after female reconstructive surgery.

Hormonal assessment in female sexual dysfunction

Investigation

Hormones such as estrogen, progestin, and androgen influence sexual function and imbalance may lead to various symptoms including decreased libido, lack of arousal, vaginal dryness and dyspareunia. Depending on the underlying suspected conditions associated with sexual dysfunction, hormonal investigations such as estradiol (or FSH if symptoms of deficiency), serum testosterone, dehydroepiandrosterone acetate sulphate (DHEAS), free testosterone, dihydrotestosterone, prolactin, and thyroid function testing may be considered. Moreover, the evaluation of vaginal pH and vaginal maturation index (ie, percentage of parabasal cells, intermediate cells, and superficial cells) can be helpful in women with vulvovaginal atrophy as it has been shown to be correlated with patient's symptomatology.

Hygiene

Conservative Management – Female

Bladder hygiene: Bladder hygiene prevents UTI by using techniques such as wiping the urethral meatus with clean wipes in an anterior-to-posterior direction after voiding, wearing clean underwear, keeping the genital area clean, and emptying the bladder before and after sexual intercourse. Vulval hygiene: involves maintaining a clean perineum by means of washing the area on a regular basis, and wearing cotton underwear. To avoid vulval irritation, shampoo, perfumed creams or soap should be avoided. Anal hygiene:

involves keeping the perianal region clean, which is especially important when fecal seepage is present. Advice includes using soft toilet paper or moist wipes (avoiding any with an alcohol base), always wiping from front to back, washing after a bowel movement, then gently patting dry. To avoid irritation from products, the vulval hygiene advice above should be followed.

Hypersensitivity

Symptom

Increased nerve activity from a standardized stimulus with an expected tissue/clinical response. The underlying mechanism remains to be defined.

Hypertonicity

Sign

An increase in muscle tone related to either elevated contractile activity

and/or passive tension in the muscle. This term is used to describe increased muscle tone of neurogenic origin.

Hypospadias

Sign

Urethral meatus sited on ventral surface of the penis, either congenital or acquired, proximal to its normal position at the tip of the glans. Types: glans penis (glandular hypospadias); sulcus (coronal hypospadias); shaft (penile hypospadias); scrotum (scrotal hypospadias); perineum (perineal hypospadias).

ICS STANDARD

Investigation

Best practice, based on evidence, with the use of standard terms and standard techniques, evaluated and reported clinically or scientifically, in a complete and validated manner.

ICS Standard Urodynamic Information Leaflet

Investigation

Overview of the content of an ICS Standard Information Leaflet for Urodynamics.

- What is a urodynamic investigation?
- That the tests involves insertion of catheters into the bladder and rectum, and relevant technical issues.
- What is the usefulness of urodynamics? Why is the testing done?
- What are the different steps of urodynamic investigation and how they are performed (e.g. uroflowmetry, cystometry, urethral pressure measurement and pressure-flow)
- How dignity, communication and comfort during the investigation are maximized (What you do or offer in this regard).
- The symptoms that may occur following the investigation, what they indicate and how can they be handled or prevented, e.g. the fact that mild discomfort, frequency, dysuria and haematuria may be experienced, and a urinary tract infection may occasionally develop.
- Additional information including length of the investigation, sterility of relevant parts of equipment, lack of 'injections'.
- That the test is done interactively and that communication with the patient is a necessary part of the test.
- What the patient should do before the test (e.g. arrive if possible with a full bladder for uroflow, and also with an empty bowel if possible).
- Whether the patient should continue medication before the test, or whether there are specific medications that the patient should not take in (a defined period) before the test. Note: This should be individualized, e.g. with a tick box or a written instruction of the requester.
- What the patient should do after the test.
 - o e.g.: Immediately drink one portion of ½ - 1L extra fluid to ensure prompt voiding again, in order to relieve urethral irritation rapidly.
 - o All usual activities are permitted after the test.
 - o Symptoms and signs of urinary tract infection and what steps to take if these arise.

ICS STANDARD URODYNAMIC PROTOCOL (ICS-SUP)

Investigation

A patient undergoing collection of a clinical history (should include (a) valid

symptom and bother score(s) and medication list), relevant clinical examination, (3 days-) bladder diary, representative uroflowmetry with post-void residual (PVR) and a complete ICS standard urodynamic test, is referred to as having had the 'ICS standard urodynamics protocol (ICS-SUP).

ICS Standard Urodynamic Test

Investigation

Free uroflowmetry, postvoid residual, cystometry and pressure-flow study are termed ICS standard urodynamic test (ICS-SUT).

ICS Standard Urodynamics Report

Investigation

- Overall judgement of the technical quality and the clinical reliability of the test to represent the lower urinary tract function 'as usual', to be evaluated by the person who performed the tests.
- Uroflowmetry: Voiding position, urge (before the test) and representativeness, as reported by the patient.
- Introduction of catheters: sensation; (if occurring; pain), muscular (pelvic or adductor) defence and -perceptibly unusual- obstruction(s) during insertion.
- Position(s) during cystometry and pressure flow study.
- Patient's ability to report filling sensations and/ or urgency and/ or urine loss.
- Method of urodynamic stress test (if applicable).
- Pressure-flow: position and representativeness as reported by the patient.
- Accessory tests or measurements (if applicable -no further standard).
- Representativeness of the tests to reflect the 'usual LUT behaviour' as reported by the patient.
- Filling sensation (with volumes) -diagnosis or urodynamic condition.
- Cystometry (detrusor) pressure pattern -diagnosis.
- Pressure-flow -diagnosis (compared with uroflowmetry) includes:
 - Bladder outflow function, or obstruction (and the method for assessment)
 - Detrusor contraction, (and the method for assessment)

Idiopathic (primary) detrusor overactivity (DO) - filling cystometry

Investigation

No identifiable cause for involuntary detrusor contraction(s).

Impaired cognition urinary incontinence*Symptom*

Complaint of periodic urinary incontinence that the individual with cognitive impairment reports to have occurred without being aware of it.

Impaired mobility urinary incontinence*Symptom*

Complaint of inability to reach the toilet on time for voiding because of physical or medical disability (similar to “disability associated urinary incontinence”).

Implant

Surgery – Female

A surgically inserted or embedded prosthesis or graft.

Inability to void*Symptom*

Complaint of inability to initiate voiding despite an intensive effort (by abdominal straining, Valsalva or suprapubic pressure).

Incompetent urethral closure mechanism - filling cystometry*Investigation*

Leakage occurs during activities which might raise intra-abdominal pressure in the absence of a detrusor contraction.

Incompetent urethral closure mechanism (female)*Investigation*

Leakage of urine occurs during activities which might raise intra-abdominal pressure in the absence of a detrusor contraction.

Increased bladder filling sensation*Symptom*

Complaint that the sensation of bladder filling occurs earlier or is more intense or persistent to that previously experienced. n.b. This differs from urgency by the fact that micturition can be postponed despite the desire to void.

Increased daytime defecation (female)*Symptom*

Complaint that defecation occurs more frequently during waking hours than previously deemed normal by the woman.

Increased daytime urinary frequency*Symptom*

Complaint that voiding occurs more frequently during waking hours than previously deemed normal by the individual (or caregivers).

Increased (high) semen volume*Symptom*

Complaint of higher amount of seminal fluid than normal or previously experienced.

Increased libido (male)*Symptom*

Complaint of increased interest in sexual activity in comparison with previous experience.

Increased rectal sensation (rectal hypersensitivity)*Symptom*

Complaint of a desire to defecate (during rectal filling) that occurs earlier or

is more persistent to that previously experienced. Can be (i) first sensation; (ii) urge sensation; (iii) maximum tolerated volume.

Increased Urinary Frequency*Symptom*

Complaint that voiding occurs more frequently than deemed normal by the man or woman. Time of day and number of voids are not specified.

Increased urinary frequency*Symptom*

Complaint that voiding occurs more frequently than deemed normal by the individual (or caregivers). Time of day and number of voids are not specified.

Indwelling catheterization

Conservative Management – General

An indwelling catheter remains in the bladder, urinary reservoir or urinary conduit for a period longer than one emptying.

Inflammatory Bowel Disease (IBD)*Diagnosis*

Inflammatory Bowel Disease (IBD)—Complaint of recurrent abdominal pain and discomfort of at least 3 days per month in the last 3 months. The majority of IBD patients experience periods of flares and remission.

i. Abdominal and anal pain, diarrhea which may be associated with blood, suggestive of ulcerative colitis. ii. Abdominal pain, fatigue, prolonged diarrhea with crampy abdominal pain, weight loss, and fever, with or without gross bleeding. Irregular bowel habits, with possible blood in the stool, are suggestive of Crohn's disease.

Infrasacral (cauda equina or peripheral nerves) lesion (CEPNL)*Diagnosis*

This is a neurological lesion affecting the cauda equine and/or peripheral nerves. Neurogenic lower urinary tract dysfunction in CEPNL: an acontractile detrusor and/or stress urinary incontinence may be present. In diabetic neuropathy, detrusor overactivity can be seen in combination with the above.

Inguinal protrusion*Sign*

Examination and differentiation of hernia from hydrocele or cyst of spermatic cord or groin lymph nodes.

Insensible urinary incontinence*Symptom*

Complaint of urinary incontinence where the individual is aware of urine leakage but unaware of how or when it occurred.

Insertion

Surgery – Complication related

Putting in.

Intercurrent pathology - ultrasound imaging (male)*Investigation*

Prostate volume (transrectal), tumor, hydronephrosis, scrotal abnormalities.

Intermittency (Intermittent stream)*Symptom*

Complaint of urine flow that stops and starts on one or more occasions during one voiding episode.

Intermittent catheterization (IC)*Conservative Management – General*

Drainage of the bladder or a urinary reservoir with subsequent removal of the catheter mostly at regular intervals.

Interpretation of Normality of Free Uroflowmetry (Female)*Investigation*

Because of the strong dependency of urine flow rates on voided volume, they are best referenced to nomograms where the cutoff for abnormally slow (MUFR, AUFR) has been determined and validated, as under the 10th centile of the respective Liverpool nomogram. References to a specific urineflow rate as the lower limit of normal provided a specific volume has been voided require further validation studies.

Interpretation of normality of free uroflowmetry (men)*Investigation*

Because of the strong dependency of urine flow rates in men on voided volume and age, they are best referenced to nomograms where the cutoff for normality has been determined and validated. Ideally, abnormal uroflowmetry studies should be repeated.

Interstitial Cystitis*Diagnosis*

As for Bladder Pain Syndrome (BPS), i.e. Persistent or recurrent chronic pelvic pain, pressure or discomfort perceived to be related to the urinary bladder accompanied by at least one other urinary symptom such as an urgent need to void or urinary frequency, though with a known Hunner's lesion present. Pain, pressure or discomfort often increases with bladder filling.

Intravaginal Devices*Conservative Management – Female*

Intravaginal devices are intended to provide some support to the bladder neck and possibly some compression to the urethra, to correct urinary stress incontinence. These can be traditional tampons, pessaries, and contraceptive diaphragms and devices designed specifically to support the bladder neck (removable, reusable intravaginal ring or single-use disposable devices).

Intravenous urography (IVU)*Imaging*

This provides an anatomical outline of the urinary tract including a nephrogram prior to passage of the contrast to the calyces, renal pelvis, ureter and bladder.

Intravesical pressure (Pves - cm H₂O)*Investigation*

The pressure within the bladder (as directly measured by the intravesical catheter)

Intravesical prostatic protrusion (IPP) - ultrasound imaging (male)*Investigation*

The distance from the bladder base until the tip of the prostate in the bladder lumen. It is recommended to fill the bladder with 100-200mLs of fluid in order to receive representative measurements; bladder filling over 400 mL will lower IPP values. The IPP measurement can be divided into three grades: grade I = 0-4.9 mm; grade II = 5-10 mm; grade III = > 10 mm. IPP grade III is associated with prostate-related BOO.

Intrinsic sphincter deficiency (ISD)*Diagnosis*

Very weakened urethral closure mechanism.

Intrinsic sphincter deficiency (ISD) - Filling cystometry*Investigation*

Very weakened urethral closure mechanism.

Intusseption*Diagnosis*

Full thickness invagination of the upper rectum without extrusion through the anus leading to interruption of flow of the fecal stream.

Invagination*Surgery – Complication related*

Vaginal mucosa folded and entrapped on itself, characterized by a fixed and tight area on examination.

Invasive Urodynamics*Investigation*

Any test that is invasive, as it involves insertion of one or more catheters or any other transducers into the bladder and/ or other body cavities, or insertion of probes or needles, for example for EMG measurement.

Irritable Bowel Syndrome (IBS) - Functional (non-inflammatory)*Diagnosis*

i. Recurrent episodes of abdominal pain. ii. Changes in frequency, form or consistency of the stool. iii. Sensation of incomplete evacuation, straining, fecal urgency. iv. Sensation of nausea, fatigue, fullness, vomiting. v. Recurrent abdominal pain or discomfort at least 3 days/month in the last 3 months associated with two or more of the following: 1. Improvement of pain with defecation. 2. Onset associated with change in frequency of stool. 3. Onset associated with a change in the form (appearance) of stool

J**Joint therapies***Conservative Management – Female*

1. Mobilization: skilled passive movement of a skeletal joint including graded passive oscillations at the joint to improve joint mobility, e.g., movement of the coccyx. 2. Manipulation: a passive (for the patient) therapeutic movement, usually of small amplitude and high velocity, at the end of the available joint range. Manipulation is a sudden small thrust that is controlled by the clinician.

L

Labial thermistor

Investigation

Temperature measurement evaluated with a small metal clip attached to the labia minorum and equipped with a sensitive thermistor.

Laparoscopic Assisted Vaginal Hysterectomy

Surgery – Female

A laparoscopic approach is used to divide the three uterine pedicles (broad ligament, uterine vessels and uterosacral/cardinal). The uterus is removed vaginal with the vaginal vault oversewn laparoscopically.

Laser Doppler imaging of genital blood flow

Investigation

An imager positioned close to the vulva allows the assessment of skin/mucosae microcirculation at a depth of up to 2-3 mm. This method has been used to assess response to sexual stimulation and correlated with subjective arousal. It has also led to a better understanding of microvascular differences in women with provoked vestibulodynia compared to asymptomatic controls.

Leak point pressure

Investigation

The leak point pressure is the pressure (spontaneous or provoked) that has caused fluid to be expelled from the bladder at the moment that it is visible outside the urethra (may also be used for extra-urethral urine loss or stoma). This may be Abdominal, Cough or Valsalva LPP or Detrusor LPP. Provocation and pressure recording site ('type of LPP') should be reported.

Levator defects/ trauma

Sign

Per-vaginal palpation for levator injury/defect/ "avulsion".

Lifestyle Modification for Pelvic Floor Dysfunction

Conservative Management – Female

Lifestyle modification is the application of interventions in the management of lifestyle-related health problems, e.g., change to a healthy diet and regular participation in physical activity and smoking cessation. The following lifestyle modifications may be applied to treat pelvic floor dysfunctions, either in combination with other therapies or as "stand alone" treatments.

1. Fluid consumption/restriction: fluid consumption is the intake of fluid over 24h. Fluid restriction is the limitation of fluid to a prescribed amount over a period of 24h. These measures are often undertaken as part of a bladder training process.
2. Dietary modification: an alteration or adjustment of food to treat bowel disorders (e.g., constipation and fecal incontinence) or urinary disorders (e.g., incontinence or urgency), for example, increasing fiber to treat constipation. The specifics of the dietary changes should be described.
3. Elimination diet: a form of dietary modification. A diet designed to detect what ingredient in the food causes symptoms in the patient, food items to which the patient may be sensitive are withdrawn separately and successfully from the diet until the item that causes the symptoms is discovered. This is used frequently in patients with fecal incontinence, urinary urgency and urinary urgency incontinence (bladder diet). Physical activity: any body movement produced by the skeletal muscles that results in a substantial increase above resting energy expenditure. Physical activity can be done at work, as transportation, as household and other chores, and as leisure time/sport and fitness activities.

Localised Vulvar Pain Syndrome

Symptom

i. Vestibular pain syndrome—pain localized to one or more portions of the vulvar vestibule. ii. Clitoral pain syndrome—pain localized to or perceived in the clitoris.

Low backache related to POP

Symptom

Complaint of low, sacral (or "period-like") backache associated temporally with pelvic organ prolapse (POP)

Lower urinary tract symptom (LUTS)

Symptom

A symptom related to the lower urinary tract. It may originate from the bladder, urethra, prostate (men) and/or adjacent pelvic floor or pelvic organs, or at times be referred from similarly innervated anatomy e.g. lower ureter.

M

Magnetic resonance imaging - male - general comments

Imaging

MRI provides the opportunity to examine the soft tissue structures of the pelvic support apparatus. It is non-invasive, has excellent soft tissue contrast resolution without exposure to ionizing radiation and allows the study of function of pelvic floor structures under different dynamic conditions. Several anatomical landmarks used for pelvic measurements are also easily identified in MRI and most measurements are thus highly reproducible. T-weighting assists enhancement of fluid-filled structures.

Magnetic resonance imaging - uses in female

Imaging

MRI provides the opportunity to examine the soft tissue structures of the pelvic support apparatus in toto. It is non-invasive, has excellent soft tissue contrast resolution without exposure to ionizing radiation and allows the study of function of pelvic floor structures under different dynamic conditions such as increased abdominal pressure during Valsalva. Several anatomical landmarks used for pelvic measurements are also easily identified in MRI and most measurements are thus highly reproducible. Currently the clinical value of these examinations is still under investigation with its impact on therapeutic decisions not yet fully evaluated.

Magnetic Resonance Imaging in Urogynecology - Current Possible Measurements

Imaging

Bladder neck and cervical descent/mobility: . Position of bladder neck and cervix at rest and on Valsalva. Pubo-coccygeal line: A line extending from the inferior border of the pubic symphysis to the last joint of the coccyx. Bladder neck or cervical descent >2 cm below this line with straining indicates weakness of the pelvic floor. If alternative landmarks are used in scientific papers they should be clearly described.

(b) Intercurrent pelvic pathology: For example, fibroids, ovarian pathology. (c) Uterine version :Anteverted or retroverted; flexion at the isthmus. (d) Bladder abnormalities: For example, tumor; foreign body. (e) Urethral abnormality: For example, diverticulum. (f) Postoperative findings: For example, bladder neck mobility. (g) Pelvic floor measurements/levator defects: Assessment of the configuration of pelvic floor muscles, in particular, the levator ani. (h) Descent of pelvic organs

Magnetic resonance imaging (MRI) - current female applications

Imaging

(i) Bladder neck and cervical descent / mobility: position of bladder neck and cervix at rest and on Valsalva; (ii) Intercurrent pelvic pathology: e.g. fibroids, ovarian pathology; (iii) Uterine version: anteverted or retroverted; flexion at the isthmus; (iv) Bladder abnormalities: e.g. tumor; foreign body; (v) Urethral abnormality: e.g. diverticulum; (vi) Postoperative findings: e.g. bladder neck mobility; (vii) Pelvic floor measurements / levator defects: assessment of the configuration of pelvic floor muscles, in particular, the levator ani; (ix) Descent of pelvic organs:

Magnetic resonance imaging (MRI - male)

Imaging

Excellent soft tissue contrast resolution looking for benign enlargement, cancer, cysts, prostate-rectal fistulae.

Magnetic resonance imaging (MRI) - (male) - current possible measurements

Imaging

(1) Bladder abnormalities: e.g. tumor; foreign body, bladder wall abnormalities, intestine-vesical fistulae; (2) Urethral abnormality: e.g. diverticulum, recto-urethral fistulae. (3) Urethral sphincter length: prediction of post-prostatectomy incontinence; (4) Prostate abnormalities: e.g. benign enlargement, cancer, cysts, prostato-rectal fistulae; (5) Intercurrent abnormalities: e.g. rectum - rectal dynamics are assessed during evacuation after adding ultrasound gel to the rectum. Anorectal and pelvic floor motion can be imaged providing pelvic images at rest and when the subject strains; (6) Congenital abnormalities: Detection of Mullerian duct remnants, aberrantly inserted ureters and duplicated pelvic structures; (7) Standardized MRI prostate imaging: PI-RADS – prostate imaging reporting and data system.

Magnetic Resonance Imaging (MRI) in Urogynecology

Imaging

MRI provides the opportunity to examine the soft tissue structures of the pelvic support apparatus in toto. It is noninvasive, has excellent soft tissue contrast resolution without exposure to ionizing radiation, and allows the study of function of pelvic floor structures under different dynamic conditions such as increased abdominal pressure during Valsalva. Several anatomical landmarks used for pelvic measurements are also easily identified in MRI and most measurements are thus highly reproducible. Currently, the clinical value of these examinations is still under investigation with its impact on therapeutic decisions not yet fully evaluated.

Magnetic resonance imaging (MRI -male) - Bladder abnormalities

Imaging

Excellent soft tissue contrast resolution looking at bladder tumor, foreign body, bladder wall abnormalities, intestinal-vesical fistulae.

Magnetic resonance imaging (MRI -male) - Urethral abnormalities

Imaging

Excellent soft tissue contrast resolution looking for urethral diverticula, para-urethral cysts, recto-urethral fistulae.

Magnetic Resonance Imaging (MRI) of the Pelvic Floor

Imaging

Magnetic resonance imaging (MRI) of the pelvic floor: MRI allows the detection of ligamentous and muscular pelvic floor structures in fine detail. Although it does not use ionising radiation, it is a high cost technique. Static MRI relies on static sequences and high spatial resolution images, to delineate the passive and active elements of the pelvic organ support system. Most commonly, images are acquired in axial, sagittal and coronal planes. MRI has been proposed to be a useful method for diagnosing and staging POP. Several lines and levels of reference have been described in the literature. The most commonly used ones are either a line drawn from the inferior margin of the pubis symphysis to the last coccygeal joint (pubococcygeal line—PCL), in the sagittal plane, noted as midpubic line (MPL). Other applications of MRI are the assessment of the LAM morphology (size, thickness volume) and detection of LAM injuries/ defects/ (“avulsion”).

Magnetic resonance imaging (MRI-male)

Imaging

Excellent soft tissue contrast resolution looking for detection of mullerian remnants, aberrantly inserted ureters and duplicated pelvic structures.

Magnetic resonance imaging of the vulvar area

Imaging

Evaluation of the increase in clitoral structure volume related to tissue engorgement occurring during arousal.

Magnetic stimulation

Conservative Management – Female

Magnetic stimulation (or extracorporeal magnetic innervation): a pulsed magnetic technology developed for the transmission of nerve impulses that is aimed at causing PFM contraction. Patients receive therapy by sitting in a chair, which contains the device that produces the pulsing magnetic fields.

Main (Chief) complaint

Symptom

The primary symptom that an individual states is the main reason for seeking medical advice.

Main sleep period

Sign

The period from the time of falling asleep to the time of rising for the next day (as recorded on chart or diary).

Male Chronic Genital Pain Syndromes

Diagnosis

Male genital pain syndromes are often associated with symptoms suggestive of lower urinary tract and sexual dysfunction. Common complaints: genital pain, uncomfortable urination, dysuria, sensation of residual urine, increased daytime frequency, slow stream, urgency, dyspareunia. Absence of infection, previous operations, or other obvious pathology.

Male examination - General principles.

Sign

A comprehensive physical examination is done to seek potential influences on symptoms. It should include abdominal examination, focussing on the suprapubic area to detect an enlarged bladder, or other abdominal mass, and digital examination of the rectum (prostate) as well as examination of

the external genitalia, the perineum and lower limbs. The hernia orifices should also be evaluated. Penile lesions including meatal stenosis, phimosis and penile cancer must be excluded. If a neurological diagnosis is suspected, then a focused neurological examination with evaluation of perianal crude and pinprick sensations need to be tested. Also, the anal muscle tone can be assessed with finger in the rectum and asking the patient to squeeze.

Male foreskin abnormalities

Sign

. Tumor or infection (balanoposthitis i.e. inflammation of the glans penis and overlying foreskin).

. Phimosis: Partial or complete inability to retract the prepuce due to adhesion between the glans and the prepuce or a preputial ring.

Paraphimosis: Entrapment of the prepuce behind the glans.

Male general (visual) observations

Sign

(I) Mobility: generalized muscle strength and ability to ambulate independently or with assistance.

(ii) Skin: jaundice or pallor or skin irritation due to urinary loss.

(iii) Nutritional Status: cachexia (possible underlying malignancy); obesity (possible endocrine abnormality including metabolic syndrome).

(iv) Edema of genitalia and lower extremities: Possible cardiac decompensation, renal failure, nephrotic syndrome, or pelvic and/or retroperitoneal lymphatic obstruction.

Manual defecatory assistance: External - perineal pressure or buttock separation.

Symptom

Complaint of the need to press on the perineum or separate the buttocks to assist defecation.

Manual defecatory assistance: Internal - anorectal digitation

Symptom

Complaint of the need to use of fingers in the rectum to manually assist in evacuation of stool contents by scooping, stretching and/or stimulation.

Manual Therapy (female)

Conservative Management – Female

Manual therapy is a clinical approach utilizing skilled, specific hands-on techniques, including but not limited to, massage, manipulation or mobilization.

Maximum cystometric capacity - filling cystometry (mL)

Investigation

In individuals with normal sensation, this is the volume during filling cystometry when voiding can no longer be delayed.

Maximum detrusor pressure (Pdet-max – unit: cm H20) - pressure flow studies

Investigation

Maximum registered detrusor pressure during voiding.

Maximum urethral closure pressure (MUCP) - female

Investigation

Maximum pressure in the UCPP, i.e. the maximum difference between the urethral pressure and the intravesical pressure.

Maximum urethral pressure (MUP) - female

Investigation

Maximum pressure in the UPP.

Maximum urine flow rate (MUFR - mL/s) - Qmax

Investigation

Maximum measured value of the urine flow rate (corrected for artefacts).

Maximum voided volume

Sign

Highest voided volume recorded during an assessment period of a frequency-volume chart (FVC).

Mean maximum voided volume (functional capacity)

Sign

Mean maximum voided volume in everyday activities (as recorded in chart or diary).

Measurements of labial and vaginal oxygenation

Investigation

A heated electrode and oxygen monitor are used to evaluate the arterial partial pressure of oxygen (PO₂) transcutaneously. The temperature of the electrode is kept at a constant elevated temperature by an electric current. Increase in blood flow under the electrode results in more effective temperature dissipation (heat loss) with the result that more current is needed to maintain the electrode at its prefixed temperature. The changes in current provide an indirect measurement of blood flow during sexual stimuli. The electrode also monitors oxygen diffusion across the skin.

Measuring Outcome in POP Surgery

Surgery – Female

Measuring Outcome in POP surgeries: As per IUGA-ICS Report on outcome measures for POP surgery, every study evaluating POP surgery should report. (i) Perioperative data: i.e. blood loss, operating time, length of hospital stay, return to normal activities and complications. (ii) Subjective (patient-reported) outcomes: At its simplest level this can be reported as the presence or absence of vaginal bulge. Patient satisfaction and quality of life can be measured by validated instruments that cover prolapse, urinary, bowel and sexual function. (iii) Objective outcomes: POP-Q measurement generally and should be tabulated with absolute values and percentages to allow other studies to compare results. (iv) Secondary outcomes (e.g. lower urinary tract symptoms, stress urinary incontinence or bowel and sexual dysfunction) in their studies whenever possible.

