Committee 6

Dynamic Testing

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Keywords

The following are the words and phrases that were used by the committee members in their search of the literature. PubMed was the source predominantly used by all the committee members.

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anal electrosensitivity
anal fatigability
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vector manometry ultrasound
vector volume
vector volume ultrasound
vesicoureteral reflux

(urinary AND incontinen*) AND ((urge* OR overactiv*) OR stress) AND (urethr* AND leak OR press* OR valsal*) OR urodynam*

Abbreviations

ALPP	abdominal leak point pressure
ANCOVA	analysis of covariance
APV	anal pressure vectography
ARM	anorectal malformation
ARPS	anorectal physiology studies
AUS	artificial urinary sphincter
AVP	anal pressure vectography
BOO	bladder outlet obstruction
BOOI	bladder outlet obstruction index
BPE	benign prostatic enlargement
BPH	benign prostatic hyperplasia
BPO	benign prostatic obstruction
BPS	bladder painful syndrome
CLPP	cough leak point pressure
CMAP	compound muscle action potential
DHIC	detrusor hyperactivity with impaired contractile function
DLPP	detrusor leak point pressure
DO	detrusor overactivity
DOI	detrusor overactivity incontinence
EMG	electromyogram/ electromyography
FDV	first desire to void
FSF	first sensation of filling
FUL	functional urethral length
GI	gastrointestinal
HPZ	high pressure zone
ICI	International Consultation on Incontinence
ICS	International Continence Society
IDC	involuntary detrusor contraction(s)
IDO	idiopathic detrusor overactivity
IPAA	ileal pouch anal anastomosis
IPSS	International Prostate Symptom Score
IQR	interquartile range
ISD	intrinsic sphincter deficiency
IWT	ice water test
LPP	leak point pressure
LUT	lower urinary tract
LUTD	lower urinary tract dysfunction
LUTS	lower urinary tract symptoms
MCC	maximum cystometric capacity
MES	mucosal electrosensitivity
MS	multiple sclerosis
MUCP	maximum urethral closure pressure
MUP	maximum urethral pressure
NDO	neurogenic detrusor overactivity
NDV	normal desire to void
NICE	National Institute for Health and Clinical Excellence
NPV	negative predictive value
OAB	overactive bladder
POP	pelvic organ prolapse
PNTML	pudendal nerve terminal motor latency
PPV	positive predictive value
PVP	photoselective laser vaporisation prostatectomy
PVR	post-void residual urine (volume)
QoL	quality of life
RAIR	recto-anal inhibitory reflex
SCI	spinal cord injury
SD	standard deviation
SDV	strong desire to void
SEM	standard error of the mean
SPT	specificity
STV	sensitivity
SUI	stress urinary incontinence
TURP	transurethral resection of the prostate
TVT	tension-free vaginal tape
UDS	urodynamic studies
UPP	urethral pressure profile/ profilometry
UPR	urethral pressure reflectometry
URP	urethral retro-resistance pressure
USI	urodynamic stress urinary incontinence
UUI	urgency urinary incontinence
VLPP	Valsalva leak point pressure
VUR	vesico-ureteric reflux
VV	voided volume

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A. INTRODUCTION

The first two reports of the International Consultation on Incontinence (ICI) contained chapters on "Urodynamic Testing"[1, 2]. Urodynamics is the umbrella term used to describe measurements of the function of the lower urinary tract. These measurements can be used in the management of urinary incontinence. The third report of the ICI expanded this topic to include physiological measurements of the lower gastrointestinal tract. These measurements can be used in the management of faecal or anal incontinence. Consequently, the chapter was then renamed 'Dynamic Testing'. [3]

This is the successor to that chapter and, in this fourth consultation, we have further updated the evidence for the technical performance, clinical utility and responsiveness to treatment of these measurements. We have used the chapter on 'Dynamic Testing' from the previous consultation as a template for this report; retaining some of the original text and tables where there has been no change since the previous consultation.

The primary aim of the chapter is to discuss the value of the various tests to diagnose the mechanisms of continence in general, to discuss what tests ought to be performed to elucidate these mechanisms in the individual; and to make recommendations for what tests should be performed for certain groups of patients. Thus we have tried to present an overview of the best scientific evidence with regard to the role of urodynamics and lower gastrointestinal tract testing. On the basis of this we provide recommendations for the current state of assessment of the patient with incontinence, and recommendations for future scientific evaluation or analysis of dynamic testing. The overview of scientific evidence in paragraphs, with ***conclusion(s)*** and ***recommendation(s)*** and ***topics(s) for research*** are highlighted in the text and are therefore also suitable for 'express reading'.

The third ICI report expressed the hope that faecal (anal) incontinence and urinary incontinence could be dealt with by an integrated approach by future consultations. However, although the two topics clearly have much in common with regard to both pathophysiological mechanisms and clinical application, this committee thought it was appropriate to continue to address the two topics separately in this report.

Therefore, following this introduction, the chapter firstly considers urodynamics before considering dynamic testing for anal incontinence. For each, the tests are described and then there is a review of data about normal values and reliability of the measured parameters. This is followed by reviews of the literature regarding clinical urodynamic evaluation of different patient groups with urinary incontinence (women, men, children, neurogenic dysfunction, and the frail elderly). This is followed by reviews from the literature regarding the clinical evaluation of patients with anal incontinence. Each section concludes with the committee's recommendations regarding dynamic testing.

B. URODYNAMICS

I. WHAT IS URODYNAMICS?

The term 'Urodynamic studies' (UDS) was defined by the International Continence Society (ICS) in 1988 and involves the assessment of the function and dysfunction of the urinary tract by any appropriate method. [4] A more recent report in 2002 did not alter the definition of 'urodynamic studies' or 'urodynamics' but did include a new definition of 'urodynamic observations'. [5]

The conventional view – implicitly adopted in the previous standardisations and consultations – is that urodynamics is a series of more or less agreed-upon clinical tests, such as flow studies, filling cystometry, pressure-flow studies and/or urethral function measurements. These can be combined with simultaneous electromyography (EMG) recording and/or

imaging by either X-rays or ultrasound. Also implicitly agreed upon is that urodynamics is the only objective way to determine why people have lower urinary tract symptoms (LUTS). The attempt to gain understanding of lower urinary tract (LUT) behaviour, on the basis of test observations, in relation to what is known about normal – or expected abnormal- physiology, is what constitutes urodynamics.

Urodynamic studies can answer questions such as: 'What causes the increased voiding frequency in this patient' as well as: 'Why does this patient have urinary incontinence'? These questions not only can be posed for individual patients but also can form part of clinical or laboratory research.

Conventionally, UDS involves the patient being connected to equipment in the laboratory in order to measure physiological parameters, such as pressures, inside the patient. The data is analysed as the test is being carried out and adjustments can be made to correct for technical problems and artefacts as they arise. If conventional urodynamic studies fail to provide an answer to the question being posed then ambulatory urodynamics may be employed in an attempt to obtain the answer. [6] In ambulatory urodynamics, pressures and other physiological parameters from the patient are fed into a small, body-worn solid-state recorder and the patient is free to move about and carry out normal activities. The test can last for many hours and the physiological data is analysed once the test has been completed.

II. WHAT SHOULD BE THE ROLE OF URODYNAMIC STUDIES IN CLINICAL PRACTICE?

There is an agreement among experts that the immediate aim of urodynamic testing is to reproduce the symptom(s) of the patient under controlled and measurable conditions, so that the cause of the symptoms can be determined and useful, objective information can be provided to the clinician. The role of urodynamic studies in broad clinical perspective can be:

a) to identify or to rule out factors contributing to the LUT dysfunction (e.g. urinary incontinence) and assess their relative importance

b) to obtain information about other aspects of LUT dysfunction

c) to predict the consequences of LUT dysfunction for the upper urinary tract

d) to predict the outcome, including undesirable side effects, of a contemplated treatment

e) to confirm the effects of intervention or understand the mode of action of a particular type of treatment; especially a new one

f) to understand the reasons for failure of previous treatments for urinary incontinence, or for LUT dysfunction in general.