Median functional bladder capacity

Sign

Median maximum voided volume in everyday activities (as per frequency-volume chart -FVC)

Mesh

Surgery – Female

A (prosthetic) network fabric or structure; open spaces or interstices between the strands of the net. The use of this term would be for POP surgery with synthetic materials.

Mesh kit

Surgery – Female

A set of articles or equipment utilised for POP surgery containing mesh with a system of trocars designed to achieve mesh fixation or allow mesh passage to or through specific areas within the pelvis.

Mesh, Tape & Graft Surgery Complication - CTS Classification - Category (C) 1A - 3A

Surgery – Complication related

1A–3A: Asymptomatic—Abnormal mesh finding These are generally phy-

sician-diagnosed at any episode of clinical care. It can be argued that the “abnormal prosthesis or graft finding” aspects of category 1A, in particular, aren’t really complications as the patient isn’t bothered by the potential problem. It may be, however, that the woman may not have engaged in an activity that is likely to provoke symptoms for herself, e.g. pain or bleeding during sexual intercourse (or for her partner), which would convert these complications to category 1B. 1Aa–3Aa: Asymptomatic—Abnormal mesh finding —No pain. The addition of an “a” specifies that the patient experiences no pain in association with the abnormal finding.

Mesh, Tape & Graft Surgery Complication - CTS Classification - Category (C) 2
Surgery – Complication related

Vaginal complication—(smaller) exposure: A smaller (1 cm or less) degree of vaginal epithelial separation is involved.

Mesh, Tape & Graft Surgery Complication - CTS Classification - Category (C) 3
Surgery – Complication related

Vaginal complication—(larger) exposure or extrusion: A larger degree (more than 1 cm) of vaginal epithelial separation or prosthesis or graft extrusion is involved.

Mesh, Tape & Graft Surgery Complications - CTS Classification - Category (C) 1
Surgery – Complication related

Vaginal complication—no epithelial separation: This incorporates the terms prominence (e.g. due to wrinkling or folding) or contraction (shrinkage). Also incorporated here is the palpation of mesh fibres.

Mesh, Tape and Graft Complication - CTS Classification - Category (C) 1B - 3B
Surgery – Complication related

1B–3B: Symptomatic—Unusual discomfort or pain; dyspareunia (for either partner). Bleeding or discharge may be possible symptoms. 1Bb–3Bb: Symptomatic—Provoked pain only (during vaginal examination) The addition of a “b” to the category code specifies that pain, provoked only during vaginal examination, is associated with the abnormal finding. 1Bc–3Bc: Symptomatic—Pain during sexual intercourse The addition of a “c” to the category code specifies that pain, provoked during sexual intercourse (patient only), is associated with the abnormal finding. 1Bd–3Bd: Symptomatic—Pain during physical activities The addition of a “d” to the category code specifies that pain, provoked during physical activities, is associated with the abnormal finding. 1Be–3Be: Symptomatic—Spontaneous pain: The addition of an “e” to the category code specifies that pain, spontaneously present (i.e. without physical activity), is associated with the abnormal finding.

Mesh, Tape and Graft Surgery Complication - CTS Classification - Category 6
Surgery – Complication related

Category 6: Skin and/or musculoskeletal complications: 6A: Asymptomatic: Physician-diagnosed complication at any episode of care. 6B: Symptomatic: For example, discharge, pain, lump. 6C: Infection from skin or musculoskeletal complication: Including sinus tract formation 6D: Abscess formation from skin or musculoskeletal complication.

Mesh, Tape and Graft Surgery Complication - CTS Classification - Category (C) 1C - 3C
Surgery – Complication related

1C–3C: Clinical Infection: This is always a possibility with a synthetic prosthesis or graft. Signs of local tenderness are suggestive with the combination of redness and a purulent discharge being more conclusive. 1C–3C (b–e): Infection—Pain. The addition of the letters “b” through to “e” specifies that pain (as defined in Table 3) is part or all of the infected abnormal finding.

Mesh, Tape and Graft Surgery Complication - CTS Classification - Category (C) 4
Surgery – Complication related

Category 4: Urinary tract compromise or perforation. This category class has been subdivided into:

4A: Small intraoperative defect: For example, bladder perforation. Such a complication does not generally create longer-term compromise for the bladder if recognized, prosthesis (graft) removed as indicated, defect oversewn (if necessary), and some minor precautions are taken, for example, short-term bladder drainage, with suitable antibiotics commenced. 4B: Other lower urinary tract (bladder or urethral) complication or compromise: This division would incorporate injuries causing longer-term bladder issues, for example, ongoing prosthesis or graft perforation, fistula, calculus around the prosthesis, or graft. This category also incorporates urinary retention directly related to the procedure requiring subsequent surgical intervention (apart from any form of bladder drainage). The time and site divisions relates to those for the surgical intervention. 4C: Ureteric or upper tract complication or compromise: This division is self-explanatory.

Mesh, Tape and Graft Surgery Complication - CTS Classification - Category (C) 5
Surgery – Complication related

Category 5: Rectal or Bowel compromise or perforation. This category class has been subdivided into:

5A: Small intraoperative defect: Such a complication may not generally be expected to cause compromise if the defect is recognized, prosthesis (graft) removed as indicated, defect oversewn (as necessary) with appropriate precautions taken, for example, short-term bowel rest is instituted with suitable antibiotics commenced. 5B: Rectal injury or compromise: This division would incorporate injuries causing longer-term rectal issues, for example, ongoing prosthesis (graft) perforation, fistula. 5C: Small or large bowel injury or compromise: This division would incorporate injuries causing longer-term bowel issues, for example, ongoing prosthesis (graft) perforation, fistula, obstruction. 5D: Abscess formation from bowel injury/compromise.

Mesh, Tape and Graft Surgery Complication - CTS Classification - Category (C) 7
Surgery – Complication related

Category 7: Patient compromise. This category recognizes that the patient might be brought into systemic danger with some of the complications in addition to any localized issue. 7A: Bleeding complication including hematoma: This division refers to any clinically diagnosed hematoma as well as those where blood transfusion or surgical intervention is a consideration. 7B: Major degree of resuscitation or intensive care: This division refers to significant hemodynamic or cardiopulmonary resuscitation directly related to the procedure, and/or patient transfer for management in intensive care facilities. 7C: Mortality: The insertion of the prosthesis, whilst not necessarily fatal at the time, has set in train further morbid events leading to mortality. N.B. Because of their systemic nature, 7B and 7C will not have a specific site division. They will be denoted S0.

Mesh, Tape and Graft Surgery Complication - CTS Classification - Time Divisions
Surgery – Complication related

The time (T) for the complication is when it is clinically diagnosed. This section incorporates four time periods, all of the possible episodes where clinical care might be given by the physician or sought by the patient. It might not always be possible to predict with any prosthesis or graft when complications might be more frequently seen. This would depend on the results of a procedure-specific surgical audit using the classification. The earliest time division (T1) might involve more insertion issues, whilst later divisions (T2–T4) might be biased towards healing abnormality issues. T1: Intraoper-

ative—48 hr: Insertion complications more likely. T2: 48 hr–2 months: Healing or infection complications more likely. T3: 2–12 months: Later healing abnormalities more likely. T4: Over 12 months: Late healing abnormalities and other mesh complications more likely.

Mesh, Tape and Graft Surgery Complications - CTS Classification - Category (C) 1D - 3D

Surgery – Complication related

1D–3D: Abscess formation: This is a more serious possibility with a synthetic prosthesis or graft. 1D–3D (b–e): Infection—pain: The addition of the letters b through to e specifies that pain (as defined in Table 3) is part of the abnormal finding associated with abscess formation.

Mesh, Tape and Graft Surgery Complications - CTS Classification - Site Divisions

Surgery – Complication related

The selection of these divisions incorporates the current sites where prosthesis or graft complications have been noted: S0: Systemic complications (no specific site): As mentioned earlier, category divisions 7B and 7C which are systemic complications will be denoted S0. S1: Vaginal: area of suture line: Perhaps the commonest site for prosthesis and graft complications from vaginal surgery is close to the vaginal suture line. S2: Vaginal: away from the vaginal suture line: As most suture lines would be midline, this would generally be lateral in the vagina. S3: Trocar passage: The passage of any sharp surgical instrument can cause damage along the path of insertion. This division incorporates any extraperitoneal, bladder, or rectal complication, but not intra-abdominal complications which are S5. S4: Other skin or musculoskeletal site: This division is relevant to any skin or musculoskeletal complications away from the sites of trocar entry or exit. Included might be cutaneous sinus or fistula formation. S5: Intra-abdominal: Included in this section would be bowel perforation or obstruction.

Micturating cystogram (MCU) - female

Imaging

The principal use is the detection of vesico-ureteric reflux, some fistulae and diverticula.

Mid-perineal thickness (MPT)

Surgery – Female

Thickness (cm) of the mid-perineum in the midline.

Mid-vaginal laxity (MVL - undisplaced - cm)

Surgery – Female

Laxity of the vaginal mucosa (anterior traction) midpoint in the vagina super-posteriorly and in the midline with the vaginal vault held in an undisplaced position (similar to that after vault fixation).

Mid-vaginal laxity (MVL - undisplaced) - posterior colporrhaphy

Surgery – Female

Laxity (cm) of the vaginal mucosa (anterior traction) midpoint in the vagina super-posteriorly and in the midline with the vaginal vault held in an undisplaced position (similar to that after vault fixation).

Miscellaneous Techniques for Bladder and Bowel Control

Conservative Management – Female

Other techniques consist of doing something that takes the patient's mind off the condition. Distraction techniques utilized in urgency may include (but are not limited to) counting backward from 100 in 7s, reciting a poem, doing breathing exercises, reading or working. Urgency suppression techniques: are methods/maneuvers that are used to decrease the feeling of urgency, which may include, but are not limited to: distraction, PFM contraction, perineal pressure such as sitting on a hard chair, relaxation and

breathing, toe curling or plantar flexion of the ankle. Double voiding: the patient is taught to urinate, relax, and attempt to urinate again. Defecatory dynamics: is a postural and respiratory technique to aid defecation. The mechanics involves co-ordination of the diaphragm, abdominal and PFM, with the intent to maintain rectal support whilst releasing the anal outlet with sufficient expulsion to be effective. Bowel habit training: is aimed at establishing a regular, predictable pattern of bowel evacuation by patient teaching and adherence to a routine to achieve a controlled response to bowel urgency (modified from NICE guideline).

Mixed bladder outlet obstruction and detrusor underactivity (male -BOO-DU)

Diagnosis

Urodynamically confirmed BOO occurring simultaneously with urodynamically confirmed DU in pressure-flow analyses.

Mixed detrusor overactivity and bladder outlet obstruction (male - DO-BOO)

Diagnosis

Detrusor overactivity (filling cystometry) in the presence of bladder outlet obstruction (pressure-flow studies). This is a relatively common diagnosis.

Mixed detrusor overactivity with detrusor underactivity (male - DO-DU)

Diagnosis

Urodynamically confirmed detrusor contractions during filling cystometry in combination with detrusor underactivity on pressure-flow.

Mixed neuronal lesion

Diagnosis

This results from lesions of the neural pathway at different levels of the central nervous system concurrently.

Mixed storage and voiding dysfunction

Diagnosis

(A) Bladder Outlet Obstruction and Detrusor Underactivity (BOO-DU): Urodynamically BOO occurring synchronous with urodynamically DU in pressure-flow analyses. (B) Detrusor Overactivity and Bladder Outlet Obstruction (DO-BOO): Urodynamically DO on filling cystometry in the presence of BOO on pressure-flow studies. (C) Detrusor Overactivity with Detrusor Underactivity (DO-DU)

Urodynamically DO on filling cystometry) in combination with urodynamically DU on pressure-flow studies. This diagnosis is intended to supersede the old expression "detrusor hyperactivity with impaired contractility" (DHIC) and detrusor overactivity with impaired contractility (DOIC). It is most common in the elderly group.

Mixed urinary incontinence (MUI)

Symptom

Complaints of both stress and urgency urinary incontinence, i.e. involuntary loss of urine associated with urgency and also with effort or physical exertion including sporting activities or on sneezing or coughing.

Modified Manchester (Fothergill) Procedure

Surgery – Female

This procedure combines anterior vaginal wall repair with amputation of the cervix and uterosacral ligament suspension with or without concurrent vaginal posterior wall repair.

(Modified) Manchester repair (Fothergill operation)

Surgery – Female

This procedure combines anterior vaginal wall repair (colporrhaphy) with amputation of the cervix and uterosacral ligament suspension with or without concurrent vaginal posterior wall repair (colporrhaphy).

Moschovitz procedure

Surgery – Female

Concentric purse string suture(s) are placed around the cul-de-sac to include the posterior vaginal wall, pelvic side-walls and serosa of the sigmoid.

Muscle Action Characteristics*Investigation*

The decrease in size of muscle fibers as a result of inactivity, illness or aging.

Muscle Action Characteristics - Anatomic Cross-sectional Area*Investigation*

For an individual muscle, the largest cross-sectional area along the length of that muscle and 90° on the muscle length.

Muscle Action Characteristics - Antagonistic Contraction*Investigation*

Contraction of muscle/ muscle groups with the opposite action to the desired action (activity that hinders the targeted muscle/ muscle group from contracting).

Muscle Action Characteristics - Bulk*Investigation*

The absolute volume of a muscle measured using imaging techniques such as anatomical magnetic resonance imaging and ultrasound.

Muscle Action Characteristics - Co-Contraction*Investigation*

Contraction of two or more muscles at the same time. Co-contraction of muscles can be synergistic (e.g., resulting in an augmentation of motor activity) or it could be counterproductive to normal function (e.g., contraction of antagonistic muscles resulting in abnormal movement or training other muscles instead of the targeted ones, e.g., training of gluteal muscles instead of the PFM).

Muscle Action Characteristics - Coordination*Investigation*

Property of movement characterized by the smooth and harmonious action of groups of muscles working together to produce a desired motion.

Muscle Action Characteristics - Exteroception*Investigation*

Sensory information from receptors in the skin registering touch, vibration, heat, and cold.

Muscle Action Characteristics - Flexibility*Investigation*

The ability of a muscle to lengthen and allow one joint (or more than one joint in a series) to move through a range of motion. Loss of flexibility is defined as a decrease in the ability of a muscle to deform.

Muscle Action Characteristics - Hypertrophy

Sign

The increase in size (volume) of the muscle fibers.

Muscle Action Characteristics - Maximum Voluntary Contraction (MVC)*Investigation*

The attempt to recruit as many fibers in a muscle as possible for the purpose of developing force. MVC of the pelvic floor can be assessed by vaginal palpation, manometers, and dynamometers.

Muscle Action Characteristics - Maximum Voluntary Contraction (MVC)*Investigation*

The attempt to recruit as many fibers in a muscle as possible for the purpose of developing force. MVC of the pelvic floor can be assessed by vaginal palpation, manometers, and dynamometers.

Muscle Action Characteristics - Motor Control*Investigation*

The ability of the nervous system to control or direct the muscles in purposeful movements and postural adjustment by selective allocation of muscle tension across appropriate joint segments.

Muscle Action Characteristics - Muscle Power*Investigation*

The explosive aspect of strength; the product of strength and speed of movement (force \times distance/time).

Muscle Action Characteristics - Muscle Strength*Investigation*

Force-generating capacity of a muscle. It is generally expressed as maximal voluntary contraction measurements and as the one repetition maximum (1RM) for dynamic measurements.

Muscle Action Characteristics - Physiological Cross-sectional Area*Investigation*

The total area of cross-section perpendicular to the muscle fibers.

Muscle Action Characteristics - Proprioception*Investigation*

Sensory information from receptors of muscles, joints, capsules, and ligaments that provides information related to posture and movement.

Muscle Action Characteristics - Submaximal contraction*Investigation*

All contractions without maximal effort, expressed as a percentage of one repetition maximum (1RM).

Muscle Action Characteristics - Synergistic Contraction*Investigation*

The combination of several muscle actions that serve to optimally achieve a motor task.

Muscle Action Characteristics - Local Muscle Endurance*Investigation*

The ability to sustain near maximal or maximal force, assessed by the time a patient is able to maintain a maximal static or isometric contraction, or the ability to repeatedly develop near maximal or maximal force determined by assessing the maximum number of repetitions the patient can perform at a given percentage of 1RM.

Muscle contracture

Sign

An involuntary shortening of a muscle. Clinically, a muscle cramp and contracture may appear similar; however, contractures are electrically silent.

Muscle Cramp

Sign

A painful involuntary muscle contraction that occurs suddenly and can be temporarily debilitating. Pain is intense and localized. It tends to occur when the muscle is in the shortened position and contracting, is generated by motor units, and displays a high firing rate (20–150Hz).

Muscle Fasciculation*Investigation*

A single, spontaneous, involuntary discharge of an individual motor unit. The source generator is the motor unit or its axon, before its terminal branches. Fasciculations display an irregular firing pattern of low frequency (0.1–10Hz). Clinically, fasciculations are recognized as individual brief twitches. They may occur at rest or after muscle contraction and may last several minutes.

Muscle Hypertonicity*Sign*

An increase in muscle tone related to the contractile or viscoelastic components that can be associated with either elevated contractile activity and/or passive stiffness in the muscle. The terms neurogenic hypertonicity and non-neurogenic hypertonicity are recommended to describe the diagnosis and inform management.

Muscle Hypotonicity (female)*Sign*

A decrease in muscle tone related to the contractile or viscoelastic components that can be associated with either reduced contractile activity and/or passive stiffness in the muscle. The terms neurogenic hypotonicity and non-neurogenic hypotonicity are recommended to describe the diagnosis and inform management.

Muscle spasm*Sign*

Persistent contraction of striated muscle that cannot be released voluntarily. If the contraction is painful, this is usually described as a cramp. Spasms occur at irregular intervals with variable frequency and extent and over days or weeks may lead to a contracture.

Muscle stiffness*Sign*

Resistance to deformation. Passive elastic stiffness is defined as the ratio of the change in the passive resistance or passive force (ΔF) to the change in the length displacement (ΔL) or $\Delta F/\Delta L$. The term should only be used if stiffness is measured quantitatively, such as with the use of instruments such as dynamometry or myotonometry.

N**Native**

Surgery – Complication related
Pertaining to birth; autologous.

Native Surgery Complications (CTS Classification) - Category (C) 1

Surgery – Complication related

Vaginal complication—no epithelial separation: This incorporates the terms prominence or excessive degrees of scarring or tethering.

Native (tissue)

Surgery – Female

Pertaining to birth - “in situ autologous”

Native Tissue Surgery Complications - CTS Classification - Category 4

Surgery – Complication related

Category 4: Urinary tract compromise or perforation: This category class has been subdivided into:

Muscle Tension*Sign*

May have a similar meaning to tone and stiffness. Muscle tension can be increased or decreased because of exogenous factors such as the amount of pressure applied and endogenous factors such as thickness/cross-sectional area of the muscle itself, fluid present within the muscle (swelling, inflammation), position (e.g., standing versus sitting) or increased neural activity.

Muscle tone*Sign*

State of the muscle, usually defined by its resting tension, clinically determined by resistance to passive movement. Muscle tone has two components: the contractile component, created by the low frequency activation of a small number of motor units, and the viscoelastic component, which is independent of neural activity and reflects the passive physical properties of the elastic tension of the muscle fiber elements and the osmotic pressure of the cells.

Muscle Tone - Measurement (female)*Investigation*

There is no single tool that is able to measure all components of muscle tone. Some tools may be able to measure aspects of tone such as contractility, stiffness or elasticity. Instrumented methods may play a role in the valid and reliable evaluation of muscle tone, e.g., surface electromyography (sEMG), wire and concentric electromyography, dynamometry, real-time ultrasound, elastometry, myotonometry.

Myalgia*Symptom*

Muscle pain. Pelvic floor myalgia (a symptom) may be present with or without a change in PFM tone (a sign).

Myofascial Pain*Symptom*

Pain caused by the presence of trigger points within muscles or their fascia.

4A: Small intraoperative defect: e.g., bladder perforation. Such a complication does not generally create longer-term compromise for the bladder if the defect is recognised and oversewn (if necessary), and some minor precautions are taken, e.g., short-term bladder drainage, with suitable antibiotics commenced. 4B: Other lower urinary tract (bladder or urethral) complication or compromise: This division would incorporate injuries causing longer-term bladder issues, e.g., ongoing suture perforation, fistula, calculus around the suture. This category also incorporates urinary retention directly related to the procedure requiring subsequent surgical intervention (apart from any form of bladder drainage). The time and site divisions relates to those for the surgical intervention. 4C: Ureteric or upper tract complication or compromise: This division is self-explanatory.

Native Tissue Surgery Complications - CTS Classification) - Category (C) 1D - 3D

Surgery – Complication related

1D—3D: Abscess formation: This is a more serious possibility. 1D—3D (b–e): Infection—Pain The addition of the letters “b” through to “e” specifies that

pain (as defined in Table 3) is part of the abnormal finding associated with abscess formation.

Native Tissue Surgery Complications - CTS Classification - Category (C) 1B - 3B

Surgery – Complication related

1B—3B: Symptomatic—Unusual discomfort or pain; dyspareunia (for either partner). Bleeding or discharge may be possible symptoms. 1Bb—3Bb: Symptomatic—Provoked pain only (during vaginal examination) The addition of a “b” to the category code specifies that pain, provoked only during vaginal examination, is associated with the abnormal finding. 1Bc—3Bc: Symptomatic—Pain during sexual intercourse The addition of a “c” to the category code specifies that pain, provoked during sexual intercourse (patient only), is associated with the abnormal finding. 1Bd—3Bd: Symptomatic—Pain during physical activities: The addition of a “d” to the category code specifies that pain, provoked during physical activities, is associated with the abnormal finding. 1Be—3Be: Symptomatic—Spontaneous pain The addition of an “e” to the category code specifies that pain, spontaneously present (i.e., without physical activity), is associated with the abnormal finding.

Native Tissue Surgery Complications - CTS Classification - Category (C) 1C - 3C

Surgery – Complication related

1C—3C: Clinical Infection/Inflammation: Signs of local tenderness are suggestive with the combination of redness and a purulent discharge being more conclusive. The presence of granulation should be accepted as representing ongoing inflammation. 1C—3C (b–e): Infection Pain: The addition of the letters “b” through to “e” specifies that pain is part or all of the infected abnormal finding.

Native Tissue Surgery Complications - CTS Classification - Category (C) 5

Surgery – Complication related

Rectal or Bowel Perforation or Compromise: this is subdivided into: 5A: Small intraoperative defect: Such a complication may not generally be expected to cause compromise if the defect is recognized and oversewn (as necessary) with appropriate precautions taken, e.g., short term bowel rest is instituted with suitable antibiotics commenced. 5B: Rectal injury or compromise: This division would incorporate injuries causing longer-term rectal issues, e.g., ongoing suture perforation, fistula. 5C: Small or large bowel injury or compromise: This division would incorporate injuries causing longer-term bowel issues, e.g., ongoing suture perforation, fistula, obstruction. 5D: Abscess formation from bowel injury/compromise.

Native Tissue Surgery Complications - CTS Classification - Category (C) 6

Surgery – Complication related

Category 6: Skin and/or musculoskeletal complications: 6A: Asymptomatic: Physician-diagnosed complication at any episode of care. 6B: Symptomatic: e.g., discharge, pain, lump. 6C: Infection from skin or musculoskeletal complication: including sinus tract formation. 6D: Abscess formation from skin or musculoskeletal complication.

Native Tissue Surgery Complications - CTS Classification - Category (C) 7

Surgery – Complication related

Category 7: Patient compromise: This category recognizes that the patient might be brought into systemic danger with some of the complications in addition to any localized complication. 7A: Bleeding complication including hematoma: This division refers to any clinically diagnosed hematoma as well as those where blood transfusion or surgical intervention is a consideration. 7B: Major degree of resuscitation or intensive care: This division refers to significant hemodynamic or cardiopulmonary resuscitation directly related to the procedure, and/or patient transfer for management in intensive care

facilities. Included in this division is hematoma associated with sepsis, thus increasing patient compromise. 7C: Mortality: The native tissue surgery, whilst not necessarily fatal at the time, has set in train further morbid events leading to mortality. N.B. Because of their systemic nature, 7B and 7C will generally not have a specific site division. They will then be denoted S0.

Native Tissue Surgery Complications - CTS Classification - Site Divisions S0 - S5

Surgery – Complication related

SELECTION OF SITE (S) DIVISIONS: The selection of these divisions incorporates the current sites where complications have been noted: S0: Systemic complications (no specific site): As mentioned earlier, category divisions 7B (septic hematoma a possible exception) and 7C which are generally systemic complications will be denoted S0. S1: Vaginal: area of suture line: Perhaps the commonest site for complications from native tissue vaginal surgery is close to the vaginal suture line. S2: Vaginal: away from the vaginal suture line: As most suture lines would be midline, this would generally be lateral in the vagina. S3: Adjoining viscus: This division incorporates any extraperitoneal, bladder or rectal complication, but not intraabdominal complications which are S5. S4: Skin or musculoskeletal site: This division is relevant to any skin or musculoskeletal complications away from the sites of the primary wound. Included might be cutaneous sinus or fistula formation and deep muscle pain from suture fixation. S5: Intra-abdominal: Included in this section would be bowel perforation or obstruction.

Native Tissue Surgery Complications - CTS Classification - Time (T) - T1 - T4

Surgery – Complication related

The time (T) for the complication is when it is clinically diagnosed. This section incorporates four time periods, all of the possible episodes where clinical care might be given by the physician or sought by the patient. It might not always be possible to predict with any particular surgery when particular complications might be more frequently diagnosed. This would depend on the results of a procedure-specific surgical audit using the classification. The earliest time division (T1) might involve more perioperative issues, whilst later divisions (T2–T4) might be biased towards healing abnormality issues. T1: Intraoperative—48 hr: Perioperative complications clearly more likely. T2: 48 hr—2 months: Bleeding, infection or healing complications more likely. T3: 2 months—12 months: Later healing abnormalities more likely. T4: Over 12 months: Late healing abnormalities and other suture complications more likely.

Native Tissue Surgery Complications (CTS Classification) - Category (C) 1

Surgery – Complication related

Vaginal complication—no epithelial separation: This incorporates the terms prominence or excessive degrees of scarring or tethering.

Native Tissue Surgery Complications (CTS Classification) - Category (C) 1A - 3A

Surgery – Complication related

1A—3A: Asymptomatic - Abnormal finding. These are generally physician-diagnosed at any episode of clinical care. It can be argued that the “abnormal finding” aspects of category 1A, in particular, are not really complications, as the patient is not bothered by the potential problem. It may be, however, that the woman may not have engaged in an activity that is likely to provoke symptoms for herself, e.g. pain or bleeding during sexual intercourse (or for her partner), which would convert these complications to category 1B. 1Aa—3Aa: Asymptomatic—Abnormal finding The addition of an “a” specifies that the patient experiences no pain in association with the abnormal finding.

Native Tissue Surgery Complications (CTS Classification) - Category (C) 2

Surgery – Complication related

Vaginal complication—smaller epithelial separation or ulcer: A smaller (1 cm or less) degree of vaginal epithelial separation or ulcer formation is involved.

Native Tissue Surgery Complications (CTS Classification) - Category (C) 3

Surgery – Complication related

Vaginal complication—larger epithelial separation or ulcer or suture extrusion: A larger degree (more than 1 cm) of vaginal epithelial separation or ulcer formation or suture extrusion is involved.

Native Tissue Surgery Complications (CTS Classification) - Category (C) 3

Surgery – Complication related

Vaginal complication—larger epithelial separation or ulcer or suture extrusion: A larger degree (more than 1 cm) of vaginal epithelial separation or ulcer formation or suture extrusion is involved.