The International Continence Society has provided standards for urodynamic terminology and techniques to optimise interpretation and facilitate comparison between different studies [5]. Some of the urodynamic terminology is given in **Table 1**.

Table 1. Some urodynamic diagnoses and corresponding urodynamic observations

Urodynamic diagnosis observation	Urodynamic
Urodynamic stress urinary incontinence	Loss of urine as result of an abdominal pressure increase without detrusor overactivity during the storage phase of urodynamic testing.
Detrusor overactivity incontinence	Loss of urine as a result of involuntary detrusor activity during the storage phase of urodynamic testing.
Urodynamic mixed urinary incontinence	Occurrence of urodynamic stress incontinence in combination with urodynamic urgency urinary incontinence or detrusor overactivity.
Urodynamic urgency	Detrusor overactivity during urodynamic testing with urgency sensation that the patient reports as representative for his or her symptoms.

III. THE TESTS OF CONVENTIONAL URODYNAMICS

1. UROFLOWMETRY

This is the non-invasive measurement of urine flow rate. The patient micturates into a flow meter in private when they have a normal desire to empty their bladder. [7] Urine flow rate is continuously measured and displayed graphically. Various parameters from the trace are automatically calculated and printed out together with the trace. The volume voided, shape of the curve and the maximum flow rate are usually the principal determinants of whether or not the patient is emptying their bladder normally. If an abnormal recording is obtained, it is usual to repeat the assessment to check that the result is reproducible.

Several factors, such as patient apprehension, can give an abnormal recording in patients who have no voiding difficulty. Repeating the assessment can eradicate the effect of such confounding factors and will confirm or refute the validity of the first assessment. .

2. FILLING CYSTOMETRY

This is the measurement of the pressure inside the bladder to assess its storage capabilities. It is an invasive test which involves a pressure sensor being placed into the bladder, usually transurethrally, and another pressure sensor being placed rectally or vaginally (or sometimes through an abdominal stoma) to measure abdominal pressure. Subtracting the abdominal pressure from the pressure measured inside the bladder (intravesical pressure) gives a representation of pressure changes due to the action of the detrusor smooth muscle.

During this assessment, the bladder is usually filled with normal saline solution (or x-ray contrast solution in the case of videourodynamics) either through a separate catheter placed transurethrally or through the filling channel of a dual lumen catheter if such is used to measure intravesical pressure. Usually the filling rate is much faster than physiological bladder filling.

The intravesical, abdominal and detrusor pressure are monitored as the bladder is filled and before the patient has been given 'permission to void'. The storage ability of the bladder is assessed in terms of the volumes required to elicit various sensations from the patient, its capacity, its compliance and its stability. The filling (storage) phase of cystometry is also the only method of demonstrating urodynamic stress incontinence (USI).

3. PRESSURE-FLOW STUDIES (VOIDING CYSTOMETRY)

This is a measurement of the mechanics of micturition. When the filling (storage) phase of cystometry is complete, the patient is given 'permission to void' and will empty their bladder on a flow meter whilst intravesical, abdominal and detrusor pressures are being monitored. The simultaneous measurement of flow rate and pressure enables voiding to be assessed and, when bladder emptying is poor, it can help determine whether poor flow is due to an outflow obstruction or poor detrusor contractility.

4. URETHRAL PRESSURE PROFILOMETRY

This is a test carried out in some centres and measures the urethra's ability to act as a valve to contain urine within the bladder. A pressure sensor is placed transurethrally into the bladder and then withdrawn along the urethra (usually by a mechanical puller at a constant rate). The pressure along the length of the urethra is measured, usually relative to the pressure inside the bladder. The maximum pressure measured in the urethra gives an indication of the closure function of the urethra and may be of help in determining the management of the patient with USI.

5. ABDOMINAL LEAK POINT PRESSURE

This is a test carried out in some centres and is another measure of the urethra's ability to act as a valve to contain urine within the bladder. Intravesical or abdominal pressure is measured whilst the patient is asked to increase their abdominal pressure by valsalva or by coughing. The abdominal pressure required to produce leakage from the bladder gives an indication of the closure function of the urethra. The greater the pressure required to produce leakage, the better the closure function of the urethra. This test may be of help in determining the management of the patient with USI.