Native Tissue Surgical Complications (CTS Classification) - Category (C) 1

Surgery – Complication related

Vaginal complication—no epithelial separation: This incorporates the terms prominence or excessive degrees of scarring or tethering.

Native Tissue Surgical Complications (CTS Classification) - Category (C) 2

Surgery – Complication related

Vaginal complication—smaller epithelial separation or ulcer: A smaller (1 cm or less) degree of vaginal epithelial separation or ulcer formation is involved.

Native Tissue Surgical Complications (CTS Classification) - Category (C) 3

Surgery – Complication related

Vaginal complication—larger epithelial separation or ulcer or suture extrusion: A larger degree (more than 1 cm) of vaginal epithelial separation or ulcer formation or suture extrusion is involved.

Need to immediately re-void (“encore” or “double” voiding)

Symptom

Complaint that further voiding is necessary soon after passing urine (cessation of flow).

Neural lesions

Diagnosis

These are described according to the time of onset, risk of neurological progression, completeness and neurological level. The extent of loss of neurological function depends on which part(s) of the nervous system is affected. Relevant diagnoses (see separate descriptions) are (i) Spinal Shock Phase; (ii) Suprapontine Lesion (SPL); (iii) Suprasacral cord/pontine lesion (SSL); (iv) Sacral Spinal Cord Lesion (SSCL); (v) Infracacral (cauda equine and peripheral nerves) lesion (CEPNL); (vi) Mixed Neuronal Lesion.

Neurogenic

Diagnosis

Occurs in the presence of relevant neurological pathology ONLY.

Neurogenic acontractile detrusor - pressure flow studies

Investigation

No visible detrusor contraction during voiding attempt in a man with evidence of a neurological disorder (either visible or measurable neurological deficit or history of neurological disease). This should replace the term “areflexia”.

Neurogenic detrusor overactivity - compound

Investigation

A phasic detrusor contraction with a subsequent increase in detrusor and

base pressure with each subsequent contraction occurs during filling cystometry in the setting of a clinically relevant neurologic disease.

Neurogenic detrusor overactivity - general

Investigation

Involuntary detrusor muscle contractions occur during filling cystometry in the setting of a clinically relevant neurologic disease.

Neurogenic detrusor overactivity - high pressure

Investigation

A phasic, terminal, sustained or compound high maximal detrusor overactivity with high detrusor pressure occurs during filling cystometry in the setting of a clinically relevant neurologic disease. The investigator may consider whether such contractions might be potentially detrimental to the patient’s renal function and/or health.

Neurogenic detrusor overactivity - phasic

Investigation

Phasic detrusor muscle contractions (characteristic waveform) occur during filling cystometry in the setting of a clinically relevant neurologic disease. These may or may not lead to urinary incontinence.

Neurogenic detrusor overactivity - sustained

Investigation

Continuous detrusor muscle contractions (without returning to the detrusor resting pressure) occur during filling cystometry in the setting of a clinically relevant neurologic disease.

Neurogenic detrusor overactivity - terminal

Investigation

Involuntary detrusor muscle contractions occur near or at the maximum cystometric capacity, in the setting of a clinically relevant neurologic disease. These contractions generally cannot be suppressed resulting in urinary incontinence or even reflex bladder emptying (reflex voiding).

Neurogenic detrusor overactivity incontinence

Investigation

Incontinence due to detrusor muscle contractions during filling cystometry in the setting of clinically relevant neurologic disease.

Neurogenic detrusor overactivity (NDO)

Diagnosis

In men and women with LUT/PF symptoms (more commonly storage symptoms) detrusor muscle contractions occur during filling cystometry in the setting of a clinically relevant neurologic disorder.

Neurogenic (secondary) detrusor overactivity

Investigation

Detrusor overactivity and evidence (history; visible or measurable deficit) of a relevant neurological disorder

Neurological assessment of female sexual dysfunction

Investigation

Related to intact sensation, neurological innervation is important for arousal and orgasm. Peripheral neuropathy or central nervous system disorders (eg, diabetic neuropathy, spinal cord injury) may lead to anorgasmia and decreased arousal. Different approaches can be used to evaluate motor and sensory neurological function.

1. Functional magnetic resonance imaging: Investigation of neural activa-

tion in anatomically localized cerebral regions evaluated through monitoring subtle changes in regional cerebral blood flow that occur with activation of the neurons. These patterns of activation and deactivation are used to examine the cerebral and cognitive response to sexual stimulation; 2: Quantitative sensory testing: Assessment of the sensitivity by applying different stimuli (light touch, pressure, temperature, or vibration) using an ascending or descending method in order to evaluate the detection threshold. These methods can be used to evaluate different vulvovaginal sites including the clitoris, labia minora, and majora as well as vaginal and anal margins; 3: Reflex examination: Evaluating sacral arc integrity, the bulbocavernosus reflex can be elicited by squeezing the clitoris and assessing the contraction of the anal sphincter. The external anal reflex is tested by repetitive pricking delivered to perianal skin and observing anal sphincter contraction. Latencies can also be evaluated by stimulating the nerve and evaluating muscle response through a needle electrode.

Neurological examination (female)

Sign

For patients with possible neurogenic lower urinary tract or pelvic floor dysfunction, there should be particular note of those neurological signs related to S2-4, but these should be complemented by a more general neurological examination as indicated.

Neurological examination (male)

Sign

. Overall neurological status: abnormalities of speech, gait as well as upper and lower extremity dexterity should be noted as they may indicate a neurological cause for the urological symptoms. Neuropathy may impact also on management options.

. Level of neurologic abnormality: can occasionally be localized by the pattern of sensory or motor deficit noted during physical examination using a dermatome map.

. Penile, scrotal, or perianal sensory deficits: may indicate damage or injury to sacral roots or nerves. Reflex testing in the genital area may also be performed. The most important of these is the Bulbospongiosus reflex (BSR).

. Bulbospongiosus reflex (BSR) - a reflex contraction of the striated muscle of the pelvic floor (anal sphincter) and the bulbo-spongiosus muscle that occurs in response to various stimuli in the perineum or genitalia.

. Cremasteric reflex: contraction of the ipsilateral cremaster muscle, drawing the testis upwards, when the upper inner aspect of the thigh is stroked longitudinally.

Neuromuscular Electrical Stimulation Parameters

Conservative Management – Female

Neuromuscular electrical stimulation parameters: 1. Pulse frequency (or rate): the number of pulse cycles that are generated per unit of time (seconds). This is reported in hertz (Hz). 2. Pulse width: the determined period of time elapsing from the beginning to the end of one pulse cycle, usually expressed in microseconds or milliseconds. 3. Current amplitude: the magnitude of current relative to the isoelectric baseline, expressed in amperes (A). The current amplitude of therapeutic electrical stimulators ranges from micro- to milliamps. 4. Train: the continuous series of pulse cycles over time, usually lasting seconds. For example, a train of impulses may be the results of successive pulse cycles delivered at 50Hz for a duration of 5s. 5. Train ramp-up time and ramp-down time: ramp-up time is the time elapsed from the onset (or baseline) to the plateau current amplitude (or maximum) of the train, whereas ramp-down time is the time elapsed from the plateau current amplitude to zero baseline. 6. Duty cycle (D): the ratio of ON time to the summation of ON time+OFF time, expressed as a percentage ($\text{duty cycle} = (\text{ON}) / (\text{ON} + \text{OFF time}) \times 100$, e.g., a duty cycle of 20 % is calculated when the ON and OFF times equal 10 and 40s respectively. 7. Impedance (electric resistance): the opposition of our biological tissues to the flow of an elec-

trical current. Measured in ohms and designated as Z. 8. Evoked potentials: electrical potentials recorded from the nervous system following a delivered stimulus.

Night-time

Sign

The individual's main daily period of sleep. It commences at the time of falling asleep and concludes when the individual decides to no longer attempt to sleep and rise for the next day (ideally recorded on chart or diary).

Night-time (urinary) frequency

Sign

Total number of night-time voids irrespective of sleep, i.e. the number of voids recorded from the time the individual goes to bed with the intention of sleeping till the time the individual wakes with the intention of rising.

Nociceptive pain

Symptom

Pain which arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors.

Nocturia

Symptom

The number of times urine is passed during the main sleep period. Having woken to pass urine for the first time, each urination must be followed by sleep or the intention to sleep. This should be quantified using a bladder diary.

Nocturia

Sign

The number of times an individual passes urine during their main sleep period, from the time they have fallen asleep up to the intention to rise from that period. This is derived from the bladder diary.

Nocturia - General Advice

Conservative Management – General

General lifestyle advice, e.g. reducing caffeine and alcohol intake, and limiting excessive liquid/food volume intake before bedtime, can in some cases be sufficient to elicit a satisfactory response. However, care should be taken not to impose a general fluid restriction as this could have serious consequences in patients with undiagnosed diabetes insipidus. Patients should be encouraged to return to their doctor for further evaluation if they are not content with the results after their initial advice.

Nocturia related to Bladder Storage

Investigation

Reduced functional bladder capacity (e.g. significant post void residual); Reduced nocturnal bladder capacity Detrusor overactivity; Neurogenic (e.g. multiple sclerosis); Non-neurogenic Bladder hypersensitivity Bladder outlet obstruction with post void residual urine; Urogenital ageing.

Nocturia related to Sleep Disorders

Investigation

Insomnia Obstructive and central apnoea syndrome; Periodic legs syndrome; Restless legs syndrome Parasomnias; Sleep disorders related to medical diseases, e.g. chronic obstructive lung disease, cardiac diseases etc; Sleep disorders related to neurological diseases, e.g. Alzheimer's, Parkinson's and nocturnal epileptic seizures.

Nocturnal

Sign

Occurring or active at night.

Nocturnal defecation*Symptom*

Complaint of interruption of sleep one or more times because of the need to defecate.

Nocturnal enuresis*Symptom*

Complaint of involuntary voiding that occurs at night during the main sleep period (i.e. bedwetting)

Nocturnal (night-time) polyuria*Sign*

Increased proportional production of urine during the night-time compared with the 24 hour urine volume. Nocturnal polyuria index (NPI) is most commonly used definition (night-time urine volume/24 hour urine volume) x 100%.

- 33% in elderly e.g. > 65 years.
- >20% in younger individuals
- 20 - 33% in "middle age"

Nocturnal polyuria*Symptom*

Complaint of passing large volumes of urine at night-time (during the main sleep period).

Nocturnal polyuria*Sign*

Excessive production of urine during the individual's main sleep period. Should be quantified using a bladder diary.

Nocturnal polyuria - Causes*Sign*

Water diuresis: Circadian defect in secretion or action of antidiuretic hormone Primary (Idiopathic). Secondary: (Excessive evening intake of fluid, caffeine, alcohol); Solute/water diuresis • Congestive heart failure • Autonomic dysfunction • Sleep apnoea syndrome • Renal insufficiency • Oestrogen deficiency.

Nocturnal urine volume*Sign*

Total volume of urine produced during the individual's main sleep period. This includes the first void of the morning. Should be quantified using a bladder diary.

Non coital sexual pain*Symptom*

Pain induced by non coital stimulation.

Non-specific (atypical) bladder filling sensation (bladder dyesthesia)*Symptom*

The individual reports no specific bladder filling sensation, but may perceive, for example, abdominal fullness, vegetative symptoms (nausea, vomiting faintness), urethral sensations or spasticity as bladder filling awareness.

Non-coital sexual pain*Symptom*

Pain induced by non-coital stimulation.

Non-Functioning Pelvic Floor Muscles*Sign*

(Modified from Messelink et al, 2005): A situation in which there is no PFM action measurable either on instruction to contract (inability) or as the absence of an automatic response to an increase in intraabdominal pressure. This condition can be based on any pelvic floor symptom and on the sign of a non-contracting or non-relaxing pelvic floor.

Non-functioning Pelvic Floor Muscles*Diagnosis*

A situation in which there is no pelvic floor muscle action palpable. This condition can be based on any pelvic floor symptom and on the sign of a non-contracting, non-relaxing pelvic floor.

Non-functioning pelvic floor muscles (female)*Sign*

Pelvic floor muscles where there is no voluntary action palpable.

Non-inflammatory anorectal pain*Symptom*

Complaint of blunted anorectal pain, as opposed to sharp stinging or burning type of pain (proctalgia fugax, Levator ani syndrome, pudendal neuralgia)

Non-invasive Urodynamics*Investigation*

All urodynamics done without the insertion of catheters: e.g. uroflowmetry, PVR, penile compression-release test, penile cuff, condom catheter, or sonography.

Non-neurogenic acontractile detrusor - pressure flow studies*Investigation*

No visible detrusor contraction during voiding attempt in a man without evidence of a neurological disorder.

Non-neurogenic (secondary) detrusor overactivity (DO) - filling cystometry*Investigation*

An identifiable possible non-neurological cause exists for involuntary detrusor contraction(s) during bladder filling. e.g. functional (obstruction); pathology stone, tumor (e.g. carcinoma in situ), UTI.

Non-specific (atypical) bladder filling sensation (bladder dyesthesia)*Symptom*

Complaint of abnormal bladder filling sensation such as the perception of vague abdominal bloating, vegetative symptoms (nausea, vomiting, faintness) or spasticity. It differs from normal bladder filling sensation or pain, pressure or discomfort of the bladder.

Non-specific bladder awareness*Symptom*

The individual reports no specific bladder sensation, but may perceive, for example, abdominal fullness, vegetative symptoms, urethral sensations or spasticity as bladder filling awareness or a sign of bladder fullness.

Non-specific bladder awareness - Filling cystometry*Investigation*

Perception of bladder filling as abdominal fullness, vegetative symptoms (nausea, vomiting, faintness), spasticity or other "non-bladder" awareness, in the setting of a clinically relevant neurologic disorder (e.g. incomplete spinal cord lesion).

Non-Standard (Urodynamic) Tests*Investigation*

ICS Standard Urodynamic Testing (ICS-SUT) may be supplemented with EMG, with imaging, with continuous urethral pressure(s) and/ or with urethral pressure profile measurement. Cystometry may be done via a suprapubic catheter (specify supplements).

Normal bladder filling sensation.*Symptom*

The individual is aware of bladder filling and increasing sensation up to a strong desire to void.

Normal desire to void - filling cystometry*Investigation*

The feeling that leads the individual to void at the next convenient moment, but voiding can be delayed if necessary.

Normal detrusor activity/function - filling cystometry*Investigation*

There is little or no change in detrusor pressure with filling or any provocative activities.

Normal detrusor contractile function - pressure flow studies.*Investigation*

Normal voiding is achieved by an adequate continuous detrusor contraction that leads to complete bladder emptying within a normal time span.

Normal detrusor function (female)*Investigation*

Normal voiding in women is achieved by an initial (voluntary) reduction in intraurethral pressure (urethral relaxation). This is generally followed by a continuous detrusor contraction that leads to complete bladder emptying within a normal time span. Many women will void successfully (normal flow rate and no PVR) by urethral relaxation alone, without much of a rise in detrusor pressure. The amplitude of the detrusor contraction will tend to increase to cope with any degree of bladder outflow obstruction.

Normal Pelvic Floor Muscles*Diagnosis*

A situation in which the pelvic floor muscles can voluntarily and involuntarily contract and relax. Voluntary contraction will be normal or strong and voluntary relaxation complete. Involuntary contraction and relaxation are both present.

O**Obstetric Anal Sphincter Injuries (OASIS)***Diagnosis*

OASIS are reported to occur in 0.5–14% of vaginal deliveries (2.9–19% of primiparous vaginal deliveries). It has previously been shown in a prospective study that about one third of OASIS can be diagnosed 8 weeks after delivery by endoanal ultrasound alone. As these were not identified clinically, the injuries were believed to be “occult.” However, it has subsequently been proven that such injuries are not necessarily occult but in fact undiagnosed due to lack of expertise of midwives and doctors. Training in diagnosis and management of perineal trauma has been shown to be suboptimal and dedicated hands-on courses have shown significant improvements in diagnosis and classification of OASIS. Sultan therefore proposed a more descriptive classification of OASIS that has now been accepted internationally to support consistency in reporting. To avoid underestimation of the inju-

Normal pelvic floor muscles (female)*Sign*

Pelvic floor muscles which can voluntarily and involuntarily contract and relax.

Normal urethral closure mechanism (female)*Investigation*

A positive urethral closure pressure is maintained during bladder filling, even in the presence of increased abdominal pressure, although it may be overcome by detrusor overactivity.

Normal urethral closure pressure - Filling cystometry*Investigation*

A positive urethral closure pressure is maintained during bladder filling, even in the presence of increased abdominal pressure, although it may be overcome by detrusor overactivity.

Normal urethral function during voiding - pressure flow studies (male +/- VCU, EMG)*Investigation*

The urethra opens and is continuously relaxed to allow micturition at a normal pressure and urine flow and results in complete emptying. The voiding is prompted by a detrusor contraction and simultaneous relaxation of the smooth and striated sphincters of the urethra and pelvic floor muscles.

Normal urethral function during voiding (female)*Investigation*

The urethra opens and is continuously relaxed to allow micturition at a normal pressure, urine flow and PVR.

No-touch technique intermittent catheterization

Conservative Management – General

This was introduced as an easier way for the patient to perform self-intermittent catheterization with a ready-to-use catheter (pre-lubricated catheter, usually a hydrophilic catheter). A pull-in aid or special packages are used to handle the catheter without directly touching the sliding surface of the hydrophilic catheter.

ry, if there is uncertainty regarding the full extent of the injury it should be classified as the greater degree, for example, if one is unsure as to whether an injury is a Grade 3a or 3b it should be classified as 3b. This classification also has clinical relevance as it ensures increased vigilance for internal sphincter injuries that are best repaired soon after delivery as persistent internal sphincter defects are associated with fecal incontinence. Examination techniques to improve detection of these injuries and avoiding pitfalls in diagnosis have been described in detail.

Obstructed Defecation Syndrome*Diagnosis*

Obstructed defecation: incomplete evacuation of fecal contents from rectum due to physical blockage of the fecal stream during defecation attempts. It includes symptoms such as straining to defecate, sensation of blockage, digitation, and splinting. Constipation due to slow transit ,irri-

table bowel syndrome, Hirschsprung's disease, megarectum, anismus are not within the remit of this standardization document. Associated features of obstructed defecation are: 1: Rectocele: Bulge in posterior vaginal wall associated with herniation of anterior wall of the rectum; 2: Enterocele/sigmoidocele: Bulge of upper wall of vagina associated with herniation of peritoneal sac and small bowel (enterocele) or sigmoid colon (sigmoidocele). 3: Intussusception: Full thickness invagination of the upper rectum without extrusion through the anus leading to interruption of flow of the fecal stream; 4: Internal mucosal prolapse: Mucosal prolapse of the anterior, posterior, or circumferential mucosal layer. 5: External rectal prolapse: Full thickness rectal prolapse outside the anal canal.

Obstructed intercourse (female)

Symptom

Vaginal intercourse is difficult or not possible due to obstruction by genital prolapse or shortened vagina.

Obstructed intercourse (male)

Symptom

Complaint that vaginal intercourse is not possible due to perceived obstruction. Whilst this may be a partner issue, it can occur in cases of penile curvature (Peyronie's disease) or penile carcinoma.

"Occult" urodynamic stress incontinence

Diagnosis

Where the diagnosis of urodynamic stress incontinence is only made when co-existent pelvic organ prolapse (POP) is reduced.

Opening Time

Investigation

The time elapsed from initial rise in pressure to the onset of flow. This is the initial isovolumetric contraction period of micturition. It reflects the time taken for the fluid to pass from the point of pressure measurement to the uroflow transducer. Flow measurement delay should be taken into account when measuring the opening time.

Orgasmic urinary incontinence (female)

Symptom

Urinary incontinence at orgasm.

Outcome measurement in POP surgeries - objective outcomes

Surgery – Female

POP-Q measurement generally and should be tabulated with absolute values and percentages to allow other studies to compare results.

Outcome measurement in POP surgeries - perioperative data

Surgery – Female

These data include blood loss, operating time, length of hospital stay, return to normal activities and complications.

Outcome measurement in POP surgeries - subjective (patient reported outcomes)

Surgery – Female

At its simplest level this can be reported as the presence or absence of vaginal bulge. Patient satisfaction and quality of life can be measured by validated instruments that cover prolapse, urinary, bowel and sexual function.

Outcomes measurement in POP surgeries - secondary outcomes

Surgery – Female

For example, lower urinary tract symptoms, stress urinary incontinence or bowel and sexual dysfunction in their studies whenever possible.

Outcomes of Female Pelvic Floor Surgery - Economic Evaluation / Cost Analysis

Surgery – Female

Despite considerable cost, sparse cost-effectiveness data exists related to POP surgery. Investigators are encouraged to include economic analyses in their studies whenever possible. Economic evaluation techniques provide systematic methods of comparing the costs and consequences of clinical and other health sector interventions. Cost-utility analysis (CUA), a form of cost-effectiveness analysis (CEA), is by far the most commonly used and requires quantifying the effects of interventions on both morbidity and mortality. In a CUA, benefits are measured in units of health gain (or loss), most commonly using quality-adjusted life-years (QALYs) and combined with estimates of cost to create a ratio of incremental costs to incremental consequences (e.g., "incremental cost per QALY"). QALYs are usually calculated using a generic health status measure, such as Short Form (SF)36 or Euro-QOIEQ-5D, which can be used with a standard set of health state values or by other measures of utility, such as the standard gamble or time-trade off technique. These incremental cost effectiveness ratios (ICERs) enable comparison of competing interventions on the basis of the cost at which they create improvements in health-related quality-of-life. In economic evaluations, it is important to consider the perspective (e.g., patients, hospital, third-party payer, government and society) of the evaluation, as this will have significant influence on which costs should be included in the analysis. For example, the perspective of the analysis will influence whether it should include both direct and indirect costs. Direct medical costs typically relate to the intervention and the immediate impact of the intervention on the health system: e.g., personnel costs/time (physician, nurse, technician), diagnostic and laboratory tests, hospital costs, treatment costs (drugs, operating room time, etc.), treatment of side effects and outpatient visits. Indirect costs will be of more relevance to a patient and/or societal perspective (e.g., loss of productivity, time lost from work, loss of service to family and community and premature mortality) and are often more difficult to quantify and to put a monetary value on.

Outcomes of Female Pelvic Floor Surgery - Patient Reported Outcomes

Surgery – Female

The primary patient reported outcome should be subjective and would usually be the absence of a bulge. This can be regarded as a "subjective cure" and can be recorded as part of a symptom scale. Details of validated questionnaires for patient reported outcomes can be found on ICI's website. To adhere with the SMART criteria, patient/subjective outcomes should be defined at a specific time interval and classified on a 7-point Likert scale (i.e. very much better, moderately better, a little better, no change, slightly worse, moderately worse, very much worse) such as the Patient Global Impression of Improvement (PGI-I) scale.

Outcomes of Female Pelvic Floor Surgery - Reporting Complications

Surgery – Female

Complications specifically related to prostheses and grafts and native tissues should be reported as per the IUGA-ICS classifications of complications directly related to the insertion of prostheses and grafts or the use of native tissue in female pelvic floor surgery. These classifications both use the CTS Classification System: (C) Category of complication. (T) Time the complication was diagnosed in relation to primary surgery. (S) Site of the complication. There are seven Categories with subdivisions of (A–D). For the majority of complications, this would mean: (A) Asymptomatic, (B) Symptomatic, (C) Infection, (D) Abscess. For complications involving bowel or bladder injury or patient compromise, variations in the pattern of the increasing index of severity exist: e.g., Category 5: rectal or bowel injury (both classifications) (A) Small intraoperative defect; (B) rectal injury or compromise; (C) small

or large bowel injury or compromise; (D) abscess. Studies, in particular of a specific surgical procedure, should have a procedure-specific list of complications using the CTS Classification Systems as part of the reporting. Only in this way can the nature and chronology of possible complications be determined (in relation to time of surgery) and at which sites they might most commonly occur. Note is also made of the generic Clavien-Dindo complication classification which consists of four severity grades of complications. This has been modified to include a fifth category. Grade IV IC/ICU organ or system dysfunction (a: single organ; b: multi-organ dysfunction) Grade V Death. Grade I requires no treatment; Grade II requires drug therapy; Grade III requires a procedure or intervention (a: in local; b: general anesthesia).

Outcomes of Female Pelvic Floor Surgery - Reporting Demographics

Surgery – Female

The reporting of minimum demographics in POP surgery should include: A. Age, B. Parity, C. Body mass index (BMI), D. Menopause status, E. Hormone replacement (HRT) usage, F. Prior hysterectomy, G. Prior POP surgery, H. Prior continence surgery, I. Chronic cough, J. Chronic constipation, K. Smoking

Outcomes of Female Pelvic Floor Surgery - Reporting Objective Outcomes

Surgery – Female

Objective outcomes (e.g., POPQ) should be tabulated with percentages achieving each level to allow studies to compare results, as definitions of success will vary among studies (see below). This report does not attempt to provide a definition for success and failure, as these are unknown. However, authors should report data on the leading edge of the prolapse for each site (e.g. patients who achieve points 1 and 0 postoperatively having had prolapse greater than 1 or 0 before surgery). These data, which may help identify the level of anatomical restoration that leads to improvement in symptoms, should be reported separately. When possible, raw data should be provided for POPQ, quality of life measures and all primary symptoms. These should be reported in separate tables, which can be published as supplementary material in the electronic (online) version rather than the printed version.

Outcomes of Female Pelvic Floor Surgery - Reporting of Methodological Data

Surgery – Female

General Criteria: The following should be defined: A. Inclusion criteria. B. Exclusion criteria. C. Recruitment time span. D. Flow diagram including: (i) Number of patients evaluated. (ii) Number suitable for inclusion. (iii) Number agreed to participate. (iv) Clear documentation accounting for all patients' progress throughout the study period. Comparative Studies: A. Clear explanation of patient allocation to treatment groups. B. Allocation concealment from surgeon and/or patient. C. Randomized trials: explanation of randomization process. D. Stratification of associated issues utilized such as concomitant continence surgery or hysterectomy. Interventions: A. Clear documentation of interventions performed, experience level of surgeons and number of interventions performed prior to study commencement. B. Criteria for performing concomitant surgery. Evaluation Process: A. Who performed the evaluation and the training received. B. Were reviewers and/or participants blinded. C. Evaluation tools: were validated, patient-completed assessments standardized. D. Evaluation timeline: i. Very early (up to 3 months). ii. Early (up to 1 year). iii. Intermediate (12–36 months). iv. Late (3–5 years). v. Very late (>5 years). Power Analysis: Details of the assumptions made in the power calculation, estimate of the type 1 error and sample size should be reported.

Outcomes of Female Pelvic Floor Surgery - Reporting of Patients' Preoperative Goals and Expectations

Surgery – Female

To date, few studies have provided data on patients' preoperative goals and

expectations. These might have advantages over objective measures of outcome. With this in mind, goals should be reported using SMART criteria. The aim of the SMART criteria is to help clinicians review and confirm the utility of the chosen endpoint and how it will relate to other studies and reports. Criteria comprise: Specific Defining goal (for POP: absence of bulge). Measurable validated symptom scale or objective measure such as the POPQ appropriate relevant to improving patient lifestyle realistic achievable by treatment Timely For example at 6 months/2 years. The following is an example of good and poor reporting of patient expectations and outcomes, using the SMART Schema: Good example: "The absence of bother from a vaginal bulge as measured using a defined tool at 2 years." This statement has Specific, Measurable, Appropriate, Realistic, and Timely attributes. Poor example: "Feeling perfect" when followed-up. "Perfect" is not specific (OB compared with absence of bulge), is less measurable (because it is difficult to define), has no defined timepoint and is not appropriate or relevant to the surgery as many factors define "perfect." Definitions relating to the SMART criteria should be derived from the symptoms the researchers feel are important. When designing a study, the symptoms should be listed and then SMART should be applied. Authors should use this as a checklist to ensure that the methodology is sound and relevant.