IV. TECHNOLOGICAL INNOVATIONS IN URODYNAMICS

1. AIR-CHARGED CATHETERS FOR PRESSURE MEASUREMENT

Air-charged catheters have been used for pressure measurement in urodynamics for many years. However, until recently, they have been the sole preserve of enthusiasts who have manufactured and used them 'in-house'.

Recently, commercial, single-use, air-charged catheters have been developed and used for intravesical, intraurethral and abdominal pressure measurement in urodynamics (T-Doc, Wenonah, NJ). Initial reports from a female cadaveric study showed that these catheters gave more reproducible measurements of maximum urethral closure pressure compared to microtip catheters, water filled catheters and fibreoptic catheters. [8] In a more recent study in 2004 on 45 women, their performance has been shown to be comparable to microtransducers in the measurement of maximum urethral closures pressure and Valsalva leak point pressure (VLPP). [9] However, the same study showed a difference in functional urethral length (FUL) which was attributed to the different diameters of the two catheters.

A criticism of this study was that the catheters were not used in a random order. Therefore in 2008, Zehnder et al carried out a randomised comparison of these catheters with microtip catheters in 64 women. The measured MUCP and FUL and found that the air-charged catheter was as least as reliable as the microtip for measuring these parameters. However, because the air-charged catheter gives a higher reading of both parameters compared to the microtip device, they concluded that they cannot be used interchangeably for clinical purposes. [10]

These devices are being actively marketed for the

measurement of intravesical and intraabdominal pressure during filling and voiding cystometry. However, there have been no published studies in the peer-reviewed literature concerning their performance in this way; there are only the studies mention above which predominantly relate to the measurement of urethral pressure. There is no reason to suspect that these devices are inappropriate for the measurement of such pressures and, indeed, the measurement of VLPP by Pollak et al [9] is encouraging that they can be used to measure intravesical pressure. Nevertheless, a comparison of the air-charged catheters with the traditional fluid-filled lines for intravesical and intra-abdominal pressure measurement would be useful; particularly comparing their measurements during relatively fast events such as coughing.

Air-charged catheters have several practical advantages over fluid-filled pressure lines because there is no fluid connection between the patient and the urodynamic equipment; just air. This means there is no hydrostatic pressure effect to account for so that there is no need to position anything at the level of the symphysis pubis. There is no need to flush the system through to exclude air; a process that is essential in a fluid-filled pressure-sensing environment. There are no artefactual fluctuations in pressure produced when the patients move. Essentially, these devices are 'plug and play' which means they are much easier to set up and use compared to the fluid-filled system. Therefore, they have the potential to overcome one of the problem areas of urodynamics; that of setting up. However, although they may make urodynamics easier to set up, the conduct and interpretation of a urodynamic study still requires an experienced, appropriately trained practitioner.

Conclusions (level 3)

- Air-charged catheters may provide an acceptable alternative to other techniques for measuring the pressure closing the female urethra.
- There have been no studies to show whether air-charged catheters provide an acceptable alternative to fluid-filled lines for measuring intravesical and intra-abdominal pressure in urodynamics.

Recommendation (grade C)

- Investigators planning to use air-charged catheters for intravesical and intra-abdominal pressure in urodynamics would be advised to check for themselves that they have an equivalent performance to their current system for measuring pressure

Topic for research

- That a study is set up to compare the performance of air-charged catheters with fluid-filled pressure lines in the measurement of intravesical and intra-abdominal pressure during filling and voiding cystometry; particularly during 'fast' events such as coughing.

2. OBJECTIVE ASSESSMENT OF BLADDER SENSATION

Bladder sensation during urodynamics is usually recorded by the simple expedient of asking the patient to inform the investigator when they experience different sensations. This is a somewhat subjective measurement which can be confounded by the investigators inadvertently distracting the patient whilst bladder filling is being carried out. Investigators can also bias the measurement by inadvertent prompting of the patient.