Outcomes of Female Pelvic Floor Surgery - Reporting of Randomized Controlled Trials

Surgery – Female

There are already accepted standards for reporting RCTs such as the CONSORT (Consolidated Standards of Reporting Trials) which requires detailed information provided by authors to reviewers with a checklist added as an appendix. However, many studies fail to provide complete descriptions of critical information.

Outcomes of Female Pelvic Floor Surgery - Reporting Patient Satisfaction

Surgery – Female

Patient satisfaction can be measured using qualitative measures, such as a patient-defined measure or a validated instrument (PGI-I scale). Qualitative assessment can include Expectations, Goal setting, Goal achievement and Satisfaction (EGGS). Again these should be in accordance with the SMART acronym. The number of pre-specified goals and the number achieved post-operatively should be recorded and reported for responsiveness and reliability of goal achievement.

Outcomes of Female Pelvic Floor Surgery - Reporting Perioperative Data

Surgery – Female

Perioperative data includes blood loss (ml) and/or hemoglobin change, operating time, length of hospital stay, return to normal daily activities and complications.

Outcomes of Female Pelvic Floor Surgery - Reporting Postoperative Pain

Surgery – Female

Pain associated with surgical complications is addressed separately in the IUGA-ICS classifications of complications of female pelvic floor surgery. The addition of a letter (a to e), as part of a subclassification to the CTS Classification System, specifies the presence of pain as part or all of the abnormal finding or complication and the grade in terms of the presence and severity of symptoms.

(a) Asymptomatic or no pain. (b) Provoked pain only (during vaginal examination). (c) Pain during sexual intercourse. (d) Pain during physical activities. (e) Spontaneous pain.

Additional information on pain may include "permanent or temporary" and "severity" as measured by impact on quality of life and treatment required (e.g., simple oral analgesia, compound analgesia, opiates, referral and management by pain team or further surgery).

Outcomes of Female Pelvic Floor Surgery - Reporting Quality of Life

Surgery – Female

Appropriate and fully validated quality of life instruments should be used to cover prolapse, urinary, bowel and sexual function. New questionnaires can be included when they have demonstrated good psychometric properties (i.e., validity, reliability and responsiveness) in women with POP. It is important to verify that the questionnaire has been validated in the language of the trial investigator(s).

Outcomes of Female Pelvic Floor Surgery - Reporting Secondary Outcomes

Surgery – Female

Secondary outcomes to be reported include an assessment of other symptoms known to be associated with prolapse: Lower urinary tract symptoms (LUTS): Overactive bladder, stress urinary incontinence (either pre-existing or de-novo) and voiding dysfunction. Bowel dysfunction: Obstructed defecation, feeling of incomplete emptying, constipation and digitation. Sexual dysfunction: Dyspareunia, loss of libido, abstinence due to prolapse symptoms and change in sexual satisfaction. Authors should report numbers of all patients who are sexually active with and without pain, pre and post-intervention. All participants in trials should be accounted for pre- and post-intervention. De novo/new onset symptoms (if not previously reported): LUTS, sexual dysfunction, pain and bowel dysfunction. Backache: Backache is a common presenting symptom, the resolution of this may be an important outcome.

Outcomes of Female Pelvic Floor Surgery - Reporting Systematic Reviews and Meta-Analyses

Surgery – Female

Due to the lack of consistent descriptions of critical information reported from RCTs, a new instrument, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), has been introduced to evaluate systematic reviews and meta-analyses. The aim of the PRISMA statement is to give authors an evidence-based minimum set of items to improve the reporting of systematic reviews and metaanalyses in POP issues. Other standards include the Standards for the Reporting of Diagnostic (STARD) accuracy studies, and STROBE (STrengthening the Reporting of OBServational studies in Epidemiology). Researchers should quote which standard they adopt and reference accordingly.

P

Pad testing

Sign

For individuals with urinary (fecal) incontinence symptoms, the quantification of the amount of urine (feces) lost over the duration of testing, by measuring the increase in the weight of the pads (weighed pre- and post-testing) used. This may give a guide to the severity of incontinence. Different durations from a short (1 hour) test to a 24 and 48-hour tests have been used with provocation varying from normal everyday activities to defined regimens.

Pad testing

Sign

For individuals with urinary (fecal) incontinence, the quantification of the amount of urine (feces) lost over the duration of testing, by measuring the increase in the weight of the pads (weighed pre-and post-testing).

Pain

Symptom

Outcomes of Female Pelvic Floor Surgery - Timelines for Reporting

Surgery – Female

Timelines should be described chronologically, as outlined below, using the classification above. Of note, these timescales are different to those described in the classifications of complications reports related to female pelvic floor surgery using either prosthesis and meshes or native tissue. I. Very early (up to 3 months). II. Early (up to 1 year). III. Intermediate (12–36 months). IV. Late (3–5 years). V. Very late (>5 years).

Overactive bladder (OAB, Urgency) syndrome

Symptom

Urinary urgency, usually accompanied by increased daytime frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry), in the absence of urinary tract infection or other detectable disease.

Overactive Pelvic Floor Muscles

Diagnosis

A situation in which the pelvic floor muscles do not relax, or may even contract when relaxation is functionally needed for example during micturition or defecation. This condition is based on symptoms such as voiding problems, obstructed defecation, or dyspareunia and on signs like the absence of voluntary pelvic floor muscle relaxation.

Overactive pelvic floor muscles (female)

Sign

Pelvic floor muscles which do not relax, or may even contract when relaxation is functionally needed, for example, during micturition or defecation.

Overflow fecal incontinence

Symptom

Complaint of involuntary loss of stool due to an overfull rectum or fecal impaction.

Overflow urinary incontinence.

Symptom

Complaint of urinary incontinence in the symptomatic presence of an excessively (over-) full bladder (no cause identified).

A variably unpleasant sensation. It may be described as pressure or discomfort by the patient. Pain should be characterized by site, type, frequency, duration, precipitating and relieving factors.

Pain

Symptom

A subjective phenomenon described as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Pain should be characterized by site, type, frequency, duration, precipitating and relieving factors. NB: The word pain comes from the Latin “poena” meaning a fine or a penalty.

Pain - filling cystometry

Investigation

The complaint of pain during filling cystometry is abnormal. Its site, character and duration should be noted.

Pain - Neurobiology

Symptom

Alterations in gut and bladder motility, visceral perception and central processing of pain and motor function due to abnormalities in the visceral and central nervous systems may account for the symptoms.

Pain - psychology

Symptom

Pain is modulated by cognitive factors and emotional experience, memory, attention and context represented in descending modulation of pain, affecting pain experience from moment to moment and longer term. Pain has an impact on many aspects of daily life, affecting mood, sleep, relationships and activities. Therefore, attention to the psychological aspects of pain is an important part of effective assessment and treatment.

Pain (during) - Filling cystometry

Investigation

The complaint of pain during filling cystometry is abnormal. Its site, character and duration should be noted.

Pain during straining/defecation (female)

Symptom

Complaint of pain during defecation or straining to defecate.

Pain Evaluation and Measurement

Investigation

Pain rating(s) are essential in patient evaluation including: baseline and ongoing regular evaluation of severity, quality of life, questions about thoughts, emotions and behavior associated with the pain (questionnaires). Pain measurement: one of the most commonly used tools is the visual analogue scale (VAS), which is a 10cm line from "0" no pain to "10" extreme pain. Pain evaluation involves additional pain mapping by identifying pain generators through diagnostic procedures. These include EMG, Q-tip touch sensitivity testing, trigger point injections, nerve blocks and imaging.

Pain experience

Symptom

According to the most common views, pain constitutes the internal perception of bodily damage. It is unknown whether chronic pelvic pain syndromes (CPPS) are primarily an abnormal perception of a normal stimulus or a normal perception of an abnormal physiologic sensory stimulus.

Painful bladder syndrome

Symptom

Painful bladder syndrome is the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and night-time frequency, in the absence of proven urinary infection or other obvious pathology.

Paraphimosis

Sign

Entrapment of the prepuce behind the glans usually due to a preputial ring.

Paravaginal repair - open, laparoscopic, robotic

Surgery – Female

Extraperitoneal bilateral reattachment of the lateral edge of the damaged fascia to the Arcus Tendineus Fasciae Pelvis (alt: white line).

Paruresis ("bashful" or "shy" bladder)

Symptom

Complaint of the inability to initiate voiding in public (i.e. voiding in the presence of other persons) despite there being no difficulty in private.

Passive fecal incontinence (female)

Symptom

Fecal soiling without sensation or warning or difficulty wiping clean.

Passive fecal leakage (female)

Symptom

Involuntary soiling of liquid or solid stool without sensation or warning or difficulty wiping clean.

Passive (insensible) fecal incontinence.

Symptom

Complaint of involuntary soiling of liquid or solid stool without sensation or warning.

Patient Preparation and Information in advance of Invasive Urodynamics

Investigation

Although evidence indicates that urodynamics is generally well tolerated, studies have examined pain and embarrassment, using a variety of questionnaire methods. Younger patients have been identified as a group that may experience more pain and apprehension associated with depression, anxiety and/or bladder pain syndrome. Effectiveness of patient information leaflets requires comprehensibility and communicative effectiveness. However, reports analysing existing information conclude that this is of poor quality. Studies to develop a detailed explanatory leaflet, which were used in a double-blind randomized controlled trial to conclude that 'leaflet' or 'no leaflet' intervention had a disappointing satisfaction outcome. Poor understanding of the test has been associated with lack of satisfaction with care and with, for example, the perception that the investigation in itself is therapeutic. Some evidence exists that information leaflets about urodynamic investigations are too difficult for patients to understand.

Young adults and patients with a bladder pain syndrome may have a relatively negative experience with urodynamic investigation. Conflicting evidence exists about which precise information is helpful to give to patients before urodynamic testing to reduce distress. Effective communication is an expectation in modern healthcare, so that patients become actively engaged in the test and their care delivery. A leaflet with a minimum set of items would facilitate informed decision making. Good information before and during the test increases a patient's acceptance and confidence, and will reduce confusion. Although in the absence of good evidence, that an explanatory leaflet about urodynamic investigation with sufficient information, which uses clear, unambiguous wording will be appreciated by the majority of patients.

Pelvic Congestion Syndrome

Symptom

i. Pressure, heaviness, dull aching pain in the pelvis and/or in the back. ii. Dysmenorrhoea.

Pelvic electrical stimulation

Conservative Management – General

This is the application of electrical current to stimulate the pelvic viscera or their nerve supply.

Pelvic Floor

Conservative Management – General

The term pelvic floor relates to the compound structure, which closes the bony pelvic outlet. The term pelvic floor muscles refers to the muscular layer of the pelvic floor. The pelvic floor consists of different layers, the most cranial being the peritoneum of the pelvic viscera and the most caudal being the skin of vulva, scrotum and perineum. The middle layers of the pelvic floor are made up of predominantly muscular tissue. Apart from the pure pel-

vic floor muscles, fibro-muscular and fibrous elements, like the endo-pelvic fascia are found in this layer. Different well recognizable muscles together form the muscular layer of the pelvic floor: levator ani, striated urogenital sphincter, external anal sphincter, ischiocavernosus and bulbospongiosus. All these muscles are working together to seal the lower aspect of the pelvic cavity. Urethra, vagina, and rectum pass through the pelvic floor and are surrounded by the pelvic floor muscles. The pelvic bones are the structures to which the muscular layer is attached.

Pelvic Floor - Voluntary Contraction

Sign

Voluntary contraction of the pelvic floor muscles means that the patient is able to contract the pelvic floor muscles on demand. A contraction is felt as a tightening, lifting and squeezing action under the examining finger. A voluntary contraction can be absent, weak, normal or strong.

Pelvic floor assessment in female sexual dysfunction - Pelvic floor manometry

Investigation

Measurement of resting pressure or pressure rise generated during contraction of the PFM using a manometer connected to a sensor which is inserted into the urethra, vagina, or rectum. Pelvic floor manometric tools measuring pressure in either mmHg, hPa, or cmH₂O can be used to assess resting pressure, maximal squeeze pressure (strength), and endurance.

Pelvic Floor Dynamometry

Investigation

A dynamometer is an instrument that measures power or force. Pelvic floor dynamometry: Measurement of PFM resting and contractile forces using strain gauges mounted on a speculum (a dynamometer), which is inserted into the vagina. Dynamometry measures force in Newton units (N=1kg×m/s (sq)).

Pelvic Floor Function - General

Conservative Management – General

The function of the pelvic floor is to support the pelvic organs. The function of the pelvic floor muscles is performed by contraction and relaxation. In its resting state, the pelvic floor gives support to the pelvic organs. Whether the support function is normal depends on the anatomical position of the muscles on the activity of the pelvic floor muscles at rest (active support) and on the integrity of the fascia (passive support). During intra-abdominal pressure rise, the pelvic floor muscles must contract to maintain the support function of the pelvic floor. A contraction of the pelvic floor muscles results in a ventral and cranial movement of the perineum, and an upward movement of the pelvic organs together with an anterior movement caused primarily by the vaginal and rectal parts of the levator ani. When the pelvic floor muscles contract the urethra closes, as do the anus and the vagina. This contraction is important in preventing involuntary loss of urine or rectal contents. For women it can also function as a defense mechanism against sexual intercourse. For maintaining continence, it is also important to realize that detrusor activity is inhibited by pelvic floor muscle contraction.

Pelvic Floor Manometry

Investigation

A manometer is a device for measuring pressure. Pelvic floor manometry: measurement of resting pressure or pressure rise generated during contraction of the PFM using a manometer connected to a sensor, which is inserted into the urethra, vagina or rectum. Pelvic floor manometric tools measure pressure in mmHg, hPa or cmH₂O. Conversion of data to the international standard unit of measurement (hPa) is recommended. Perineometer: the first PFM vaginal pressure device connected to a manometer developed by Kegel.

Pelvic Floor Muscle - Pain Assessment (female)

Investigation

Pain evaluation consists of baseline and ongoing regular evaluation of severity, quality of life, thoughts, emotions, and behavior associated with the pain (via direct consultation or questionnaires) and investigations to identify well-defined/ confusable/non-pain syndromes. 1. Pain measurement: pain can only be measured subjectively. Patient-reported outcome measures include: a) Numerical rating scale (NRS), from 0 (no pain) to 10 (extreme pain), with half-points marked. b) Visual analogue scale (VAS), a 10-cm line with the same labels at the ends. c) A simple verbal rating scale can be used, e.g., "none," "mild," "moderate," "severe." 2. Pain mapping: identifying pain generators through diagnostic procedures such as questionnaires, digital palpation, EMG, quantitative sensory threshold measurement, trigger point injections, nerve blocks, and imaging. a) Questionnaires: several pain questionnaires can be used in the evaluation of musculoskeletal pain in the pelvis; the choice will be determined by which is most appropriate to the presenting pelvic floor dysfunction: McGill Pain Questionnaire, Pelvic Floor Distress Inventory (PFDI), Female Sexual Function Index, Female Sexual Distress Scale, Pelvic Pain and Urgency/Frequency Questionnaire. b) Pain chart/body map: a simple line drawing of an outline of the front and back (or relevant body part) of the human body, onto which the patient sketches or ticks or marks areas of bodily pain to demonstrate the site and extent of perceived pain; c) Pain checklist: a list of anatomical locations from which the patient selects sites that are relevant to her complaint.

Pelvic floor muscle assessment in female sexual dysfunction - general comments

Investigation

Assessment of pelvic floor muscle (PFM) function involves evaluating the tone, strength, endurance, coordination, reflex activation during rises in intra-abdominal pressure as well as the capacity to properly relax this musculature. These muscles are involved in sexual function as PFM contraction occurs during arousal and intensifies with orgasm and PFM tone is related to vaginal sensation. Superficial PFM such as the bulbospongiosus and ischiocavernosus are also involved in erection of the clitoris by blocking the venous escape of blood from the dorsal vein. Thus, reduction in PFM strength and endurance has been related to lower sexual function. Likewise, PFM hypotonicity may be related to vaginal hypoesthesia, anorgasmia and urinary incontinence during intercourse while hypertonicity may lead to dyspareunia.

Pelvic floor muscle assessment in female sexual dysfunction - Pelvic floor dynamometry

Investigation

Measurement of PFM resting and contractile forces using strain gauges mounted on a speculum (a dynamometer), which is inserted into the vagina. Dynamometry measures force in Newton (N). Several parameters such as tone, strength, endurance, speed of contraction and coordination can be evaluated.

Pelvic floor muscle assessment in female sexual dysfunction - Pelvic floor electromyography (EMG)

Investigation

The recording of electrical potentials generated by the depolarization of PFM fibers. Intra-muscular EMG consists in the insertion of a wire or needle electrode into the muscle to record motor unit action potentials while surface EMG requires electrodes placed on the skin of the perineum or inside the urethra, vaginal or rectum. EMG amplitude at rest and contraction can be recorded.

Pelvic floor muscle assessment in female sexual dysfunction - Pelvic floor ultrasound imaging

Investigation

Evaluation of PFM morphology at rest, during maximal contraction and Val-salva. Several parameters pertaining to assess the bladder neck and anorectal positioning and hiatus dimensions can be measured.

Pelvic Floor Muscle Contraction - Repetition and Set

Conservative Management – Female

Repetition: the completion of a whole cycle from the starting position, through the end of the movement, and back to the start e.g. one PFM contraction with relaxation. Set: the number of times the desired number of repetitions is performed e.g., three sets of 12 PFM contractions

Pelvic Floor Muscle Dyssynergia

Sign

Incoordination of the PFM and another muscle group during a functional activity, for example, the pelvic floor muscles may not relax appropriately during micturition or defecation.

Pelvic floor muscle endurance (female)

Sign

The ability to sustain near maximal or maximal force, assessed by the time one is able to maintain a maximal static or isometric contraction, or ability to repeatedly develop near maximal or maximal force determined by assessing the maximum number of repetitions one can perform at a given percentage of 1 RM (one-repetition maximum).

Pelvic Floor Muscle Exercises - Kegels

Conservative Management – Female

A PFM contraction or PFM exercise. This term is named after Arnold Kegel, an American gynecologist who first described the clinical effect of PFMT in the late 1940s. ICS recommends the use of the term PFMT (not the word Kegels) to refer to exercises that specifically target the PFM.

Pelvic floor muscle hypertonicity (female)

Sign

A general increase in muscle tone that can be associated with either elevated contractile activity and/or passive stiffness in the muscle. As the cause is often unknown the terms neurogenic hypertonicity and non-neurogenic hypertonicity are recommended.

Pelvic floor muscle hypotonicity (female)

Sign

A general decrease in muscle tone that can be associated with either reduced contractile activity and/or passive stiffness in the muscle. As the cause is often unknown the terms neurogenic hypotonicity and nonneurogenic hypotonicity are recommended.

Pelvic Floor Muscle Injury (PFMI)

Sign

On clinical palpation, PFMI is diagnosed when one or more of the following is present: a) A discontinuity of the puborectalis muscle at its attachment to the inferior pubic ramus; b) A distance of >3.5 finger widths between the two sides of puborectalis muscle insertion; c) A gap in the continuity of the pubovisceral muscle between the pubic rami and the ano-rectum.

Pelvic Floor Muscle Injury (PFMI) - Detection by Magnetic Resonance Imaging (MRI)

Imaging

PFM injury: can represent a full spectrum, from disruption of a single fascicle, to complete disruption of the muscle origin. At present, there is no

universally accepted system for the diagnosis and evaluation of the extent of the injury. Essentially, abnormalities are judged to have occurred when the morphology of the pubococcygeal portion of the levator ani muscle deviates from what is seen in normal nulliparous women. Several groups have studied and defined levator damage on MRI when one or more of the following is present: absence of pubococcygeal muscle fibers in at least one 4-mm section, or two or more adjacent 2-mm sections in both the axial and the coronal planes. The degree of injury can be assessed based on the amount of muscle involved in the injury, with reasonable repeatability among different examiners in a single group. More than half the expected muscle bulk is associated with the presence of POP.

Pelvic Floor Muscle Injury (PFMI) - Ultrasound detection

Imaging

PFMI is diagnosed on ultrasound when at least one of the following is present: a) Undetected puborectalis-to-ipsilateral sidewall attachment on any of the three central slices (full avulsion); b) Undetected puborectalis-to-ipsilateral sidewall attachment on at least one slice (partial avulsion); c) A levator-urethra gap (LUG) of greater than 2.5cm. PFM position in the pelvis: can be measured in the sagittal plane in relation to defined landmarks, and may be related to PFM dysfunction (elevated or descended pelvic floor). Hiatal dimension: is the cross-sectional area of the pelvic floor/levator hiatus, including anteroposterior and transverse distances.

Pelvic floor muscle (PFM) function (male) - contractile function

Sign

- . Voluntary contractility: the individual is able to contract the PFM on demand. A contraction is felt as a tightening, lifting and squeezing action under/around the finger.
- . Strength: Force-generating capacity of a muscle. It is generally expressed as maximum voluntary contraction.
- . Endurance: the ability to sustain near maximal or maximal force, assessed by the time a patient is able to sustain a maximal static or isometric contraction.
- . Repeatability: the ability to repeatedly develop near maximal or maximal force, determined by assessing the maximum number of repetitions the patient can perform before detectable decline in force. Record number of contractions in a row.
- . Co-contraction: contraction or activation of two or more muscles at the same time. Identify which muscles are co-contracting and whether the co-contraction is synergistic.
- . Relaxation ability: return of the PFM to its original resting tone following the voluntary contraction. Also includes the ability to maintain PFM relaxation in anticipation of or during any type of touch.

Pelvic floor muscle (PFM) function (male) - Diagnoses related to PFM examinations

Sign

- . Overactive pelvic floor muscles: Pelvic floor muscles which do not relax, or may even contract when relaxation is functionally needed, for example, during voiding or defecation.
- . Underactive pelvic floor muscles: Pelvic floor muscles which cannot voluntarily contract when instructed to do so or when required.

Pelvic floor muscle (PFM) function (male) - Examinations at rest

Sign

- . Myalgia: provoked by palpation. Levator muscle pain/tenderness may be elicited by palpation of these muscles via rectal examination.
- . Tender point: Tenderness to palpation at a specific soft tissue body site.
- . Tone: state of the muscle, usually defined by its resting tension, clinically determined by resistance to passive movement. Muscle tone has two com-

ponents, the contractile component and the viscoelastic component. Muscle tone may be altered in the presence or absence of pain.

. Increased PFM tone (non-neurogenic hypertonicity): increased tone in a patient without an intercurrent neurological diagnosis.

. Decreased PFM tone (non-neurogenic hypotonicity): decreased tone in a patient without an intercurrent neurological diagnosis.

. Symmetry: if examining in the left lateral, there will be a gravity effect and the dependent side will have a different feel to the upper side and appear as asymmetrical. This may affect PFM tone. Not so common in men.

. PFM injury: e.g. palpable anal sphincter gap though overall not common unlike women.

Pelvic floor muscle (PFM) function (male) - General

Sign

The following signs of PFM function may be assessed via the perineum (visual or tactile examination) or per rectum (digital palpation) examination. Digital rectal examination (DRE) may be less useful in male urinary dysfunctions where the urethral sphincter, inaccessible to DRE, has a more important role.

Pelvic floor muscle (PFM) function (male) - Perineal examination

Sign

When the patient is asked to cough or bear down, the perineum should only show limited downward movement; ventral movement may occur because of the guarding actions of the pelvic floor muscles.

- Perineal elevation: This is the inward (ventro-cephalad) movement of the perineum and anus. Look for testicular lift and penile retraction. These need to be checked against movement of the scrotum and the whole penis. Correct movement occurs with the PFM only: the shaft of the penis draws in and the testes lift in a cephalad direction. These movements may be better visualized in standing than supine position.

- Perineal descent: This is the outward (dorso-caudal) movement of the perineum and anus.

Pelvic Floor Muscle Relaxation

Conservative Management – General

Pelvic floor muscle relaxation following contraction results in a reduction in the support given to the urethra, vagina and anus. The perineum and the pelvic organs return to their anatomical resting position. The pelvic floor muscles must relax in order to remove the passive continence mechanisms, thereby favoring normal micturition. The same is true for relaxation before and during defecation, allowing the anorectal angle to become obtuse, favoring rectal emptying

Pelvic floor muscle strength (female)

Sign

Force-generating capacity of a muscle. It is generally expressed as maximal voluntary contraction measurements and as the one-repetition maximum (1RM) for dynamic measurements.

Pelvic floor muscle tenderness (female)

Sign

Occurrence of the sensation of pain or painful discomfort of the pelvic floor muscles elicited through palpation.

Pelvic floor muscle tone (female)

Sign

In normally innervated skeletal muscle, tone is created by “active” (contractile) and “passive” (viscoelastic) components clinically determined by resistance of the tissue against stretching or passive movement.

Pelvic Floor Muscle Training

Conservative Management – Female

Exercise to improve PFM strength, endurance, power, relaxation or a combination of these parameters.

Pelvic Floor Muscle Training - Biofeedback Training

Conservative Management – Female

Feedback: is sensory information that is available as the result of an activity that a person has performed. It can be provided by an intrinsic source (from within the individual), or an extrinsic source (from the clinician), and can occur concurrently with the activity or post-activity, e.g., verbal information from the clinician to the patient during or following PFM assessment. Biofeedback: is the use of an external sensor to give an indication with regard to bodily processes, usually with the purpose of changing the measured quality. It is an adjunctive therapy.

Pelvic Floor Muscle Training - Detraining

Conservative Management – Female

Cessation of training, but also planned or unplanned reduced volume or intensity of training.

Pelvic Floor Muscle Training - Dilator Therapy

Conservative Management – Female

Dilator therapy: a conical or cylindrically shaped device (made of an inert material) inserted intravaginally or intra-anally, with the aim of increasing the flexibility or elasticity of the soft tissues via application of a prolonged elongation or stretch. Dilators may also be used as a desensitizer device, to reduce fear, anxiety or pain associated with vaginal touch and in conjunction with vaginismus or sexual pain. When combined with EMG, dilators can be used to train PFM relaxation during penetration. Dilators may also be used to increase the tolerance of skin to sliding when the dilator is moved in and out.

Pelvic Floor Muscle Training - Dose-response issues related to exercise training

Conservative Management – Female

1. Dose–response: amount/volume of training and its effect on the speed and degree of the effect of the training program. 2. Frequency of exercise: the number of activity sessions per day, week, or month. 3. Duration of exercise: the unit of time (number of seconds/ minutes) of activity in each repetition or session, e.g., a 10-s PFM contraction. It also refers to the length of the whole training period (intervention), e.g., 3/6 months. 4. Intensity: the amount of resistance used or the effort associated with the physical activity. For strength training, it is often expressed as a percentage of one repetition maximum: 1RM (the maximum load a person can lift once), e.g., 70 % of maximum. 5. Session/bout: the block of time devoted to the training, e.g., a 1-h session.

Pelvic Floor Muscle Training - EMG assessment of PFM

Conservative Management – Female

Electromyography assessment of PFM consists of the use and interpretation of the surface EMG recording of a muscle for rehabilitation purposes should be done cautiously, recognizing that the main goal is the qualitative description of the muscle activation pattern, and not a qualitative diagnosis.

1. Baseline muscle activity: amount of microvolts generated by the target muscle during rest. 2. Peak microvolts: the highest EMG amplitude achieved. 3. Slow recruitment: slow initiation of muscle activation contraction. 4. Slow de-recruitment or slow latency to return to baseline: slow relaxation of the muscle contraction. 5. Inconsistent resting baseline: variation of baseline between contractions, between sets, or between days may be related to a change in patient symptoms, e.g., hypertonic PFM. 6. Excessive accessory

muscle contraction: increased amplitude in accessory muscles often resulting in cross talk and is indicative of poor isolation of target muscle contraction.

Pelvic Floor Muscle Training - EMG Biofeedback Unit Instrumentation

Conservative Management – Female

1. EMG signal amplitude: number of microvolts (μV) a muscle is generating. EMG biofeedback units can deliver either the actual amount of EMG activity in μV or an average μV value. 2. Artifact: extraneous information non-recognizable in the EMG signal from sources other than the target muscle such as the environment or other body functions. 3. Cross talk: muscle activity from nearby muscles that can artificially increase EMG amplitude; a type of artifact. 4. Dual-channel EMG: use of two channels to monitor two separate muscles or muscle groups at the same time, such as the PFM and abdominal muscles, with the goal of either promoting synergist activity or reducing EMG activity of one muscle while increasing the other. 5. Band pass: limits muscle fiber frequencies that are monitored and displayed in the EMG tracing.

Pelvic Floor Muscle Training - EMG Training of PFM

Conservative Management – Female

1. Up-training: EMG biofeedback training to increase the EMG activity of a hypotonic muscle with low EMG activity. 2. Down-training: EMG biofeedback training to decrease EMG activity and relax muscles.

Pelvic Floor Muscle Training - Facilitation Technique

Conservative Management – Female

Any method of increasing recruitment/response of a non-responding muscle. In the case of non-contractile or very weak PFMs, this may include a quick stretch of the PFM, with tapping or stretching the PFM digitally. An overflow effect from a strong contraction of a nearby synergistic muscle (e.g. external rotators) may also assist facilitation or recruitment of PFMs.

Pelvic Floor Muscle Training - Functional Training

Conservative Management – Female

Functional training consists of training for tasks of daily living and self-care activities, e.g., squatting to train quadriceps and gluteal muscles. 1. Functional PFM training: training and exercises that incorporate a correct PFM contraction into activities of daily living such as lifting, transferring out of bed, or sneezing. A PFM contraction before a rise in intraabdominal pressure, e.g., a cough (“the Knack”) is part of functional PFM training. 2. Coordination training: the ability to use different parts of the body together smoothly and efficiently. Related to PFM training, coordination training means PFM contraction with other muscles or other muscle groups, e.g. respiratory muscles. 3. Functional mobility training: an intervention directed at improving the physical ability to perform a daily task. For voiding/defecation, this may include: gait training, transfer training, stair training, and other mobility training to improve speed and safety in reaching the toilet.

Pelvic Floor Muscle Training - Individualized, Supervised, Group and Home

Conservative Management – Female

1: Individualized PFMT: an individual PFM program aimed at improving the specific deficiencies in PFM structure or function based on assessment of the woman’s ability to contract the PFM. 2: Supervised PFMT: a PFMT program taught and monitored by a health professional/clinician/instructor. 3: Group PFMT: PFMT conducted in an exercise class. Class participation may occur with or without previous individualized PFM instruction. Home training: home PFM exercise program: an unsupervised PFMT program, which the individual performs at home.

Pelvic Floor Muscle Training - Isometric/Static Contraction

Conservative Management – Female

A muscular action during which no change in the length of the total muscle or joint angle takes place.

Pelvic Floor Muscle Training - Isotonic or eccentric contraction

Conservative Management – Female

Isotonic contraction: A muscular action during which the tension developed by the muscle remains almost constant while the muscle shortens. Eccentric contraction: a muscular action in which the muscle lengthens in a controlled manner.

Pelvic Floor Muscle Training - Local Muscle Endurance Training

Conservative Management – Female

Training with a low load and a high number of repetitions or holding the contraction over time.

Pelvic Floor Muscle Training - Maintenance Training

Conservative Management – Female

A program designed to prevent loss of the previous level of functioning.

Pelvic Floor Muscle Training - Muscle Power Training

Conservative Management – Female

All training with the aim of generating power; can be close to maximal contraction training and/or rapid contractions.

Pelvic Floor Muscle Training - Overload

Conservative Management – Female

A situation in which the body is required to perform exercise beyond that to which the neuromuscular system is accustomed during routine activities. Training adaptation occurs in response to a progressive “overload”. Progressive overload: the gradual increase in stress placed upon the body during exercise training.

Pelvic Floor Muscle Training - Relaxation Training

Conservative Management – Female

Relaxation: the ability to control muscle activity such that muscles not specifically required for a task are quiet and those that are required are fired at the minimal level needed to achieve the desired results. Relaxation can be considered a motor skill in itself because the ability to reduce muscle firing is as important to control as the generation of firing. a) General relaxation technique: a technique that involves the whole body, with the aim of effecting a global relaxation, including a decrease in the skeletal and smooth muscles, a decrease in the heart rate and respiration rate and an increase in parasympathetic activity. General relaxation techniques can also be used aimed at relaxing local muscles. b) Progressive muscular relaxation (also known as Jacobsen’s technique): monitoring tension in each specific muscle group, by contracting, then relaxing the tension, with attention paid to the contrast between tension and relaxation. This type of relaxation is also termed “contract–relax.” c) Meditation: a practice of concentrated focus upon a sound, object, visualization, the breath, movement, or attention itself to increase awareness of the present moment, reduce stress, promote relaxation, and enhance personal and spiritual growth. d) Mindfulness: intentionally bringing one’s attention to the internal and external experiences occurring in the present moment. Mindfulness is often taught through a variety of meditation exercises. e) EMG relaxation techniques: techniques to decrease EMG muscle activity or activation through a methods, including a conscious effort to relax.

Pelvic Floor Muscle Training - Resistance*Conservative Management – Female*

Resistance: the amount of force opposing a movement. Resistance devices: any object used to increase resistance to contraction, e.g., hand weights. Vaginal resistance device: objects inserted into the vagina or rectum that are inflated or spring-loaded devices to increase resistance to contraction.

Pelvic Floor Muscle Training - Strength Training*Conservative Management – Female*

Training with high resistance (close to maximal contractions) and few repetitions with the aim of increasing muscle volume and neural adaptations.

Pelvic Floor Muscle Training - Stretching*Conservative Management – Female*

Stretching (also referred to as flexibility training when the method is used on skeletal muscles where increased range of motion over the joints is the aim): the application of an external force to muscle and connective tissue to elongate it in the direction opposite to its shortened position. This can be done parallel or perpendicular to the muscle fiber direction. For the PFM this can be applied as a widening of the levator hiatus in the axial plane (latero-laterally) via a digit or use of a dilator, or a caudal movement (via a straining/bearing down maneuver) in the sagittal plane.

Pelvic Floor Muscle Training - Vaginal Cones*Conservative Management – Female*

Weighted vaginal cones: objects of different shapes, sizes, and weights, which are inserted into the vagina above the level of the PFM with the aim of providing sensory biofeedback and load on the PFM to increase muscle recruitment and strength.

Pelvic Floor Muscles - Involuntary Contraction

Sign

Involuntary contraction of the pelvic floor muscles is the contraction that takes place preceding an abdominal pressure rise, such as due to a cough, to prevent incontinence. An involuntary contraction can be absent or present.

Pelvic Floor Muscles - Involuntary Relaxation

Sign

Involuntary relaxation of the pelvic floor muscles is the relaxation that takes place when the patient is asked to strain as if defecating. An involuntary relaxation can be absent or present.

Pelvic Floor Muscles - Non-Contracting Pelvic Floor

Sign

Involuntary relaxation of the pelvic floor muscles is the relaxation that takes place when the patient is asked to strain as if defecating. An involuntary relaxation can be absent or present.

Pelvic Floor Muscles - Non-contracting, Non-relaxing pelvic floor

Sign

Non-contracting, non-relaxing pelvic floor means that during palpation, there is neither a palpable contraction nor a palpable relaxation of the pelvic floor muscles.

Pelvic Floor Muscles - Non-relaxing Pelvic Floor

Sign

Non-relaxing pelvic floor means that during palpation, there is no palpable voluntary or involuntary relaxation of the pelvic floor muscles.

Pelvic Floor Muscles - Voluntary Relaxation

Sign

Voluntary relaxation of the pelvic floor muscles means that the patient is

able to relax the pelvic floor muscles on demand, after a contraction has been performed. Relaxation is felt as a termination of the contraction. The pelvic floor muscles should return at least to their resting state. Avoluntary relaxation can be absent, partial or complete

Pelvic floor spasm (female)

Sign

The presence of contracted, painful muscles on palpation and elevated resting pressures by vaginal manometry. This persistent contraction of striated muscle cannot be released voluntarily. If the contraction is painful, this is usually described as a cramp. Pelvic floor myalgia (a symptom) may be present with or without a change in PFM tone (a sign).

Pelvic organ

Surgery – Female

This refers most commonly to the uterus and/or the different vaginal compartments and their neighboring organs such as bladder, rectum or bowel.

Pelvic organ prolapse - definition of sign

Sign

The descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy). The presence of any such sign should be correlated with relevant POP symptoms. Most commonly, this correlation would occur at the level of the hymen or beyond.

Pelvic organ prolapse - diagnosis*Diagnosis*

This diagnosis (i) by symptoms and clinical examination, assisted by any relevant imaging, involves the identification of descent of one or more of the anterior vaginal wall (central, paravaginal or combination cystocele), posterior vaginal wall (rectocele), the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar) after hysterectomy. The presence of any such sign should correlate with relevant POP symptoms.

Pelvic organ prolapse - related radiology*Imaging*

Defecography demonstrates normal anatomy of the anorectum as well as disorders of rectal evacuation. With barium paste inserted rectally prior to defecation, measurement of the anorectal angle is allowed with evidence of the presence, size or emptying of any rectocele. Enterocoeles, rectal intussusception and mucosal prolapse might be diagnosed as well as a spastic pelvic floor (anismus).

Pelvic Organ Prolapse - Signs

Sign

All examinations for POP should be performed with the woman's bladder empty (and if possible an empty rectum). An increasing bladder volume has been shown to restrict the degree of descent of the prolapse. The choice of the woman's position during examination, e.g. left lateral (Sims), supine, standing or lithotomy is that which can best demonstrate POP in that patient and which the woman can confirm as the maximal extent she has perceived e.g. by use of a mirror or digital palpation. The degree of prolapse may be worse after a lengthy time in the upright position.

Pelvic organ prolapse (anatomical definition of sign of POP)

Sign

The descent of one or more of the anterior vaginal wall, posterior vaginal

wall, uterus (cervix) or vaginal vault (cuff scar after hysterectomy). The presence of any such sign should be correlated with relevant POP symptoms.

Pelvic organ prolapse (POP) - examination

Sign

All examinations for POP should be performed with the woman's bladder empty (and if possible an empty rectum). An increasing bladder volume has been shown to restrict the degree of descent of the prolapse. The choice of the woman's position during examination, e.g. left lateral (Sims), supine, standing or lithotomy is that which can best demonstrate POP in that patient and which the woman can confirm as the maximal extent she has perceived e.g. by use of a mirror or digital palpation. The degree of prolapse may be worse after a lengthy time in the upright position

Pelvic organ prolapse (POP) surgery - complications

Surgery – Female

Complications related to POP native tissue repairs and surgeries using prostheses/grfts/mesh have been classified separately according to joint IUGA/ICS recommendations. The sorting system used in both documents utilizes specific category (C), time (T) and site (S) taxonomy together referred to as the CTS classification system. Classification is aided by on line calculators: <http://www.ics.org/complication> or <http://www.ics.org/ntcomplication>.

Pelvic organ prolapse (POP) surgery - further surgery

Surgery – Female

Any subsequent procedure relating to the primary surgery: (i) primary surgery in a different (new) site/compartments; (ii) repeat surgery in the same site/compartments for POP symptom recurrence; (iii) surgery for complications e.g. mesh exposure, pain, infection, hemorrhage; (iv) surgery for non-POP-related issues usually urinary incontinence.

Pelvic organ prolapse (POP) surgery - objective outcomes.

Surgery – Female

POP-Q measurement should be tabulated with absolute values and percentages to allow other studies to compare results.

Pelvic organ prolapse (POP) surgery - perioperative data

Surgery – Female

Blood loss, operating time, length of hospital stay, return to normal activities and complications.

Pelvic organ prolapse (POP) surgery - primary surgery

Surgery – Female

First procedure required for treating POP in any compartment.

Pelvic organ prolapse (POP) surgery - secondary outcomes

Surgery – Female

Lower urinary tract symptoms, stress incontinence, or bowel and sexual dysfunction to be included in studies whenever possible.

Pelvic organ prolapse (POP) surgery - subjective (patient-reported) outcomes

Surgery – Female

At its simplest level, this can be reported as the presence or absence of a vaginal bulge. Patient satisfaction and quality of life can be measured by validated instruments that cover prolapse, urinary, bowel and sexual function.

Pelvic organ prolapse (POP) symptoms

Symptom

Complaints by a woman in reference to the position (descent) of her pelvic organs. Symptoms are generally worse at the times when gravity might make the prolapse worse (e.g. after long periods of standing or exercise) and

better when gravity is not a factor, e.g. lying supine. Prolapse may be more prominent at times of abdominal straining, e.g. defecation.

Pelvic organ prolapse (POPQ) - stage 0

Sign

No prolapse is demonstrated.

Pelvic organ prolapse (POPQ - Stage I)

Sign

Most distal portion of the prolapse is more than 1cm above the level of the hymen.

Pelvic organ prolapse (POPQ - Stage II)

Sign

The most distal portion of the prolapse is situated between 1cm above the hymen and 1cm below the hymen.

Pelvic organ prolapse (POPQ - stage III)

Sign

The most distal portion of the prolapse is more than 1cm beyond the plane of the hymen but everted at least 2cm less than the total vaginal length.

Pelvic organ prolapse (POPQ - Stage IV)

Sign

Complete eversion or eversion at least within 2cm of the total length of the lower genital tract is demonstrated.

Pelvic organ prolapse (POPQ - Stage O)

Sign

.No prolapse is demonstrated

Pelvic pain - female

Symptom

Complaint of pain perceived to arise in the pelvis, not associated with symptoms suggestive of lower urinary tract, sexual, bowel or gynaecological dysfunction.

Pelvic pain (male)

Symptom

Complaint of pain, pressure or discomfort related to the pelvis but not clearly related to the bladder, urethra, scrotum or perineum.

Pelvic Pain Syndrome

Symptom

Pelvic pain syndrome is the occurrence of persistent or recurrent episodic pelvic pain associated with symptoms suggestive of lower urinary tract, sexual, bowel or gynecological dysfunction. There is no proven infection or other obvious pathology.

Pelvic pressure (female)

Symptom

Complaint of increased heaviness or dragging in the suprapubic area and/or pelvis.

Penetration urinary incontinence

Symptom

Urinary incontinence at penetration (penile, manual or sexual device)

Penetration urinary incontinence (female)

Symptom

Urinary incontinence at penetration (penile or sexual device).

Penile glans and shaft examination**Sign**

- . Penile plaque: palpation of node or plaque in the tunica usually on the dorsal aspect (perhaps related to Peyronie's disease).
- . Lichen sclerosus: tight foreskin, cracking and bleeding.

Penile pain with intercourse (male dyspareunia)*Symptom*

Complaint of any penile discomfort occurring during intercourse - may be caused by penile disease, vaginal anatomy (e.g. vaginal tightening, scarring or prosthesis exposure), and/or may relate to various positions with intercourse causing impingement on the uterine cervix.

Percutaneous Electrical Nerve Stimulation*Conservative Management – Female*

Percutaneous electrical nerve stimulation: a therapeutic modality that stimulates peripheral sensory nerves performed with a (few) needle electrode(s) that are placed in close proximity to the area to stimulate. Percutaneous neuromuscular electrical stimulation (e.g. posterior TNS) is a peripheral neuromodulation technique, in which the posterior tibial nerve is electrically stimulated three finger breadths above the medial malleolus, via insertion of a percutaneous needle electrode. This is coupled with an adhesive reference surface electrode placed near to the needle. This intervention is offered to patients with OAB.

Perforation

Surgery – Complication related

Abnormal opening into a hollow organ or viscus.

Perianal examination (female)**Sign**

(i) Excoriation: perianal excoriation, skin rashes. (ii) Soiling: perianal fecal soiling or vaginal fecal soiling. (iii) Discharge: perianal or vaginal bloody or mucus discharge. (iv) Gaping anus: non-coaptation of anal mucosa at rest. (v) Scars, sinuses, deformities, condylomata, papillomata, hematoma. (vi) Deficient perineum/cloacal-like defect: A spectrum of tissue loss from the perineal body and rectovaginal septum with variable appearance. There can be a common cavity made up of the anterior vagina and posterior rectal walls or just an extremely thin septum between the anorectum and vagina. (vii) Others described individually: anal fissure, hemorrhoids, anorectal prolapse, fistula-in-ano, recto-vaginal fistula, anorectal/ vaginal/perineal fistula.

Perianal itching/pruritus ani*Symptom*

Complaint of an itchy anus.

Perineal abnormalities (female)**Sign**

Scars, sinuses, deformities, condylomata, papillomata, hematoma.

Perineal body (PB)**Sign**

This is measured from the posterior margin of the hymen to the mid-anal opening.

Perineal descent (female)**Sign**

Excessive dorsocaudal movement of the vulva, perineum, and anus, for example, during coughing, Valsalva or straining.

Perineal descent (male)**Sign**

This is the outward (dorso-caudal) movement of the perineum and anus (when the individual is asked to cough or bear down).

Perineal elevation (female)**Sign**

Inward (ventrocephalad) movement of the vulva, perineum, and anus during, for example, PFM contraction.

Perineal elevation (male)**Sign**

This is the inward (ventro-cephalad) movement of the perineum and anus. Look for testicular lift and penile retraction. These need to be checked against movement of the scrotum and the whole penis. Correct movement occurs with the PFM only: the shaft of the penis draws in and the testes lift in a cephalad direction. These movements may be better visualized in standing than supine position.

Perineal examination (male)**Sign**

- . This is generally performed with the patient in the lateral supine or in the lithotomy position.
- . Perianal dermatitis: Skin infection at the perineum around the anus, usually associated with faecal incontinence or diarrhoea.
- . Fissures: A break or tear in the skin of the perineum, anal sphincter or distal rectum usually associated with anal pain.

Perineal gap (PG)

Surgery – Female

Thinned out medial area (cm) between Moynihan forceps placed bilaterally where the labia minora meet the perineum.

Perineal length (PL)

Surgery – Female

Distance from posterior margin of vestibule to anterior anal verge.

Perineal measurements - perineal length**Sign**

Distance from posterior margin of vestibule to anterior anal verge.

Perineal pain (female)*Symptom*

Complaint of pain felt between the posterior fourchette (posterior lip of the vaginal introitus) and the anus.

Perineal pain (male)*Symptom*

Complaint of pain, pressure or discomfort felt on the surface or in the depth of the tissue between the scrotum and the anus.

Perineal Pain Syndrome*Symptom*

Perineal pain syndrome is the occurrence of persistent or recurrent episodic perineal pain, which is either related to the micturition cycle or associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven infection or other obvious pathology.

Perineocele**Sign**

Bulge in the perineum associated with herniation of the anterior wall of the rectum.

Perineorrhaphy - commencement position (PCT)

Surgery – Female

Where is Level III, the perineorrhaphy is commenced, e.g. hymen, mid-vestibule, posterior margin of vestibule.

Perineorrhaphy - depth (PD)

Surgery – Female

Depth of the excised perineum.

Perineorrhaphy - mid-perineal thickness (MPT)

Surgery – Female

Thickness (cm) of the mid-perineum in the midline.

Perineorrhaphy - perineal gap (PG)

Surgery – Female

Thinned out medial area (cm) between Moynihan forceps placed bilaterally where the labia minora meet the perineum.

Perineorrhaphy - width (PW)

Surgery – Female

Width of the excised perineum.

Pessaries - General*Conservative Management – Female*

Pessaries are intravaginal devices used to try to restore the prolapsed organs to their normal position and hence to relieve symptoms. Vaginal pessaries can be broadly divided into two types: support pessaries (ring, ring with support, Gehrung, Hodge, shelf) and space-filling pessaries (donut, Gellhorn, cube, inflatable).

Phimosis

Sign

Partial or complete inability to retract the prepuce due to adhesion between the glans and the prepuce or a preputial ring.

Physiotherapy for Female Pelvic Floor Dysfunction*Conservative Management – Female*

Physiotherapy involves “using knowledge and skills unique to physiotherapists” and “is the service only provided by, or under the direction and supervision of, a physiotherapist”. Adherence: is the extent to which a client/patient’s behavior corresponds to the agreed treatment protocol and/or regime as recommended by their healthcare provider. It does not refer to the intervention itself; rather, the patient’s commitment to undertaking the behavioral change to adhere to the intervention.

Compliance: is the extent to which a client/patient’s behavior matches, or complies with their healthcare provider’s recommended treatment protocol and/or regime.

Pictorial stool chart

Sign

It is a pictorial chart of stool consistencies. The “Bristol stool chart” seems to have widespread face validity and recognition and is useful in conversations with patients about their stool consistency, despite little validation work. It has not been validated as an outcome measure and a reported change in category may not represent sufficient degree of precision for use as a trial end point.

Pneumaturia*Symptom*

Complaint of the passage of gas (or air) from the urethra during or after voiding.

Polyuria

Sign

Excessive production of urine. It has been defined as >40mls urine/kg body weight during 24 hours or 2.8 litres (70 kg individual).

Polyuria - Causes

Sign

Diabetes mellitus: Insulin dependent (Type I); Insulin independent (Type II). Diabetes insipidus: Pituitary, Renal, Gestational, Primary polydipsia (psychogenic, dipsogenic or iatrogenic).

Polyuria (global symptom)*Symptom*

Complaint that the urine excretion volume over 24 hours is noticeably larger than the previous excretion.

POP - anterior vaginal wall (compartment) prolapse*Diagnosis*

Clinically evident (symptoms, signs or any relevant imaging) descent of the anterior vaginal wall (compartment).

POP - posterior vaginal wall (compartment) prolapse*Diagnosis*

Clinically evident (symptoms, signs or any relevant imaging) descent of the posterior vaginal wall (compartment).

POP - uterine/ cervical prolapse*Diagnosis*

Clinically evident (symptoms, signs or any relevant imaging) descent of the uterus or uterine cervix.

POP - vaginal vault (cuff scar) prolapse*Diagnosis*

Clinically evident (symptoms, signs or any relevant imaging) descent of the vaginal vault (cuff scar after hysterectomy).

POPQ - anterior vaginal wall - Point Aa

Sign

A point located in the middle of the anterior vaginal wall three (3) cm proximal to the external urethral meatus. By definition, the range of position of Point Aa relative to the hymen is -3 to +3cm.

POPQ - anterior vaginal wall - Point Ba

Sign

A point that represents the most distal (i.e., most dependent) position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to Point Aa. By definition, Point Ba is at -3cm in the absence of prolapse and would have a positive value equal to the position of the cuff (Point C) in women with total uterine prolapse or post-hysterectomy vaginal eversion.

POPQ - defined points

Sign

The anatomic position of the six defined points (two on the anterior vaginal wall, two in the superior vagina, and two on the posterior vaginal wall) for measurement should be centimeters (cm) above or proximal to the hymen (negative number) or cm below or distal to the hymen (positive number) with the plane of the hymen being defined as zero (0). For example, a cervix that protruded 3 cm distal to the hymen would be + 3 cm. All points are measured on maximal straining (except total vaginal length).

POPQ - fixed point of reference**Sign**

The hymen is the fixed point of reference used throughout the POP-Q system of quantitative prolapse description.

POPQ - Genital hiatus**Sign**

The genital hiatus (GH) is measured from the middle of the external urethral meatus to the posterior margin of the hymen.

POPQ - Perineal body**Sign**

The perineal body (PB) is measured from the posterior margin of the hymen to the mid-anal opening.

POPQ- Posterior vaginal wall - Point Bp**Sign**

A point that represents the most distal (i.e., most dependent) position of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to Point Ap. By definition, Point Bp is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in a woman with total post-hysterectomy vaginal eversion.

POPQ - recording measurements**Sign**

Intraoperative measurements with traction can be quite different than measurements made during Valsalva in clinic, both in regards to cervical location and the vaginal walls. Measurements directly after removing a vaginal pessary are unreliable and will tend to understage the degree of prolapse.

POPQ - Superior vagina - Point D**Sign**

A point that represents the location of the posterior fornix in a woman who still has a cervix. It is included as a point of measurement to differentiate suspensory failure of the uterosacral-cardinal ligament "complex" from cervical elongation. When the location of Point C is significantly more positive than the location of Point D, this is indicative of cervical elongation which may be symmetrical or eccentric. Point D is omitted in the absence of the cervix.

POPQ - Superior vaginal - Point C**Sign**

A point that represents either the most distal (i.e., most dependent) edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar) after total hysterectomy.

POPQ - Total vaginal length**Sign**

The total vaginal length (TVL) is the length of the vagina (cm) from the posterior fornix to hymen when Point C or D is reduced to its full normal position.

POPQ- Posterior vaginal wall - Point Ap**Sign**

A point located in the midline of the posterior vaginal wall three (3) cm proximal to the hymen. By definition, the range of position of Point Ap relative to the hymen is -3 to +3 cm.

POP-related vaginal bleeding, discharge, infection.**Symptom**

Complaint of vaginal bleeding, discharge or infection related to dependent ulceration of uterine and/or vaginal prolapse.

Position-dependent voiding - female**Symptom**

Complaint of having to take specific positions to be able to void spontaneously or to improve bladder emptying, (female) e.g. leaning forwards or backwards on the toilet seat or voiding in a semi-standing position.

Position-dependent voiding - male**Symptom**

Complaint of having to adopt specific positions to be able to void spontaneously or to improve bladder emptying, e.g. needing (men) to void in a seated position.

Possible Intercurrent Diagnoses of POP**Diagnosis**

(i) Urodynamic stress incontinence: Involuntary leakage of urine during filling cystometry, associated with increased intraabdominal pressure, in the absence of a detrusor contraction. In the circumstances where this diagnosis is only made when the POP is reduced, the additional term "occult" is appropriate. (ii) Detrusor overactivity: The occurrence of involuntary detrusor contractions during filling cystometry. (iii) Bladder oversensitivity: Increased perceived bladder sensation during bladder filling with: an early first desire to void; an early strong desire to void, which occurs at a low bladder volume; a low maximum cystometric bladder capacity. No abnormal increases in detrusor pressure are noted. (iv) Detrusor underactivity and Acontractile detrusor.