In 2005, Craggs described a patient-activated, keypad 'urge score' device to measure sensations during bladder filling. [11] This enables patient perceptions of bladder filling and the successive stages of increasing bladder sensation to be recorded without prompting or intervention by the investigator. The accuracy of the 'urge keypad' during filling cystometrography was validated in patients with urgency incontinence, and compared with data abstracted from patient voiding diaries. Craggs concluded that the device provides reliable and repeatable measures of different bladder sensations, with excellent, statistically significant consistency between bladder volumes and corresponding levels of sensation.

The development of an objective method of recording bladder sensation during filling cystometry appears to be desirable. Whether it improves the reproducibility and sensitivity of urodynamics has yet to be determined.

3. NON-INVASIVE PRESSURE-FLOW MEASUREMENTS

Over recent years, groups in Newcastle upon Tyne (UK) and Rotterdam (The Netherlands) having been developing non-invasive techniques to measure pressure-flow in males.

The UK group has developed a penile cuff device. [12] The cuff is placed around the penis and is inflated and deflated whilst the patient voids into a urine flow meter. The pressure required to interrupt the flow is assumed to be equivalent to the bladder pressure generating the flow at that time. The group has determined that cuff widths of 40 to 50 mm are optimal for ensuring good pressure transmission from the cuff to the urethra. [13]

Further development of the technique resulted in the publication of a nomogram to classify whether individuals are obstructed or not obstructed when measured by this technique. [14]

There is apparently good agreement between experienced operators regarding the measurement of the pressure at which flow is interrupted. [15] In 2008, non-invasive measurements of pressure and flow were carried out at six different sites in the UK. [16] The measurements on individuals were repeated a median of 20 days later. Only 69% of tests produced analysable data on the two occasions. Whilst the mean differences in flow rate (0.2 ml/s) and cuff interruption pressure (4 cm H_2O) were small, 33% of men changed diagnostic category with the repeat measurement (from obstructed to non-obstructed or vice versa).

There is evidence that the method is sensitive to change. In 2007, 163 men underwent non-invasive pressure flow study using the penile cuff technique before and 4 months after transurethral prostate resection. [17] There was a significant change in flow rate and cuff-interruption pressure following removal of the obstruction in addition to 80% becoming non-obstructed on the basis of their measurements.

The same group produced retrospective evidence that categorisation of bladder outlet obstruction by the penile cuff technique improves prediction of outcome from endoscopic prostatectomy. [18] In 179 men undergoing TURP following standard assessment in the institution concerned, 37% were catergorised as having bladder outlet obstruction (BOO) by the penile cuff test and 87% of these had a good outcome from TURP. Whereas of the 19% the of deemed not obstructed, 56% experienced a good outcome ($p<0.01$). In the remaining men not categorised in these two groups, 77% had a good outcome. However, the retrospective nature of this study weakens the argument for the prognostic ability of the penile cuff test.

The penile cuff test is now commercially available as the CT3000 (Mediplus Ltd, High Wycombe, UK)

The group in Rotterdam had a similar approach to developing a non-invasive method of measuring pressure and flow in men. However, instead of using a penile cuff to interrupt flow, they used a condom catheter through which the patient voided into a urine flow meter. During flow, the stream would episodically be diverted to a pressure transducer which would record the bladder pressure at that time. [19] They were able to correctly classify most men as being obstructed or not obstructed when compared to the ICS nomogram provided that the men did not strain during voiding.

Further work on the technique in 2003 revealed that a minimum flow rate of 5.4 ml/s was necessary to produce an accurate assessment of bladder pressure during voiding using the condom catheter technique. [20]

In 2004, the technique was reported to have a reproducibility comparable to that of invasive pressure-flow studies in an interim analyis of the first 730 patients enrolled in a study of changes in urinary bladder contractility secondary to benign prostatic hyperplasia. [21] In 618 (94%) of 659 eligible participants, one condom pressure measurement was completed; two measurements were done in 555 (84%). The maximum condom pressure ranged from 28 to 228 cm H_2O (mean 101, SD 34). A difference between the two pressures of less than ±21 cm H_2O was found in 80%. The mean difference was -1 cm H_2O (SD 18), significantly different from 0.