Possible Prolapse-related Diagnoses**Diagnosis**

(i) Voiding dysfunction: A diagnosis by symptoms and urodynamic investigations is defined as abnormally slow and/or incomplete micturition, based on abnormal slow urine flow rates and/or abnormally high post void residuals, ideally on repeated measurement to confirm abnormality. Voiding cystometry can be required to determine the cause of the voiding dysfunction. (ii) Recurrent urinary tract infections (UTI): A diagnosis by clinical history assisted by the results of diagnostic tests involves the determination of the occurrence of at least three symptomatic and medically diagnosed urinary tract infections (UTI) over the previous 12 months. One possible POP-related cause is a chronically elevated postvoid residual. (iii) Defecatory dysfunction: A diagnosis by clinical history assisted, at times, by the results of diagnostic tests involving the confirmation of abnormal or difficult function in the initiation, passage or completion of defecation. (iv) Sexual dysfunction: A diagnosis by clinical history (including specific questionnaires) involving the confirmation of abnormal function and/or difficulty with sexual intercourse.

Post coital pain (female)**Symptom**

Pain after intercourse such as vaginal burning sensation or pelvic pain.

Post-coital LUT symptoms (female)**Symptom**

Such as acute cystitis, worsened urinary frequency or urgency, dysuria, suprapubic tenderness.

Post-defecatory soiling**Symptom**

Complaint of soiling occurring after defecation.

Posterior colporrhaphy - mid-vaginal laxity (MVL - undisplaced)

Surgery – Female

Laxity (cm) of the vaginal mucosa (anterior traction) midpoint in the vagina supero-posteriorly and in the midline with the vaginal vault held in an undisplaced position (similar to that after vault fixation).

Posterior colporrhaphy - posterior vaginal vault descent (PVVD)

Surgery – Female

Descent of the posterior vaginal vault (on traction) towards the anterior perineum (perineal gap). Subtract from the total posterior vaginal length (TPVL) the distance from the inferiorly displaced vaginal vault to the anterior perineum.

Posterior colporrhaphy - recto-vaginal fascial laxity (RVFL - cm)

Surgery – Female

Laxity in the recto-vaginal fascia (anterior traction) midpoint in the vagina supero-posteriorly (mucosa opened) and in the midline with the vaginal vault held in an undisplaced position.

Posterior vaginal repair (colporrhaphy) - mesh or graft reinforcement

Surgery – Female

A structural addition or inclusion used to give additional strength in function. It should be noted whether the graft is biologic, absorbable synthetic or permanent synthetic.

Posterior vaginal repair (colporrhaphy) - native tissue

Surgery – Female

Repair the vagina by excision and suturing the edges of any defect. Midline fascial plication represents the commonest procedure, involving dissection under the full thickness of the vaginal epithelium followed by central plication of the pre-rectal fascia over the rectum and excision of “excess” vaginal wall skin.

Posterior vaginal vault descent (PVVD) - posterior colporrhaphy

Surgery – Female

Descent of the posterior vaginal vault (on traction) towards the anterior perineum (perineal gap). Subtract from the total posterior vaginal length (TPVL) the distance from the inferiorly displaced vaginal vault to the anterior perineum.

Posterior Vaginal Vestibule

Sign

Posterior hymenal ring to anterior perineum (posterior margin of vestibule).

Posterior vaginal wall (compartment) prolapse

Sign

Observation of descent of the posterior vaginal wall. Commonly, this would represent rectal protrusion into the vagina (rectocele). Higher stage posterior vaginal wall prolapse after prior hysterectomy will generally involve some vaginal vault (cuff scar) descent and possible enterocele formation. Enterocele formation can also occur in the presence of an intact uterus.

Posterior vaginal wall (compartment) prolapse

Diagnosis

Diagnosis by symptoms and clinical examination, assisted at times by any relevant imaging (i.e. clinically evident) descent of the posterior vaginal wall (compartment).

Post-micturition incontinence

Symptom

Complaint of a further involuntary passage of urine following the completion of voiding

Post-micturition leakage

Symptom

Complaint of a further involuntary passage of urine following the completion of micturition.

Postoperative de novo dyspareunia

Symptom

Dyspareunia first reported after surgery or other interventions.

Postoperative de novo sexual dysfunction symptoms

Symptom

New onset symptoms of sexual dysfunction (not previously reported before surgery).

Postoperative findings - ultrasound imaging (male)

Imaging

Post-prostatectomy (urethral shape), male sling position, artificial sphincter - placement of cuff and reservoir, bulking agents.

Postural urinary incontinence

Symptom

Complaint of urinary incontinence during change of posture or position, e.g. from supine or seated to standing.

Post-void residual (PVR)

Investigation

Volume of urine left in the bladder at the completion of voiding.

Post-void residual (PVR - abdominal) - ultrasound imaging

Imaging

Volume = width (left to right) x depth (anterior to posterior) x length (cranial to caudal) x 0.52 (mL)

Post-void residual (PVR - female) - assessment of normality

Investigation

Quoted upper limits of normal reflect accuracy of measurement. Studies using “immediate” PVR measurement by ultrasound (within 60 seconds of voiding) suggest an upper limit of normal of 30ml. Studies using urethral catheterization (generally 5 - 10min delay) quote higher upper limits of 50ml or 100ml. An isolated finding of a raised PVR requires confirmation before being considered significant.

Post-void residual (PVR - female - conditions for measurement)

Investigation

PVR reading is erroneously elevated by delayed measurement due to additional urine production (1-14 mL/min). Ultrasonic techniques (transvaginal, translabial most accurately) allow immediate (within 60 s of voiding) measurement and possible repeat measurement. A short plastic female catheter provides the most effective drainage for PVR measurement by catheterization.

Post-void residual (PVR - male) - assessment of normality

Investigation

Upper limits in normal community dwelling men without LUTS are age dependent with studies reporting a cut-off value of 10-30 mL. There are no adequate currently available data from which to quote expected/typical

ranges of PVR in men with symptoms of lower urinary tract dysfunction. Such studies would need to reflect the accuracy of measurement, including whether the PVR measurement is "immediate" (e.g. by ultrasound) or by urethral catheterization (unless also "immediate"). In the absence of such studies, our consensus view (D'Ancona, Haylen et al.) is that a PVR (ultrasound) over 50mL, following double voiding, might prompt the suspicion of voiding dysfunction.

Post-void residual (PVR - male) - Conditions for measurement

Investigation

PVR reading is erroneously elevated by delayed measurement due to additional renal input (1-14mL/min) into the bladder. Ultrasonic techniques allow immediate (within 60 seconds of micturition) measurement to minimize the error. Immediate insertion of a transurethral catheter for bladder drainage can still provide an effective and accurate PVR measurement. All urethral catheters, however, may not be of equal drainage efficacy. Ultrasound PVR measurement should ideally be repeated at least once if PVR is present. An overdistended rather than "comfortably full" bladder might lead to a falsely elevated initial PVR, assessed further by repeat voiding/ repeat PVR.

Postvoiding detrusor contraction - pressure flow studies

Investigation

An increase in detrusor pressure (Pdet) following the cessation of urinary flow.

Post-voiding incontinence

Symptom

Complaint of a further involuntary passage (incontinence) of urine or dribbling following the completion of voiding.

Post-voiding symptom

Symptom

Lower urinary tract symptom experienced after voiding.

Post-voiding urgency

Symptom

Complaint of persistent urgency post-voiding.

Premature ejaculation

Symptom

Complaint of a persistent or recurrent pattern of too rapid achievement of ejaculation during partnered sexual activity, i.e. before the individual wishes it.

Premicturition pressure

Investigation

The pressure recorded immediately before the initial isovolumetric contraction.

Pressure flow studies - detrusor opening pressure (cm H2O)

Investigation

Detrusor pressure recorded immediately before the initial isovolumetric contraction.

Pressure-flow studies

Investigation

Pressure volume (urinary flow) relationship of the bladder during voiding. It begins when the "permission to void" is given and ends when the individual considers voiding has finished. Measurements to be recorded should be: detrusor pressure (Pdet); abdominal pressure (Pabd) with detrusor pressure (Pdet) calculated. Urine flow rate (mL/s) should also be recorded.

Pressure-flow studies - acontractile detrusor

Investigation

The detrusor cannot be observed to contract (i.e. no increase in Pdet) during pressure-flow studies resulting in failure to void. Limited voiding may occur by straining. May be neurogenic (evidence of a neurological disorder) or non-neurogenic (no evidence of a neurological disorder).

Pressure-flow studies - delayed relaxation of the urethral sphincter (? neurogenic)

Investigation

Impaired and hindered relaxation of the urethral sphincter during voiding attempt resulting in delay of urine flow.

Pressure-flow studies - detrusor pressure at end flow (pdet-ef - cm H2O)

Investigation

Detrusor pressure recorded at the end of urine flow.

Pressure-flow studies - detrusor pressure at maximum flow (Pdet.qmax - cm H2O)

Investigation

Detrusor pressure recorded at maximum urinary flow rate.

Pressure-flow studies - detrusor underactivity (DU)

Investigation

Low detrusor pressure or short detrusor contraction time, usually in combination with a low urine flow rate resulting in prolonged bladder emptying and/or failure to achieve complete bladder emptying within a normal time span.

Pressure-flow studies - flow delay - unit: s)

Investigation

The time elapsed from initial rise in pressure to onset of flow. It reflects the time necessary for the fluid to pass from the point of pressure measurement to the uroflow transducer.

Pressure-flow studies - initiated reflex bladder emptying (?neurogenic)

Investigation

An artificially elicited LUT reflex comprised of various manoeuvres (exogenous stimuli) performed by the patient or the therapist, resulting in complete or incomplete bladder emptying.

Pressure-flow studies - maximum detrusor pressure (Pdet-max -cm H2O)

Investigation

Maximum registered detrusor pressure during voiding.

Pressure-flow studies - neurogenic detrusor underactivity

Investigation

Low detrusor pressure or short detrusor contraction time, usually in combination with a low urine flow rate, resulting in prolonged bladder emptying and/or failure to achieve complete bladder emptying within a normal time span in the setting of a clinically relevant neurologic disease.

Pressure-flow studies - non-relaxing urethral sphincter (? neurogenic)

Investigation

A non-relaxing, obstructing urethral sphincter resulting in reduced urine flow.

Pressure-flow studies - normal detrusor contractile function.

Investigation

Normal voiding in an individual is achieved by an adequate continuous detrusor contraction that leads to complete bladder emptying within a normal time span.

Pressure-flow studies - postvoiding detrusor contraction (cm H₂O)*Investigation*

An increase in detrusor pressure (Pdet) following the cessation of urinary flow.

Pressure-flow studies - urethral opening pressure (Pdet-uo - cm H₂O)*Investigation*

Detrusor pressure recorded at the onset of measured flow.

Pressure-flow studies (male +/- VCU, EMG) - detrusor sphincter dyssynergia (DSD)*Investigation*

Dyscoordination between detrusor and smooth or striated sphincter function during voiding due to a neurological abnormality (i.e. detrusor contraction synchronous with contraction of the urethral and/or periurethral striated muscle).

Pressure-flow studies (male +/- VCU, EMG) - dysfunctional voiding*Investigation*

This is characterized an intermittent and/or fluctuating urine flow due to inadequate or variable relaxation generally of the external sphincter during voiding in neurologically normal men.

Pressure-flow studies (male +/- VCU,EMG) - abnormal urethral function during voiding.*Investigation*

The urethral sphincter(s) do not relax completely or they are (temporarily) contracted during voiding, resulting in increased detrusor pressure. Bladder emptying may be incomplete (PVR present).

Pressure-flow studies (male +/- VCU,EMG) - bladder outlet obstruction (BOO)*Investigation*

The generic term for mechanical obstruction during voiding. It is a reduced urine flow rate with an increased detrusor pressure. PVR can be present.

Pressure-flow studies (male +/- VCU,EMG) - normal urethral function during voiding.*Investigation*

The urethra opens and is continuously relaxed to allow micturition at a normal pressure and urine flow and results in complete bladder emptying. The voiding is prompted by a detrusor contraction and simultaneous relaxation of the smooth and striated sphincters of the urethra and pelvic floor muscles.

Prevention of Pelvic Floor Dysfunction*Conservative Management – Female*

Prevention is the act of preventing or decreasing the risk of disease or disability. Activities that are directed toward slowing or stopping the occurrence of both mental and physical illness and disease, minimizing the effects of a disease or impairment on disability, or reducing the severity or duration of an illness. 1. Primary prevention: prevention of the development of disease in a susceptible or potentially susceptible population through such specific measures as general health promotion efforts. 2. Secondary prevention: efforts to decrease the duration of illness, reduce the severity of diseases, and limit the sequelae through early diagnosis and prompt intervention. 3. Tertiary prevention: efforts to limit the degree of disability and promote rehabilitation and restoration of function in patients/clients with chronic and irreversible diseases.

Primary and Further Surgery

Surgery – Female

The following standardized terminology is proposed for surgical trials and clinical audit:

A. Primary Surgery: This indicates the first procedure required for the treatment of POP in any compartment. B. Further Surgery: Provides a global term for the number of subsequent procedures the patient undergoes, directly or indirectly, relating to the primary surgery. Further surgery per se should not be interpreted as a measure or failure as the definitions of success and failure will be defined within the context of the individual study. Further surgery is subdivided into: I. Primary prolapse surgery/different site: a prolapse procedure in a new site/compartment following previous surgery (e.g., anterior repair following previous posterior repair). II. Repeat surgery: a repeat operation for prolapse arising from the same site. Where combinations of procedures arise, such as new anterior repair plus further posterior repair, these should be reported separately as primary anterior repair and repeat posterior repair. III. Surgery for complications: mesh exposure or extrusion, pain, or patient compromise such as hemorrhage (see Complications section). IV. Surgery for non-POP related conditions: subsequent surgery for stress urinary incontinence or fecal incontinence.

Primary enuresis*Symptom*

Complaint of intermittent incontinence that occurs during periods of sleep that has been present lifelong.

Procidentia*Sign*

Complete eversion of the vagina and uterus (Stage IV utero-vaginal prolapse)

Proctoscopy (anoscopy)*Investigation*

The inspection of the anal canal to identify anal fissure, fistula, or hemorrhoids as a cause of anal symptoms.

Prolapse*Symptom*

A falling, slipping or downward displacement of a part or organ (Latin: Prolapsus - "a slipping forth")

Prolapse (pelvic organ) symptoms*Symptom*

A departure from normal sensation, structure or function experienced by the woman in reference to the position of her pelvic organs. Symptoms are generally worse at the times when gravity might make the prolapse worse (e.g. after long periods of standing or exercise) and better when gravity is not a factor e.g. lying supine. Prolapse may be more prominent at times of abdominal straining e.g. defecation.

Prominence

Surgery – Complication related

Parts that protrude beyond the surface (e.g. due to wrinkling or folding with no epithelial separation).

Prosthesis

Surgery – Female

A fabricated substitute to assist a damaged body part or to augment or stabilise a hypoplastic structure.

Provocative Manoeuvres*Investigation*

Provocative manoeuvres are defined as techniques used during urodynam-

ics in an effort to provoke detrusor overactivity, for example, rapid filling, use of cooled or acid medium, postural changes and hand washing.

Pudendal neuralgia

Sign

Elicited or described by the patient as burning vaginal and vulva pain (anywhere between the anus and the clitoris) with tenderness over the course of the pudendal nerve.

Pudendal pain (neuralgia)

Symptom

Complaint of pain, pressure or discomfort in one or more areas innervated by the pudendal nerve (possible inflammation or entrapment of the pudendal nerve and involving its dermatome).

Q

Q-Tip Testing

Sign

Measurement of urethral axial mobility at rest and straining to assess degree of mobility.

R

Radiological imaging (male) - defecography (evacuation proctography)

Imaging

This demonstrates the anatomy of the anorectum as well as disorders of rectal evaluation. Barium paste is inserted prior to defecation over a translucent commode.

Radiological imaging (male) - intravenous urography (IVU)

Imaging

Conventional X-ray or CT, this study provides an anatomical outline of the upper urinary tract, ureters and bladder as well as an evaluation of renal function by excretion of contrast media. Calcification may be shown in kidneys, ureter, bladder, seminal vesicles or vasa.

Radiological imaging (male) - retrograde +/- antegrade urethrography

Imaging

Unidirectional or combined contrast imaging is used to visualize the urethral lumen, to diagnose strictures and diverticula and to stage urethral trauma.

Radiological imaging (male) - videocystourethrography (VCU)

Imaging

Synchronous radiological screening of the bladder and urethra allowing direct observation of bladder events, the position and conformation of the bladder neck in relation to the pubic symphysis, diverticula of the bladder and urethra, recto-urethral fistulae and vesico-ureteric reflux.

Radiological imaging (male) - Videourodynamics (pressure-flow studies)

Imaging

A functional test of the lower urinary tract in which pressure, capacity and flow data are simultaneously combined with real-time imaging of the lower and upper urinary tract.

Radiological imaging (male) - voiding (micturitional) cystourethrography

Investigation

Imaging of the bladder neck, urethra and prostate during voiding looking for vesico-ureteric reflux, vesical or urethral fistulae, vesical or urethral diverticulae, strictures and the level of obstruction e.g. bladder neck or prostate.

Rate of Nocturnal Urine Production

Sign

Nocturnal urine volume / time asleep (i.e. night). Measured in mL/min.

Receptive anal intercourse

Symptom

Having a penis penetrating one's anus.

Receptive urethral intercourse

Symptom

Having a penis penetrating one's urethra (urethral coitus).

Rectal (and prostate) examination (male)

Sign

Digital rectal examination (DRE) is recommended as part of the physical examination. Generally done with the patient standing and bent over the examining table, or with the patient in the left lateral knees bent position, or in the lithotomy position. DRE is usually pain-free.

. Anal examination: This can detect the following findings in the anal sphincter or distal rectum:

- Benign diseases: hemorrhoids, fissure, anal sphincter injury, levator discomfort or pain.

- Possible malignant diseases: anal, distal rectal and prostate carcinoma.

- Anal tone: increased or decreased anal sphincter tone might suggest similar changes in the urinary sphincter and may indicate neurologic disease.

- Anal stricture: a circumscribed narrowing or stenosis of the anal canal.

. Prostate gland characteristics: size, symmetry, firmness, nodules, and its relation to the pelvic sidewall and rectum can be assessed. The gland is about the size of a walnut and has a consistency similar to that of the contracted thenar eminence of the thumb.

. Prostate nodularity and/or firmness – May indicate possible abnormality requiring further investigation.

. Prostate tenderness: prostate palpation, as part of a DRE, is usually pain-free. Pain with prostatic palpation is variable though if present, it may be helpful in differentiating prostate/pelvic pain syndromes.

. Rectal examination (circumferential): this might lead to the detection of non-urolological diseases such as rectal carcinoma, fistula and fecal impaction.

Rectal bleeding/mucus

Symptom

Complaint of the loss of blood or mucus per rectum.

Rectal digitation

Symptom

Use of fingers in the rectum to manually assist in the evacuation of stool contents.

Rectal Dynamics - Attempted defecation and balloon expulsion

Investigation

Patients with symptoms of prolapse and elderly patients with a history of constipation who present with passive incontinence should be thoroughly examined for the presence of a full thickness rectal prolapse. Patients are asked to strain as they would to pass stools whilst on a toilet or commode and given enough time to reproduce the prolapsing lump before examination. Expulsion of a water-filled balloon can be used in the assessment of constipated patients. The ability to expel the balloon within 1min may be a useful tool in demonstrating the absence of pelvic floor dyssynergia.

Rectal Dynamics - Rectal Impedance Planimetry

Investigation

These studies are the preserve of research institutions rather than clinical practice. The rationale is to calculate the diameter or cross sectional area of an intra rectal bag during a distension sequence. Impedance planimetry measures the cross sectional area which enables the circumferential wall tension to be calculated.

Rectal dynamics (female) - Rectal Compliance

Investigation

Rectal compliance is the term that describes the relationship between pressure and volume, reflecting the ability of the rectum to act as a reservoir and is assessed using a barostat, inflating the bag within the rectum prior to the recording inflation protocol, known as conditioning, has been shown to improve the precision of compliance testing. Typically, compliance figures between 4 and 11 mmHg/ml are quoted as the normal range.

Rectal examination (female)

Sign

Observations can include: (i) Anal sphincter tone and strength: Assessment on digital examination, as good or poor in the absence of any quantitative assessment; (ii) Anal sphincter tear: May be recognized as a clear "gap" in the anal sphincter on digital examination; (iii) Confirm presence or absence of rectocele: and if possible, differentiate from enterocele. Diagnose perineal body deficiency; (iv) Confirm presence or absence of fecal impaction; (v) Other rectal lesions: Intussusception, rectovaginal fistula or tumor; (vi) Anal lesions; Hemorrhoids, fissure; (vii) Other perianal lesions: Anocutaneous fistula.

Rectal Irrigation

Conservative Management – Female

Rectal irrigation is the use of liquid solutions given by enema to remove material from the rectum.

Rectal musculature - Endoanal ultrasonography

Imaging

(1) Internal anal sphincter - The caudal continuation of the circular smooth muscle of the rectum forms the internal anal sphincter, which terminates caudally in a clearly defined edge, at a variable distance from the anal verge. (2) Longitudinal muscle - Comprises smooth muscle cells continuous with the outer layer of the rectal wall, and striated muscle from various pelvic floor muscles. The longitudinal muscle lies between the internal and external anal sphincters in the inter-sphincteric space. (3) External anal Sphincter – It is made up of striated muscle and surrounds the longitudinal muscle forming the outer border of the inter-sphincteric space. The external sphincter is divided into deep, superficial and subcutaneous parts, with the deep and subcutaneous parts of the sphincter forming rings of muscle. Between them, elliptical fibres from the superficial part

of the external anal sphincter run anteriorly from the perineal body to the coccyx posteriorly.

(4) Puborectalis - is formed from the most anterior fibres of the pubococcygeus muscle. This forms a sling pulling the rectum forward.

Rectal prolapse

Symptom

Complaint of external protrusion of the rectum (differentiation on subsequent examination between rectal mucosal prolapse and full thickness rectal wall prolapse which includes muscle and serosal layers).

Rectocele

Sign

Bulge in posterior vaginal wall associated with herniation of anterior wall of the rectum. An aspect of posterior vaginal wall (compartment) prolapse.

Recto-vaginal fascial laxity (RVFL - cm) - posterior colporrhaphy

Surgery – Female

Laxity of the rectovaginal fascia (anterior traction) midpoint in the vagina super-posteriorly (mucosa opened) and in the midline with the vaginal vault held in an undisplaced position.

Rectovaginal fistula

Sign

Is a communication from the rectum to the vagina.

Recurrent urinary tract infection - diagnosis (female)

Diagnosis

This diagnosis by clinical history assisted by the results of diagnostic tests involves the determination of the occurrence of at least three symptomatic and medically diagnosed urinary tract infection (UTI) over the previous 12 months.

Recurrent Urinary Tract Infections (female)

Diagnosis

This diagnosis by clinical history assisted by the results of diagnostic tests involves the determination of the occurrence of at least three symptomatic and medically diagnosed UTIs over the previous 12 months.

Recurrent urinary tract infections (UTI - female)

Symptom

A history of at least three symptomatic and medically diagnosed UTI in the previous 12 months. The previous UTI(s) should have resolved prior to a further UTI being diagnosed.

Recurrent urinary tract infections (UTIs - male)

Symptom

A history of at least two symptomatic and medically diagnosed UTIs in the previous 12 months. The previous UTI(s) should have resolved prior to a further UTI being diagnosed.

Reduced bladder filling sensation

Symptom

Complaint that the sensation of bladder filling is less intense or occurs later in filling than previously experienced.

Reduced bladder sensation - Filling cystometry

Investigation

Bladder sensation perceived to be diminished during filling cystometry.

Reduced bladder sensation - filling cystometry*Investigation*

Bladder sensation perceived to be diminished during filling cystometry.

Reduced compliance (storage dysfunction - RCSD) incontinence*Diagnosis*

Urinary incontinence directly related to the RCSD.

Reduced compliance storage dysfunction (RCSD)*Diagnosis*

In individuals with lower urinary tract symptoms, more commonly storage symptoms, when there is a non-phasic (at times linear or exponential) rise in detrusor pressure during filling cystometry with generally reduced capacity indicating reduced compliance.

Reflex bladder triggering

Conservative Management – General

This comprises various manoeuvres performed by the patient or the therapist to elicit reflex bladder emptying by exteroceptive stimuli (relating to, being, or activated by stimuli received from outside the bladder).

Related

Surgery – Complication related
Connected

Repeat Cystometry*Investigation*

There is no convincing evidence that the clinical diagnosis on the basis of the first cystometry is often changed on repetition of the test. There is no definite evidence that immediate repetition of an adequately performed urodynamic test 'for confirmation' is required. ICS does not recommend routine immediate repetition of invasive urodynamics 'for confirmation' if the test was technically adequate, has been considered representative, and has

answered the clinical question. ICS recommends immediate repetition of the test when doubt exists as to whether the test has answered the clinical question. ICS recommends repetition of a urodynamic test when technical errors and artefacts have been observed at immediate post test analysis.

Retention with overflow*Diagnosis*

Involuntary loss of urine directly related to an excessively full bladder in retention.

Retrograde urethrocytography and voiding cystourethrography*Imaging*

Unidirectional or combined contrast imaging of the urethra in a patient in the 30 degree oblique position to visualize the lumen, mainly to diagnose urethral strictures or diverticula. It is also of use to diagnose and stage urethral trauma.

Retroverted uterus

Sign

The axis of the uterus is directed backwards towards the hollow of the sacrum, away from its anteverted position overlying the bladder. Cervix is noted in/towards the anterior fornix with fundus perhaps palpable in the posterior fornix.

Rigid sigmoidoscopy*Investigation*

This is a bedside test to inspect the rectal mucosa with no bowel preparation.

S**Sacral spinal cord lesion (SSCL)***Diagnosis*

This is a neurological lesion in the sacral spinal cord. Neurogenic lower urinary tract dysfunction in SSCL: findings include acontractile detrusor with or without decreased bladder compliance and usually with impaired sphincter activity.

Sacrocolpopexy - open, laparoscopic, robotic

Surgery – Female

Suspension of the cervix (and usually vagina) utilizing mesh or graft to the anterior longitudinal ligament usually at the level of the sacral promontory. This procedure tends to be performed as an adjunct following subtotal hysterectomy for advanced utero-cervical prolapse.

Sacrocolpopexy - open, laparoscopic, robotic

Surgery – Female

Suspension of the vagina utilizing mesh or graft to the anterior longitudinal ligament usually at the level of the sacral promontory.

Sacrohysteropexy - open, laparoscopic, robotic

Surgery – Female

Suspension of the cervix (with or without additional vaginal attachment) utilizing mesh or graft to the anterior longitudinal ligament usually at the

level of the sacral promontory. This tends to be performed for women who are keen to preserve their uterus.

Sacrospinous Colpopexy (SSC)

Surgery – Female

Fixation of the vaginal vault to the sacrospinous ligament: (a) Unilateral or bilateral procedure. (b) Anterior or posterior approach. (c) Permanent or absorbable suture and number of 'bites' taken. (d) Type of suture placement device employed. (e) Direct vision or with the use of a specific instrument (tactile feedback).

Sacrospinous hysteropexy

Surgery – Female

Fixation of the uterus to the sacrospinous ligament (SSL). Variations: (i) unilateral or bilateral; (ii) anterior or posterior approach; (iii) permanent or absorbable stitches; (iv) number of sutures; (v) direct vision or with use of a specific instrument (tactile feedback).

Scarred vagina - postoperative*Symptom*

Perception by the partner of a "stiff" vagina or a foreign body (stitches, mesh exposure, mesh shrinkage).

Scheduled Voiding Regimes in Female Pelvic Floor Dysfunction*Conservative Management – Female*

Toileting on a fixed schedule around the patient's normal voiding pattern, which includes a progressive voiding schedule using relaxation and distraction techniques for urgency suppression. Scheduled voiding regimes have been categorized as: bladder training, timed voiding, habit training, and prompted voiding.

Bladder training: In the past, bladder training has also been referred to as bladder drill, bladder discipline, bladder re-education, and bladder retraining. It consists of a program of patient education, along with a scheduled voiding regimen with gradually adjusted voiding intervals. Specific goals are to correct faulty habit patterns of frequent urination, improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes, and restore patient confidence in controlling bladder function. **Timed voiding:** is a passive toileting assistance program, initiated and maintained by caregivers for patients who cannot participate in independent toileting. It is a fixed voiding schedule.

Habit training: consists of a toileting schedule matched to the individual's voiding patterns based on their voiding diary. The toileting schedule is assigned to fit a time interval that is shorter than the person's normal voiding pattern and precedes the time period when incontinent episodes are expected.

Prompted voiding: is used to teach people to initiate their own toileting through requests for help and positive reinforcement from caregivers, often done in combination with a scheduled voiding regimen, typically every 2h.

Scrotal examination

Sign

Normal: The scrotum is a loose sac containing the testes and spermatic cord structures. The epididymis is palpable applied to the posterior surface of the testis as a ridge although occasionally it is sited on the anterior surface.

. Inflammation: The epididymis may be swollen and tender, and if severe, the inflammatory process may involve the whole scrotal content (i.e. testis and epididymis [epididymo-orchitis]) and the scrotal skin as well.

. Cystic dilatations of the epididymis: (epididymal cysts or spermatocele) and hydroceles (fluid collections between the visceral tunica albuginea and parietal layer of the testicular peritoneum) - usually benign. The examination of these structures would be generally non-tender and without pain.

. Inguinal bulge: Examination and differentiation of hernia from hydrocele or cyst of spermatic cord or groin lymph nodes. (Use of transillumination may assist though ultrasound is generally diagnostic).

Scrotal pain

Symptom

Complaint of pain, pressure or discomfort felt in and around the scrotum. It may be localized to the testis, epididymis, cord structures or scrotal skin.

Scrotal pain syndrome

Symptom

Scrotal pain syndrome is the occurrence of persistent or recurrent episodic scrotal pain which is associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven epididymo-orchitis or other obvious pathology.

Sensation of anorectal blockage - female

Symptom

Complaint suggestive of anorectal obstruction.

Sensory symptoms (female)

Symptom

A departure from normal sensation or function, experienced by the woman during bladder filling. Normally, the individual is aware of increasing sensation with bladder filling up to a strong desire to void.

Separation

Surgery – Complication related

Physically disconnected (e.g. vaginal epithelium).

Sexual activity urinary incontinence

Symptom

Complaint of urinary incontinence associated with or during sexual activity (nb coital urinary incontinence [female] and sexual arousal incontinence [male]).

Sexual arousal (female) - vascular assessment

Investigation

Sexual arousal results in increased blood flow allowing genital engorgement, protrusion of the clitoris and augmented vaginal lubrication through secretion from the uterus and Bartholin's glands and transudation of plasma from engorged vessels in the vaginal walls. Several instruments are available to measure blood flow during sexual stimulation. Inadequate vasculogenic response may be related to psychological factors as well as vascular compromise due to atherosclerosis, hormonal influence, trauma or surgery.

Sexual arousal incontinence

Symptom

Complaint of involuntary loss of urine during sexual arousal, foreplay and/or masturbation.

Sexual diaries (female)

Investigation

A daily log of sexual thoughts, activities; supported by the US FDA as a primary outcome measure for the efficacy of interventions to improve sexual function.

Sexual dysfunction (female)

Diagnosis

A diagnosis by clinical history (including specific questionnaires) and examination, involving the confirmation of abnormal function and/or difficulty with sexual intercourse.

Sexual event logs

Investigation

Record individual sexual events or activities. Each event is classified as a "sexually satisfying event (SSE)" or not. Event logs record individual events rather than activities on a daily basis.

Sexual Function Questionnaires - (SFQ)

Investigation

1. Pelvic floor condition specific sexual function measures: A validated sexual function measure which is developed to include concepts relevant to women with pelvic floor dysfunction. 2. Generic sexual function measures: A validated measure that was developed to evaluate sexual function but does not contain items relevant to pelvic floor dysfunction such as coital incontinence or vaginal looseness.

EXAMPLES:

. ICIQ-FLUTSsex (BFLUTS) (International Consultation on Continence Questionnaire Female Lower Urinary Tract ICIQ-VS (International Consultation of Incontinence Questionnaire -Vaginal Symptoms).

. GRISS (The Golombok-Rust Inventory of Sexual Satisfaction);

. ICIQ-VS (International Consultation of Incontinence Questionnaire -Vaginal Symptoms);

. PISQ (Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire;

. PISQ-12 (short form version of the PISQ-31;

. PISQ IR (IUGA- revised version of the PISQ;

. FSFI (Female Sexual Function Index);

- . SFQ (Sexual Function Questionnaire);
- . SQOL-F (Sexual Quality Of Life-Female).

Shortened vagina

Symptom

Perception of a short vagina expressed by the woman or her partner.

Shortened vagina (postoperative)

Symptom

Perception of a short vagina expressed by the women or her partner (following surgical intervention).

Simplified POPQ

Sign

This is based on the POP-Q with similar ordinal staging but with only four points measured instead of nine. There is no Stage 0; it is combined with Stage 1. It is performed in the dorsal lithotomy position with patient forcefully bearing down, performing Valsalva or coughing: (i) Four points used: (i) Anterior vaginal segment: point Ba (estimated around 3cm proximal to hymenal remnants); (ii) Posterior vaginal segment: point Bp (estimated around 3cm proximal to hymenal remnants); (iii) Cervix point C; (iv) Apex/posterior fornix: point D (non-hysterectomized); point C (hysterectomized). Staging I, II, III, IV.

Sinus tract formation

Surgery – Complication related

(Localized) formation of a fistulous tract towards vagina or skin, where there is no visible implant material in the vaginal lumen or overlying skin.

Situational types of urinary incontinence - neurogenic

Symptom

Giggle incontinence or incontinence associated with epileptic seizures, sphincter denervation in cauda equina and in the Onuf's nuclei lesions in multiple system atrophy.

Slow (urinary) stream

Symptom

Complaint of a urinary stream perceived as overall slower than previous performance or in comparison with others.

Soft-tissue Therapies

Conservative Management – Female

1. Touch desensitisation: the manipulation of the soft tissues of the body for the purpose of affecting the nervous, muscular, respiratory, and circulatory systems. 2. Massage: the manipulation of the soft tissues of the body for the purpose of affecting the nervous, muscular, respiratory, and circulatory systems. 3. Abdominal massage: therapist or self-directed massage of the abdominal wall with the aim of stimulating peristalsis and relieving the symptoms of constipation. Generally, the technique follows the ascending, transverse, and descending colon to aid emptying. The effect may be mechanical or sensory. 4. Myofascial release techniques: the use of deep friction and stroking of the fascia of the body to improve the ability of the fascia to deform and move within the body. 5. Skin rolling: a manual technique in which skin is pulled away from the underlying structures and elongated in various directions. 6. Scar massage: a specific application of soft-tissue mobilization to an adherent scar. 7. Perineal massage: intravaginal massage by the woman, her partner or the clinician. Technique includes alternating downward and sideward pressure, using thumb and forefinger and a natural oil, with the aim of stretching and elongating the tissue in preparation for vaginal childbirth, or for treatment of adherent scarring in the perineum. 8. Transverse friction: the operator's fingertip is placed on the exact site of the lesion and rubbed firmly across the direction of the fibers of the affected tis-

sue. 9. Thiele's massage: per-rectal digital massage of the levator ani, sweeping lengthwise along the muscle fibers. Massage is begun lightly, and pressure is increased as tenderness decreases. 10. TrP treatment: (sometimes called myofascial trigger point treatment): soft-tissue mobilization specifically targeting trigger points and may include ischemic pressure, massage, myofascial release, electrotherapy, ultrasound, laser, spray and-stretch, injection (a variety of chemicals including local anesthetic, botox or steroids), dry needling (insertion of a solid needle into the TrP), and stretching.

Soiling (female)

Sign

Perianal fecal soiling or vaginal fecal soiling.

Somatic pain

Symptom

Pain which arises from bone, joints, muscles, skin or connective tissue and is normally achy or throbbing and well localized.

Spinal shock phase

Diagnosis

This is usually temporary following acute neurologic insult or SCI that is characterized by loss of sensory, motor and reflex activity below the level of injury. Neurological lower urinary tract dysfunction in Spinal Shock is usually a temporary complete painless urinary retention.

Splinting (female)

Symptom

Support perineum or buttocks manually (usually with thumb or fingers) to assist in evacuation of stool content.

Splinting/digitation due to POP

Symptom

Complaint of the need to digitally replace the prolapse or to otherwise apply manual pressure e.g. to the vagina or perineum (splinting), or to the vagina or rectum (digitation) to assist voiding or defecation.

Spraying (splitting) of urinary stream

Symptom

Complaint that the urine passage is a spray or split rather than a single directional stream.

Sterile intermittent catheterization

Conservative Management – General

Complete sterile setting including genital skin antiseptics, sterile gloves, forceps, gown and mask.

Storage dysfunction (SD)

Diagnosis

Those diagnoses related to abnormal changes in bladder sensation, detrusor pressure or bladder capacity during filling cystometry.

Storage symptom

Symptom

A lower urinary tract symptom during the bladder storage phase.

Storage symptoms

Symptom

Lower urinary tract symptoms occurring during the bladder storage phase.

Straining to defecate

Symptom

Complaint of the need to make an intensive effort (by abdominal straining

or Valsalva) or to use abdominal massage to either initiate, maintain or improve defecation.

Straining to void

Symptom

Complaint of the need to make an intensive effort to either initiate, maintain or improve voiding or the urinary stream.

Stranguria

Symptom

Complaint of voiding which is slow, difficult and spasmodic (at times “drop by drop”), usually associated with pain.

Stress fecal incontinence (SFI)

Symptom

Complaint of involuntary loss of feces on effort or physical exertion including sporting activities, or on sneezing or coughing.

Stress incontinence on prolapse reduction (occult or latent stress incontinence)

Sign

Stress incontinence only observed after reduction of co-existent pelvic organ prolapse (POP).

Stress urinary incontinence

Symptom

Complaint of involuntary loss of urine on effort or physical exertion including sporting activities, or on sneezing or coughing.

Stress urinary incontinence (clinical stress leakage)

Sign

Observation of involuntary leakage from the urethral orifice synchronous with effort or physical exertion, or on sneezing or coughing.

Strong desire to void - Filling cystometry

Investigation

The persistent desire to void without the fear of leakage.

Superficial (introital) dyspareunia

Symptom

Complaint of pain or discomfort on vaginal entry or at the vaginal introitus.

Suprapontine lesion (SPL)

Diagnosis

This is a neurological lesion above the pons (forebrain or midbrain). Neurogenic lower urinary tract dysfunction in SPL: there is a reflex contraction of

the detrusor with impaired cerebral regulation and central inhibition and usually synergistic voiding/bladder emptying.

Suprasacral spinal cord/ pontine lesion (SSL)

Diagnosis

This is a neurological lesion in the suprasacral spine and/or pons. Neurogenic lower urinary tract dysfunction in SSL: detrusor overactivity (DO) and DO incontinence are common, with or without detrusor-sphincter dyssynergia (DSD), often resulting in a significant post-void residual (PVR) and a “high pressure” bladder.

Surgery Type and Operated Compartment

Surgery – Female

(a) Primary surgery: indicates the first procedure required for treating POP in any compartment. (b) Further surgery: provides a term for any subsequent procedure relating to primary surgery. Further surgery is subdivided into: Primary surgery in a different (new) site/compartment. Repeat surgery in the same site/compartment for POP symptom recurrence. Surgery for complications e.g. mesh exposure, pain, infection or hemorrhage. Surgery for non-POP-related conditions usually urinary or fecal incontinence.

Suture hysteropexy - laparoscopic, robotic

Surgery – Female

The plicated uterosacral ligaments are resutured to the cervix.

Symptom

Symptom

Any morbid phenomenon or departure from the normal in structure, function or sensation, possibly indicative of a disease or health problem. Symptoms are either volunteered by, or elicited from the individual, or may be described by the individual's partner or caregiver.

Symptoms of sexual dysfunction

Symptom

Complaint of abnormal sensation and/or function experienced by the individual during sexual activity.

Symptoms of sexual dysfunction (female)

Symptom

A departure from normal sensation and/or function experienced by a woman during sexual activity.

T

Tape (Sling)

Surgery – Female

A flat strip of synthetic material. The use of this term would be for incontinence surgery with synthetic materials.

Tender Point

Sign

Tenderness to palpation at soft-tissue body sites.

Tenderness

Sign

Sensation of discomfort with or without pain; discomfort elicited through palpation indicates unusual sensitivity to pressure or touch.

Tenesmus

Symptom

Complaint of an urgent desire to evacuate the bowel accompanied by involuntary straining and the passage of little fecal matter.

Tenesmus (female)*Symptom*

A desire to evacuate the bowel, often accompanied by pain, cramping, and straining, in the absence of feces in the rectum.

Terminal dribbling (dribble)*Symptom*

Complaint that during the final part of voiding there is noticeable slowing of the flow to drops or a tricking stream.

Thermal Modalities*Conservative Management – Female*

Cold treatment/cryotherapy: Cold treatment is the application of ice for therapeutic purposes. It is used in the initial management of acute musculo-skeletal injuries, to decrease edema through vasoconstriction and to reduce secondary hypoxic injury by lowering the metabolic demand of injured tissues. Heat treatment (moist or dry): Heat treatment consists of the application of heat to a body part, with the aim of relieving pain and/or stiffness. It is usually applied when an injury is older than 48h.

Thermography or thermal imaging of the genital area*Imaging*

Evaluation of genital temperature using a camera detecting infrared radiation from the skin during sexual stimulation. This method has been correlated with subjective arousal.

Tight vagina*Symptom*

Introital narrowing: vaginal entry is difficult or impossible (penis or sexual device). Vaginal narrowing: decreased vaginal calibre.

Tight vagina (postoperative)*Symptom*

(i) Introital narrowing: vagina entry is difficult or impossible (penis or sexual device).

(ii) Vaginal narrowing: decreased vaginal calibre. These are de novo postoperative findings.

Time to maximum urine flow rate (tQmax - unit: s)*Investigation*

Elapsed time from the onset of urine flow to maximum urine flow.

Tissue*Surgery – Female*

A collection of similar cells and the intercellular substances surrounding them.

Tissue*Surgery – Complication related*

A collection of similar cells and the intercellular substances surrounding them.

Total colectomy*Surgery – Female*

Total excision of the vagina in a woman with no uterus and vaginal eversion.

Total vaginal length (TVL)*Sign*

This is the length of the vagina (cm) from posterior fornix to hymen with the posterior fornix reduced to its full normal position.

Transcutaneous electrical nerve stimulation (TENS)*Conservative Management – General*

This is electrical stimulation of the nerves through intact skin to modulate function and induce therapeutic response of the LUT.

Transurethral Catheter for Urodynamics*Investigation*

ICS standard invasive urodynamics is done with the thinnest possible (6-7F) transurethral double or triple lumen catheter or a suprapubic catheter.

Trigger Point (TrP)*Sign*

A tender, taut band of muscle that can be painful spontaneously or when stimulated. The taut band is electrically silent.

Trocar*Surgery – Female*

A surgical instrument with either a pyramidal, conical or needle-type cutting or dissecting point.

Trophic*Sign*

Promoting cellular growth, differentiation, and survival. This is the normal status of an organ, tissue or cell with regard to nutrition, size, number, form, and function. Atrophic urogenital tract is usually well-estrogenized.

Twenty-four (24) hour (urinary) frequency*Sign*

Total number of daytime and night-time micturitions during a specified 24-hour period.

Twenty-four (24) hour urine volume*Sign*

Summation of all urine volumes during a specified 24-hour period. The first void after rising is discarded and the 24-hour period begins at the time of the next void and is completed by including the first void, after rising, the following day.

Twenty-four (24) hour voided volume*Sign*

Total volume of urine voided in a 24 hour period. (1st void to be discarded; 24 hours begins at the time of the next void).

U**Ulcer***Surgery – Complication related*

A lesion through the skin or a mucous membrane resulting from loss of tissue, usually with inflammation.

Ultrasound applications in male LUT/PF dysfunction

Imaging

(1) Post void residual (see separate heading); (2) Intercurrent abnormalities: prostate volume (transabdominal, intraabdominal, retroperitoneal or intrapelvic tumor, hydronephrosis); (3) Bladder abnormalities: tumor, foreign body, overdistension, stones; (4) Detrusor wall thickness (see separate heading); (5) Ultrasound estimated bladder weight (UEBW); (6) Intravesical prostatic protrusion (IPP): See separate heading; (7) Urethral abnormality: diverticulum, urethral stenosis, degree and depth of spongiofibrosis; (8) Postoperative findings: post-prostatectomy (urethral shape), male sling position, artificial urinary sphincter placement of cuff and reservoir, bulking agents; (9) Prostate ultrasound: determination of prostate and transition zone volume, prostate shape and visualization of the prostate parenchyma for calcifications, cysts, abscesses or enlargement.

Ultrasound imaging - post-void residual (PVR - abdominal)

Imaging

Volume = width (left to right) x depth (anterior to posterior) x length (cranial to caudal) x 0.52 (mL)

Ultrasound imaging - uses (female)

Imaging

(i) Bladder neck descent / mobility/ opening including position of bladder neck at rest and on Valsalva; (ii) Post void residuals; (iii) Intercurrent pelvic pathology: e.g. Uterine and adnexal pathology; (iv) Uterine version: Anteverted or retroverted; flexion at level of isthmus; (v) Bladder abnormalities: e.g. tumor; foreign body; (vi) Urethral abnormality: e.g. diverticulum; (vii) Postoperative findings: e.g. bladder neck position and mobility, position of meshes, tapes or implants; (viii) Pelvic floor / levator defects: Bladder neck elevation during pelvic floor contraction; (ix) Descent of pelvic organs: Visualization of descent of the bladder, uterine cervix and rectum during Valsalva and coughing.

Ultrasound imaging (female) - 3D imaging of ballooning of the genital hiatus

Imaging

The presence of ballooning of the genital hiatus (= excessive distensibility of the levator hiatus) on Valsalva manoeuvre has also been associated to the severity of urogenital prolapse. An area of more than 25 cm², 30 cm², 35 cm² and 40 cm² has been defined as mild, moderate, marked and severe ballooning respectively.

Ultrasound imaging (female) - 3D imaging of levator ani trauma

Imaging

The presence of levator ani trauma has been postulated to be associated to an increased risk of pelvic organ prolapse. This can be evaluated using a tomographic ultrasound imaging assessment of the levator ani muscles.

Ultrasound imaging (female) - 3D of female urethra

Imaging

3D imaging of the rhabdosphincter overcomes the limits of MRI and two-dimensional (2D) ultrasound imaging that incorrectly measure the urethral sphincter volume using mathematical formulas based upon assumptions that the shape of the urethra is similar to that of an ellipse. Since the urethral shape is neither elliptical nor spherical, but rather an atypical geometric shape, equations should not be used.

Ultrasound imaging (female) - combined with urodynamics

Imaging

Synchronous ultrasound screening of the bladder and/or urethra and measurement of the bladder and abdominal pressure during filling and voiding cystometry.

Ultrasound imaging (female) - prolapse related - 3D (modalities)

Imaging

(i) Endovaginal ultrasound imaging may inadvertently compress tissues thus distorting the anatomy; (ii) Transanal ultrasound approach requires an expensive and dedicated transducer, and it is a more uncomfortable and embarrassing test for the woman. Its most common clinical indication is the assessment of sphincter integrity following obstetric trauma. (iii) Translabial/transperineal approach overcomes the limitations of endovaginal and transrectal techniques providing minimal pressure on local structures and it is least likely to alter surrounding anatomy.

Ultrasound imaging (female) - prolapse related 3D evaluations

Imaging

The following pelvic floor abnormalities can be evaluated: (i) trauma (injury/damage) of the levator ani muscle (LAM); (ii) excessive distensibility of the puborectalis muscle and levator hiatus ("ballooning"); (iii) pathologies of the anterior vaginal compartment like urethral diverticula; (iv) bladder tumours or foreign bodies (sling, mesh, bulking agents); (v) Polypropylene meshes: highly echogenic and thus easily identified in the coronal and axial plane, unless they are obscured by vaginal prolapse; (vi) Periurethral bulking agents, used as a continence procedure, can also be depicted with 3D pelvic floor ultrasound.

Ultrasound imaging (female) - prolapse related clinical applications

Imaging

(i) Bladder neck descent/mobility. The position of the bladder neck at rest and on Valsalva; (ii) Urethral funnelling: i.e., opening of the proximal third of the urethra during coughing or on Valsalva; (iii) Post void residual: Several formulas have been described in the literature to measure the bladder volume by ultrasound. An early formula [(h x d x w) x 0.7] has been demonstrated to give reproducible results with a percentage error of 21%; (iv) Bladder abnormalities: e.g. tumor, foreign body; (v) Urethral abnormality: e.g. diverticulum; (vi) Intercurrent uterine and/or pelvic abnormality: dependent on probe range; (vii) Postoperative findings: e.g., bladder neck position and mobility, position of meshes, tapes, or implants; (viii) Descent of pelvic organs: visualization of descent of the bladder, uterine cervix, and rectum during Valsalva and coughing; (ix) Assessment of voluntary pelvic floor muscle contractility; (x) Pelvic floor/ levator ani muscle defect and hiatal ballooning; (xi) Ultrasound measurements of bladder and detrusor wall thickness, and ultrasound estimated bladder weight (UEBW) are potential noninvasive clinical tools for assessing the lower urinary tract. UEBW is higher in women with overactive bladder and detrusor overactivity.

Ultrasound imaging (male) - anal endosonography (AES)

Imaging

Looking for: Anal sphincter defects

Ultrasound imaging (male) - bladder abnormalities

Imaging

Tumor, foreign, overdistension, stones, diverticulum.

Ultrasound imaging (male) - bladder wall thickness (BWT)

Imaging

Distance from outer border of the mucosa to the outer border of the adventitia on the anterior bladder wall with a linear 7.5MHz linear array in a bladder filled over 250ml.

Ultrasound imaging (male) - detrusor wall thickness (DWT)

Imaging

Measured from the inner border of the mucosa to the inner border or the

adventitia at the anterior bladder using linear 7.5MHz array in bladder filled over 250ml. Over 2mm points to BOO.

Ultrasound imaging (male) - intercurrent pathology

Imaging

Prostate volume (transrectal), tumor, hydronephrosis, scrotal abnormalities.

Ultrasound imaging (male) - intravesical prostatic protrusion (IPP)

Investigation

The distance from the bladder base until the tip of the prostate in the bladder lumen.

Ultrasound imaging (male) - postoperative findings

Imaging

Post-prostatectomy (urethral shape), male sling position, artificial sphincter - placement of cuff and reservoir, bulking agents.

Ultrasound imaging (male) - prostatic volume (transrectal)

Imaging

Prostatic volume = Anteroposterior (cm) x transverse (cm) x transrectal (cm)

Ultrasound imaging (male) - urethral abnormality

Imaging

Diverticulum, stenosis, degree and depth of spongiofibrosis.

Ultrasound imaging modalities (female)

Imaging

(i) Perineal: Curved array probe applied to the perineum. This term incorporates transperineal and translabial ultrasound; (ii) Introital: Sector probe applied to the vaginal introitus; (iii) Transvaginal (T-V): Intravaginal curvilinear, linear array or sector scanning; (iv) Transabdominal (T-A): Curvilinear scanning applied to the abdomen.

Ultrasound imaging modalities (Male)

Imaging

Transrectal (linear array or sector); transabdominal (curved or linear array); perineal (curved array); scrotal (curved array).

Ultrasound imaging sites (male)

Imaging

Renal, bladder, prostate, scrotum urethra, ano-rectum

Ultrasound in Urogynecology

Imaging

Ultrasound has become an increasingly frequent adjunct investigation in urogynecology and female urology both in the office and in the urodynamic laboratory.

Ultrasound in Urogynecology - Current Routine Possible Uses

Imaging

(a) Bladder neck descent/mobility/opening: Position of bladder neck at rest and on Valsalva.

N.B: Ideally the Valsalva should be standardized but it is appreciated that at present a reliable non-invasive method is lacking. Consensus has not been reached on criteria for excessive bladder neck mobility nor the relationship of this finding to a diagnosis of urodynamic stress incontinence. Position of bladder neck during pelvic floor contraction. Retrovesical angle (RVA): that is, angle between proximal urethra and trigonal surface of the bladder. Urethral rotation: that is, rotation of the proximal urethra on Valsalva. Angle gamma: that is, angle defined by lines from the infero-posterior symphyseal margin to the bladder neck at rest and on Valsalva. Urethral funneling: that

is, opening of the proximal third of the urethra during coughing or on Valsalva. Urine loss: full urethral opening during coughing, Valsalva, bladder contraction, or micturition.

(b) Postvoid residuals; (c) Intercurrent pelvic pathology: for example, uterine and adnexal pathology. (d) Uterine version: Anteverted or retroverted; flexion at level of isthmus; (e) Bladder abnormalities: for example, tumor, foreign body; (f) Urethral abnormality: for example, diverticulum; (g) Postoperative findings: For example, bladder neck position and mobility, position of meshes, tapes, or implants; (h) Pelvic floor/levator defects: Bladder neck elevation during pelvic floor contraction. (i) Descent of pelvic organs: Visualization of descent of the bladder, uterine cervix, and rectum during Valsalva and coughing.

Ultrasound in Urogynecology - Modalities in Current Routine Clinical Use

Imaging

(a) Perineal: Curved array probe applied to the perineum. This term incorporates transperineal and translabial ultrasound. (b) Introital: Sector probe applied to the vaginal introitus. (c) Transvaginal (T-V): Intravaginal curvilinear, linear array, or sector scanning. (d) Transabdominal (T-A): Curvilinear scanning applied to the abdomen.

Ultrasound in Women - 3D and 4D

Imaging

The potential of 3D ultrasound in urogynecology and female urology is currently being researched with validated applications likely to be included in future updates of this report and/or separate ultrasound reports. Applications with the most current research include: (i) major morphological abnormalities such as levator defects and (ii) excessive distensibility of the puborectalis muscle and levator hiatus ("ballooning"⁴⁰). The additional diagnostic potential of 4D (i.e., the addition of movement) ultrasound awaits clarification by further research.

Underactive Pelvic Floor Muscles

Diagnosis

A situation in which the pelvic floor muscles cannot voluntarily contract when this is appropriate. This condition is based on symptoms such as urinary incontinence, anal incontinence or pelvic organ prolapse, and on signs like no voluntary or involuntary contraction of the pelvic floor muscles.

Underactive pelvic floor muscles (female)

Sign

Pelvic floor muscles which cannot voluntarily contract when this is appropriate.

Urethral caruncle

Sign

Small eversion of the urethral urothelium, generally involving the posterior lip.

Urethral closure mechanism - incompetent (female)

Investigation

Leakage of urine occurs during activities which might raise intra-abdominal pressure in the absence of a detrusor contraction.

Urethral closure mechanism - normal (female)

Investigation

A positive urethral closure pressure is maintained during bladder filling, even in the presence of increased abdominal pressure, although it may be overcome by detrusor overactivity.

Urethral closure mechanism - urethral relaxation incompetence (“urethral instability”) - female*Investigation*

Leakage due to urethral relaxation in the absence of raised abdominal pressure or a detrusor contraction.

Urethral closure mechanism - urodynamic stress incontinence (female)*Investigation*

This is the involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

Urethral closure pressure profile (UCPP) - female*Investigation*

The relevant pressure is the urethral closure pressure (urethral pressure minus the intravesical pressure).

Urethral discharge*Symptom*

Seepage of mucus, pus or blood from the urethral meatus.

Urethral diverticulum*Sign*

The presence of a sac opening from the urethra. It might be suspected by a lump or tenderness along the line of the urethra or external urethral discharge on urethral massage.

Urethral examination (male)*Sign*

Palpation: along the ventral aspect of the penis and inferiorly into the perineum to detect fibrosis, lumps or tenderness along the shaft. Tenderness: suggestive of urethral or periurethral inflammation, often secondary to a urethral stricture or sexually transmitted disease. Meatal stenosis: narrowing changes of the distal urethra; post-infection, post-surgery.

Urethral function during voiding - dysfunctional voiding*Investigation*

This is characterized by an intermittent and/or fluctuating flow rate due to involuntary intermittent contractions of the peri-urethral striated or levator muscles during voiding in neurologically normal women. This type of voiding may also be the result of an acontractile detrusor (abdominal voiding) with electromyography (EMG) or video-urodynamics required to distinguish between the two entities.

Urethral function during voiding - normal (female)*Investigation*

The urethra opens and is continuously relaxed to allow micturition at a normal pressure, urine flow and PVR.

Urethral function during voiding (female) - bladder outlet obstruction*Investigation*

This is the generic term for obstruction during voiding. It is a reduced urine flow rate and/or presence of a raised PVR and an increased detrusor pressure. It is usually diagnosed by studying the synchronous values of urine flow rate and detrusor pressure and any PVR measurements. A urethral stricture or obstruction due to higher degrees of uterovaginal prolapse or obstructed voiding after stress incontinence procedures are amongst possible causes.

Urethral function during voiding (female) - detrusor sphincter dyssynergia*Investigation*

This is incoordination between detrusor and sphincter during voiding due to a neurological abnormality (i.e. detrusor contraction synchronous with

contraction of the urethral and/or periurethral striated muscle). This is a feature of neurological voiding disorders. Neurological features should be sought. Videocystourethrography is generally valuable to conclude this diagnosis.

Urethral function during voiding (voiding urethrocytometry) - female*Investigation*

This technique may assist in determining the nature of urethral obstruction to voiding. Pressure is recorded in the urethra during voiding. This may be at one specific point e.g. high pressure zone or it may be measured as a profile. A voiding urethral pressure profile (VUPP) uses a similar technique to that described above for the UPP measured during bladder filling. Simultaneous intravesical pressure measurement is required. Localization of the site of the intraurethral pressure measurement is desirable.

Urethral meatal abnormalities (male)*Sign*

. Hypospadias: Refers to the urethral meatus sited on ventral surface of the penis, either congenital or acquired, proximal to its normal position on the tip of the glans. External urethral meatus may be on the glans penis (glandular hypospadias), sulcus (coronal hypospadias), shaft (penile hypospadias), scrotum (scrotal hypospadias) or perineum (perineal hypospadias).

. Epispadias: Refers to the urethral meatus sited on dorsal surface of the penis, either congenital or acquired, proximal to its normal position on the tip of the glans.

. Neoplastic or inflammatory lesions within the fossa navicularis.

. Post-hypospadias/epispadias repair: including post-urethroplasty urethral fibrosis: palpated near the meatus or in the penile shaft.

. Postoperative fistula: Urine is visible at or near the incision lines.

Urethral mucosal prolapse*Sign*

Prolapse, generally circumferential and larger, of the distal urethral urothelium.

Urethral opening pressure (Pdet-uo – unit: cm H₂O) - pressure flow studies*Investigation*

Detrusor pressure recorded at the onset of measured flow (consider time delay – usually under 1 s).

Urethral pain*Symptom*

Complaint of pain, pressure or discomfort felt in the urethra before, during and/or after voiding and the individual indicates the urethra as the site.

Urethral pain syndrome*Symptom*

Urethral pain syndrome is the occurrence of recurrent episodic urethral pain usually on voiding, with daytime frequency and nocturia, in the absence of proven infection or other obvious pathology.

Urethral Plugs*Conservative Management – Female*

Urethral plugs are containment products aimed at blocking urine leakage.

Urethral pressure - intraluminal (female)*Investigation*

This is the fluid pressure needed to just open a closed urethra.

Urethral pressure measurement (female)*Investigation*

Urethral pressure and urethral closure pressure are idealized concepts which represent the ability of the urethra to prevent leakage. Urethral pressure is currently measured by a number of different techniques which don't tend to have consistent results, either between methods or for a single method. For example the effect of catheter rotation will be relevant when urethral pressure is measured by a catheter mounted transducer. Urethral pressure might, nonetheless, be measured: (i) at rest, with the bladder at a given volume; (ii) During coughing or straining; (iii) During the process of voiding.

Urethral pressure profile - functional profile length (female)

Investigation

The length of the urethra along which the urethral pressure exceeds intravesical pressure in women.

Urethral pressure profile - functional profile length (on stress) - female

Investigation

The length over which the urethral pressure exceeds the intravesical pressure on stress.

Urethral pressure profile - pressure "transmission" ratio (female)

Investigation

This is the increment in urethral pressure on stress as a percentage of the simultaneously recorded increment in intravesical pressure. For stress profiles obtained during coughing, pressure transmission ratios can be obtained at any point along the urethra. If single values are given, the position in the urethra should be stated. If several transmission ratios are defined at different points along the urethra, a pressure transmission "profile" is obtained. During "cough profiles", the amplitude of the cough should be stated if possible.

Urethral pressure profile (UPP) - female

Investigation

This is a graph indicating the intraluminal pressure along the length of the urethra: (i) Resting UPP: The bladder and subject are at rest; (ii) Stress UPP: Defined applied stress (e.g. cough, strain, Valsalva).

Urethral pressure profile (UPP) - methodology (female)

Investigation

All systems are zeroed at atmospheric pressure. For external transducers, the reference point is the superior edge of the symphysis pubis. For catheter mounted transducers, the reference point is the transducer itself. Intravesical pressure should be measured to exclude a simultaneous detrusor contraction. Methodology should be noted including: patient position; catheter type; transducer orientation; fluid and rate of infusion (if fluid-filling system); bladder volume; rate of catheter withdrawal.

Urethral prolapse

Symptom

Complaint of a "lump" at the external urethral meatus.

Urethral relaxation incompetence ("urethral instability") - female

Investigation

Leakage due to urethral relaxation in the absence of raised abdominal pressure or a detrusor contraction.

Urgency

Symptom

Complaint of sudden, compelling desire to pass urine which is difficult to defer.

Urgency - filling cystometry

Investigation

Sudden, compelling desire to void which is difficult to defer.

Urgency urinary incontinence

Sign

Observation of involuntary leakage from the urethral orifice associated with the individual reporting the sensation of a sudden, compelling desire to void.

Urgency urinary incontinence (UUI)

Symptom

Complaint of involuntary loss of urine associated with urgency.

Urinary Catheters

Conservative Management – Female

Urinary catheters are small tubes inserted via the urethra or into the bladder suprapubically, to allow the drainage of urine. Catheters are made of plastic, latex, teflon or silicone, and may be impregnated with antiseptic or antibiotic solution. 1. Self-catheterization: a procedure performed intermittently to empty the bladder by inserting a catheter into the urethra when normal voiding is not possible or if the bladder cannot be emptied completely. If a caregiver undertakes this procedure it is usually a sterile procedure; if a patient undertakes it, it is termed "self-catheterization" and is generally a clean rather than a sterile procedure.

Urinary incontinence

Symptom

Complaint of involuntary loss of urine.

Urinary incontinence

Sign

Observation of involuntary loss of urine on examination.

Urinary incontinence signs

Sign

All examinations for the evaluation of urinary incontinence are best performed with the individual's bladder comfortably full.

Urinary incontinence symptoms

Symptom

Involuntary loss of urine experienced during the bladder storage phase.

Urinary retention

Symptom

Complaint of the inability to empty the bladder completely.

Urinary Tract Infection

Symptom

Scientific diagnosis of a UTI is the finding of microbiological evidence of significant bacteriuria and pyuria usually accompanied by symptoms such as increased bladder sensation, urgency, frequency, dysuria, urgency urinary incontinence, and/or pain in the lower urinary tract.

Urine flow

Investigation

Urethral passage of urine. Pattern of urine flow may be: continuous - no interruption to urine flow; intermittent - urine flow is interrupted.

Urine flow rate (UFR - mL/s)

Investigation

Volume of urine expelled via the urethra per unit time.

Urodynamic clinical sequence of testing (female)*Investigation*

This generally involves a woman attending with a comfortably full bladder for free (no catheter) uroflowmetry and post-void residual (PVR) measurement prior to filling cystometry and pressure-flow studies.

Urodynamic clinical sequence of testing (male)*Investigation*

This generally involves a man attending with a comfortably full bladder for free (no catheter) uroflowmetry and post-void residual urine volume (PVR) measurement prior to filling cystometry and pressure-flow study.

Urodynamic stress incontinence - Filling cystometry*Investigation*

Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

Urodynamic stress incontinence (female)*Diagnosis*

Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

Urodynamic Stress Incontinence (female)*Diagnosis*

The diagnosis by symptom, sign, and urodynamic investigations involves the finding of involuntary leakage during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

Urodynamic stress incontinence (USI) - filling cystometry*Investigation*

Involuntary leakage of urine during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction.

Urodynamic studies*Investigation*

These usually take place in a special clinical room (urodynamic laboratory) and involve (artificial) bladder filling with a specified liquid (ICS recommends physiological saline solution or X-ray contrast if video studies) at a specified rate.

Urodynamics*Investigation*

Measurement of physiological parameters relevant to the function of the lower urinary tract.

Uroflowmetry (female) - ideal conditions*Investigation*

For free (or spontaneous - no catheter) uroflowmetry, all studies should be performed in a completely private uroflowmetry room. Most modern uroflowmeters have a high degree of accuracy (+/- 5%) though regular calibration is important.

Uroflowmetry (female) - interpretation of normality*Investigation*

Because of the strong dependency of urine flow rates in women on voided volume, they are best referenced to nomograms (e.g. Liverpool nomograms) where the cutoff for abnormally slow maximum (MUFR) and average (AUFR) urine flow rates has been determined and validated as under the 10th centile.

Uroflowmetry (male) - ideal conditions*Investigation*

Ideally, all free uroflowmetry studies should be performed in a completely private uroflowmetry room. Most modern uroflowmeters have a high degree of accuracy (+/- 5%) though regular calibration is important.

Uroflowmetry (male) - interpretation of normality*Investigation*

Because of the strong dependency of urine flow rates in men on voided volume and age, they are best referenced to nomograms where the cutoff for normality has been determined and validated.

Urogenital aging: genitourinary syndrome of menopause*Sign*

(i) Pallor/erythema: pale genital mucosa; (ii) Loss of vaginal rugae: vaginal rugae flush with the skin; (iii) Tissue fragility/fissures: genital mucosa that is easily broken or damaged; (iv) Vaginal petechiae: is a small (1–2 mm) red or purple spot on the skin, caused by a minor bleed (from broken capillary blood vessels); (v) Urethral eversion: urethral epithelium turned outside the lumen; (vi) Urethral prolapse: complaint of a lump at the external urethral meatus; (vii) Loss of hymenal remnants: absence of hymenal remnants; (viii) Prominence of urethral meatus vaginal canal shortening and narrowing: Introital retraction.

Uterine / cervical prolapse*Diagnosis*

Clinically evident (symptoms, signs or any relevant imaging) descent of the uterus or uterine cervix.

Uterine / cervical prolapse*Diagnosis*

Clinically evident (symptoms, clinical examination, assisted at times by any relevant imaging) descent of the uterus or uterine cervix.

Uterine retroversion*Sign*

The axis of the uterus is directed backwards towards the hollow of the sacrum, away from its anteverted position overlying the bladder. Cervix is noted in/towards the anterior fornix with the fundus perhaps palpable in the posterior fornix.

Uterine/cervical prolapse*Sign*

Observation of descent of the uterus or uterine cervix.

Uterosacral ligament plication - open, laparoscopic, robotic*Surgery – Female*

Transverse plication of the uterosacral ligaments to obliterate the cul-de-sac. Successive sutures are placed into the medial portion of one ligament, into the back wall of the vagina and into the medial border of the opposing ligament.

Uterosacral (USL) Ligament vaginal vault fixation - intraperitoneal*Surgery – Female*

Intraperitoneal USL ligament plication to support the vaginal vault. This is usually associated with posterior wall fascial reconstruction and possible excision and closure of enterocele.

Uterosacral (USL) vaginal vault fixation - extraperitoneal*Surgery – Female*

Extraperitoneal plication of the uterosacral ligaments to support the vaginal

vault. This is usually combined with posterior vaginal wall fascial reconstruction with or without enterocele closure and/or excision.

V

Vaginal agglutination

Sign

Where the walls of the vagina are stuck together.

Vaginal Anatomical Levels

Sign

(i) Level I: Uterine cervix (if present) and/or upper 2.5cm of vagina. (ii) Level II: Mid-vagina from distal end of Level I to hymen. (iii) Level III (vaginal vestibule): Vaginal entrance (Latin: "vestibulum"- "a space at the entrance of a canal") from hymenal ring to just below the clitoris anteriorly (anterior vestibule), labia minora laterally and anterior perineum posteriorly (posterior margin of vestibule).

Vaginal and clitoral duplex doppler ultrasound.

Investigation

The anatomical integrity of clitoral structures and the changes in clitoral and labial diameter associated with sexual stimulation can be evaluated in B mode. Movement of the blood relative to the transducer can be expressed as measurement of velocity, resistance, and pulsatility. Blood flow in arteries irrigating the clitoris and the vagina are more commonly assessed during sexual stimulation.

Vaginal bulging

Symptom

Complaint of a "bulge" or "something coming down" towards or through the vaginal introitus. The woman may state she can either feel the bulge by direct palpation or see it with the aid of a mirror.

Vaginal digitation

Symptom

Use of thumb or fingers in the vaginal to assist in evacuation of stool.

Vaginal dryness

Symptom

Complaint of reduced vaginal lubrication or lack of adequate moisture in the vagina.

Vaginal eversion

Sign

Complete version of the vagina is Stage IV vaginal prolapse.

Vaginal examination

Sign

Examination for vaginal length and mobility, presence of scarring and/or pain, and estrogenization. The location of any vaginal pain should be noted.

Vaginal feces

Symptom

Complaint of passage of feces per vagina.

Vaginal flatus

Symptom

Complaint of passage of flatus per vaginam.

Vaginal hysterectomy

Surgery – Female

Removal of the uterus and cervix vaginally.

Vaginal hysterectomy - with adjunctive McCall culdoplasty

Surgery – Female

Culdoplasty sutures incorporate the uterosacral ligaments into the posterior vaginal vault to obliterate the cul-de-sac and support and suspend the vaginal vault after vaginal hysterectomy.

Vaginal laxity

Symptom

Feeling of vaginal looseness.

Vaginal length - anterior vaginal length

Sign

Anterior hymenal ring to anterior vaginal vault (anterior cervicovaginal junction or anterior cuff post-hysterectomy).

Vaginal length - total posterior vaginal length

Sign

Posterior vaginal vault to posterior margin of vestibule (anterior perineum - cm), i.e., Levels I, II and III posteriorly.

Vaginal length - total vaginal length

Sign

Posterior vaginal vault to hymen (cm), i.e., Levels I and II posteriorly.

Vaginal Levels - Level I

Sign

Uterine cervix (if present) and/or upper 2.5 cm of vagina.

Vaginal Levels - Level II

Sign

Mid-vagina from distal end of Level I to hymen.

Vaginal Levels - Level III (vaginal vestibule)

Sign

Vaginal entrance (Latin: "vestibulum" = "space at the end of the canal"). From hymenal ring to just below the clitoris anteriorly (anterior vestibule), labia minora laterally and anterior perineum posteriorly (posterior margin of vestibule).

Vaginal Lubricants

Conservative Management – Female

Vaginal lubricants are pharmacological preparations aimed at reducing friction during coital or any other sexual activity and thereby alleviating dyspareunia, or at reducing discomfort associated with a clinical (per vaginum or per rectum) examination. Pharmacological preparations and natural plant-based oils may be used.

Vaginal Pain Syndrome

Symptom

Vaginal pain syndrome is the occurrence of persistent or recurrent episodic vaginal pain which is associated with symptoms suggestive of urinary tract

or sexual dysfunction. There is no proven vaginal infection or other obvious pathology.

Vaginal pessary - general

Conservative Management – Female

A device that is inserted into the vagina to provide structural support to one or more of the descending vaginal compartments, i.e. the uterus, anterior vaginal wall (and bladder), posterior vaginal wall (and rectum) and/or vaginal vault (with or without small intestine) after a prior hysterectomy.

Vaginal pessary - space filling pessaries

Conservative Management – Female

Doughnut; cuboid; Gellhorn; inflatable; shelf (similar to a Gellhorn but asymmetric).

Vaginal pessary - support pessaries

Conservative Management – Female

Ring pessary with or without central support; Gehrung, Hodge pessaries.

Vaginal photoplethysmography

Investigation

A tampon shape intravaginal probe equipped with an incandescent light that projects toward the vaginal walls is inserted; the amount of light that reflects back to the photosensitive cell provides a measure of vaginal engorgement which can be expressed as vaginal blood volume or vaginal pulse amplitude depending on the mode of recording. Likewise, labial and clitoral photoplethysmography can also be evaluated.

Vaginal trachelectomy for cervical stump prolapse (previous subtotal hysterectomy)

Surgery – Female

The cervical stump is removed in an identical fashion to the initial steps of a vaginal hysterectomy.

Vaginal Trachelectomy for Cervical Stump Prolapse

Surgery – Female

(Previous subtotal hysterectomy) The cervical stump is removed in an identical fashion to the initial steps of a vaginal hysterectomy.

Vaginal vault (cuff scar) prolapse

Sign

Observation of descent of the vaginal vault (cuff scar after hysterectomy).

Vaginal vault (cuff scar) prolapse

Diagnosis

Clinically evident (symptoms, signs or any relevant imaging) descent of the vaginal vault (cuff scar after hysterectomy).

Vaginal vault (cuff scar) prolapse

Diagnosis

Diagnosis by symptoms and clinical examination, assisted at times by any relevant imaging (i.e. clinically evident) descent of the vaginal vault (cuff scar after hysterectomy).

Vaginal vestibule - Anterior

Sign

Vaginal entrance from the hymenal ring to just below the clitoris anteriorly.

Vaginal vestibule - posterior

Sign

Posterior hymenal ring to anterior perineum (posterior margin of vestibule).

Vaginal wind

Symptom

Passage of air from vagina (usually accompanied by sound).

Vaginismus

Symptom

Recurrent or persistent spasm of vaginal musculature that interferes with vaginal penetration.

Vascular assessment of female sexual dysfunction - labial thermistor

Investigation

Temperature measurement evaluated with a small metal clip attached to the labia minora and equipped with a sensitive thermistor.

Vascular assessment of female sexual dysfunction - Laser Doppler imaging of genital blood flow

Investigation

An imager positioned close to the vulva allows the assessment of skin/mucosae microcirculation at a depth of up to 2-3mm. This method has been used to assess response to sexual stimulation and correlated with subjective arousal. It has also led to a better understanding of microvascular differences in women with provoked vestibulodynia compared to asymptomatic controls.

Vascular assessment of female sexual dysfunction - Magnetic resonance imaging of the genito-pelvic area

Investigation

Evaluation of the increase in clitoral structure volume related to tissue engorgement occurring during arousal.

Vascular assessment of female sexual dysfunction - Measurements of labial and vaginal oxygenation

Investigation

A heated electrode and oxygen monitor are used to evaluate the arterial partial pressure of oxygen (PO₂) transcutaneously. The temperature of the electrode is kept at a constant elevated temperature by an electric current. Increase in blood flow under the electrode results in more effective temperature dissipation (heat loss) with the result that more current is needed to maintain the electrode at its prefixed temperature. The changes in current provide an indirect measurement of blood flow during sexual stimuli. The electrode also monitors oxygen diffusion across the skin.

Vascular assessment of female sexual dysfunction - Thermography or thermal imaging of the genital area

Investigation

Evaluation of genital temperature using a camera detecting infrared radiation from the skin during sexual stimulation. This method has been correlated with subjective arousal.

Vascular assessment of female sexual dysfunction - vaginal and clitoral duplex Doppler ultrasound

Investigation

The anatomical integrity of clitoral structures and the changes in clitoral and labial diameter associated with sexual stimulation can be evaluated in B mode. Movement of the blood relative to the transducer can be expressed as measurement of velocity, resistance, and pulsatility. Blood flow in arteries irrigating the clitoris and the vagina are more commonly assessed during sexual stimulation.

Vascular assessment of female sexual dysfunction - vaginal photoplethysmography

Investigation

A tampon shape intravaginal probe equipped with an incandescent light that projects toward the vaginal walls is inserted; the amount of light that reflects back to the photosensitive cell provides a measure of vaginal engorgement which can be expressed as vaginal blood volume or vaginal pulse amplitude depending on the mode of recording. Likewise, labial and clitoral photoplethysmography can also be evaluated.

Videocystourethrography (VCU - female)

Imaging

Synchronous radiological screening of the bladder and measurement of the bladder and abdominal pressure during filling and voiding cystometry. When indicated for complex cases, VCU allows direct observation of the effects of bladder events, the position and conformation of the bladder neck in relation to the pubic symphysis, bladder neck closure during rest and stress, diverticula of the bladder and urethra, vesico-vaginal and urethro-vaginal fistulae, vesico-ureteric reflux and voiding events.

Videourodynamics

Investigation

Functional test of the lower urinary tract where filling cystometry and pressure-flow studies are combined with real-time imaging of the lower urinary tract.

Videourodynamics

Imaging

A functional test of the lower urinary tract in which pressure, capacity and flow data are simultaneously combined with real-time imaging of the upper and lower urinary tract. It is a dynamic study with function, during bladder filling and emptying. It is a kinetic technique that records morphological and functional changes of the lower urinary tract as a function of time. This feature distinguishes this technique from the static images obtained by cystography. It is a technique that is applied simultaneously with conventional urodynamic studies.

Image acquisition for the urinary tract can be performed with X-rays (fluoroscopy) or by ultrasound. Although in a strict sense, the "video" prefix refers to the recording of the images and not to their acquisition.

Visceral pain

Symptom

Pain which arises from visceral organs, with involvement of the organ capsule with aching, and is localized. There is obstruction of hollow viscus, causing intermittent cramping, which is poorly localized.

- i. Nociceptive: direct injury or lesion of an internal organ such as: bladder stone, surgical injury.
- ii. Inflammatory: acute/chronic inflammation of an internal organ such as urinary tract infection, pelvic inflammatory disease, colitis, endometriosis.
- iii. Neuropathic: primary lesion of visceral nerves such as neuritis following mesh placement.

Voided Percentage (Void%)

Investigation

The numerical description of the voiding efficacy or efficiency which is the proportion of bladder content emptied. Calculation: $[(\text{volume voided}/\text{volume voided} + \text{PVR}) * 100]$.

Voided volume (VV - mL)

Investigation

Total volume of urine expelled via the urethra during a single void.

Voiding cystometry

Investigation

This is the pressure volume relationship of the bladder during micturition. It begins when the "permission to void" is given by the urodynamicist and ends when the woman considers her voiding has finished. Measurements to be recorded should be the intravesical, intra-abdominal, and detrusor pressures and the urine flow rate.

Voiding cystourethrography - male

Imaging

Imaging of the bladder neck, urethra and prostate during voiding. The principal use is determining the site of any obstruction e.g. bladder neck or prostate. It can detect vesico-ureteric reflux, vesical or urethral fistulae, vesical or urethral diverticula and strictures.

Voiding dysfunction - acute on chronic retention

Diagnosis

An individual with chronic retention goes into acute retention and is unable to void.

Voiding dysfunction - retention with overflow

Diagnosis

Involuntary loss of urine directly related to an excessively full bladder in retention.

Voiding dysfunction (female)

Diagnosis

(A diagnosis by symptoms and urodynamic investigations is defined as) abnormally slow and/or incomplete micturition, based on abnormally slow urine flow rates and or abnormally high post-void residuals, ideally on repeated measurement to confirm abnormality. Pressure-flow studies can be required to determine the cause of the voiding dysfunction.

Voiding dysfunction (male)

Diagnosis

Abnormally slow and/or incomplete emptying, manifest as an abnormally slow urine flow rate and/or an abnormally high post-void residual, with confirmation by pressure-flow studies (including any related imaging).

Voiding dysfunction (male) - acute urinary retention

Diagnosis

No urine is able to be passed despite the man having a full bladder, which on examination is painfully distended, and readily palpable or percussible.

Voiding dysfunction (male) - chronic retention of urine

Diagnosis

Generally (but not always) painless and palpable or percussible bladder, where there is a chronic high postvoid residual and the man experiences slow urine flow and the sense of incomplete bladder emptying. Overflow incontinence and impaired renal function and/or hydronephrosis can occur in advanced cases.

Voiding symptoms

Symptom

Lower urinary tract symptoms experienced during the voiding phase (experienced during micturition).

Voiding time (VT - unit: s)

Investigation

Total duration of micturition, i.e. included interruptions. When voiding is completed without interruption, voiding time is equal to flow time.

Voiding urethrocytometry - urethral function during voiding (female)*Investigation*

This technique may assist in determining the nature of urethral obstruction to voiding. Pressure is recorded in the urethra during voiding. This may be at one specific point e.g. high pressure zone or it may be measured as a profile. A voiding urethral pressure profile (VUPP) uses a similar technique to that described above for the UPP measured during bladder filling. Simultaneous intravesical pressure measurement is required. Localization of the site of the intraurethral pressure measurement is desirable.

Vulval agglutination

Sign

Labial lips fused.

Vulval examination

Sign

Possible abnormalities include cysts, other tumours, atrophic changes, or lichen sclerosis.

Vulval gaping

Sign

Non-coaptation of vulva at rest, commonly associated with increased size of genital hiatus.

Vulval pain*Symptom*

Complaint of pain felt in and around the vulva.

Vulval pain syndrome*Symptom*

Vulval pain syndrome is the occurrence of persistent or recurrent episodic vulval pain, which is either related to the micturition cycle or associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven infection or other obvious pathology.

Vulvar agglutination

Sign

Labial lips stuck together.

Vulvar gaping

Sign

Non-coaptation of vulva at rest, commonly associated with increased size of genital hiatus.

Vulvar pain*Symptom*

Complaint of pain felt in and around the vulva.

Vulvodynia*Symptom*

Vulvar pain of at least 3 months' duration, without clear identifiable cause, which may have potential associated factors

Vulvo-vaginal hyperaesthesia

Sign

Increased vulvo-vaginal sensitivity to touch, pressure, vibration or temperature.

Vulvo-vaginal hypoesthesia

Sign

Reduced vulvo-vaginal sensitivity to touch, pressure, vibration or temperature.

ACKNOWLEDGING EXCELLENCE IN SCIENCE

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