In the same year, the repeatability of the condom catheter technique was assessed in 457 volunteers and compared to that of the invasive pressure-flow technique in 397 comparable male patients. [22] The repeatability of the non-invasive method was found to be comparable to, or slightly better than, that of pressure-flow studies.

In 2006, the bladder volume dependency of the isovolumetric intravesical pressure measurement by the condom catheter technique was investigated. [23] In the 1,020 healthy subjects studied, it was concluded that the optimum bladder volume for isovolumetric pressure measurements, was 264 ± 122 mL (mean ± SD) and that measurements should be taken at or above this optimum volume. At volumes below the optimum volume, the pressure decreases by approximately 5% for each 10% of volume decrease. At bladder volumes smaller than 247 mL, pressure readings in 50% of subjects were suboptimal.

The same group in Rotterdam has also been exploring the measurement of perineal noise during voiding as a way of non-invasively quantifying male bladder outlet obstruction but the work has not yet progressed sufficiently beyond testing on models to determine the viability of this technique in vivo. [24, 25]

Both the penile cuff and condom catheter techniques show promise as non-invasive techniques to assess outlet obstruction in men. However, they are subject to some confounding factors and appear to give inaccurate results if the patient strains during the assessment. It remains to be seen where and if these measurements have a role in the routine clinical assessment of men with symptoms of bladder outlet obstruction.

Conclusion (level 2)

- Non-invasive measurements of pressure and flow in men by the penile cuff or condom catheter seem to be as clinically useful as the traditional invasive measurement of pressure and flow.

Recommendation (grade B)

- That non-invasive measurements of pressure and flow should be considered when the patient is not required to undergo an invasive assessment of the storage function of the lower urinary tract.

4. URETHRAL RETRO-RESISTANCE PRESSURE

In 2004, Slack et al described a 'new clinical measure of urethral function'. [26, 27] In the measurement of urethral retro-resistance pressure (URP), a small meatal plug is inserted just inside the female urethra and saline is pumped into the urethra. The pressure in the system rises until it reaches a value sufficient to overcome the resistance offered by the urethra and the fluid then retrogradely flows into the bladder. The pressure required to achieve and maintain an open sphincter is taken to be a measure of urethral closure function. Whilst the technique is new in that modern technology is used to apply the head of pressure to the urethra and the measurement of opening pressure is automatically recorded, the basic principle behind the technique has its origins in 1923 when Bonney made a simple attempt to measure the efficiency of urethral closure. [28]

In his first paper, Slack et al studied 258 stress incontinent women with the URP technique and compared their values with incontinence severity. They also compared the URP measurements with those of maximum urethral closure pressure (MUCP) and valsalva leak point pressure (VLPP). They found that URP measurements correlated well with both MUCP and VLPP. They also found that URP measurements correlated with incontinence severity whereas neither MUCP nor VLPP did so. [26]

In the second study, Slack et al showed that the URP in a group of 61 women, without symptoms of urinary incontinence and who had negative standing stress tests, was significantly greater than the group of stress incontinent women who had been tested previously. [27] This study also provided some test-retest data which showed that URP measurements were consistent in individuals.

The authors concluded from both of these pieces of work that the technique of URP shows promise as a physiological urethral pressure measurement.

In 2006, Digesu et al carried out measurements of URP on 165 women with various urodynamic diagnoses. [29] Women with urodynamic stress urinary incontinence (USI) had significantly lower URP than women with competent urethral sphincters. Women with mixed urodynamic incontinence had values of URP intermediate between women with detrusor overactivity (DO) and those with USI. In the mixed group, URP mean values were not significantly different from those with DO and competent sphincters or those with USI.

There was no significant difference between mean URP values and different urinary symptoms. The authors concluded that whilst there are significantly different URP measurements between women with DO and those with USI, the URP is not a diagnostic tool.

In 2007, Tunn et al measured URP in 48 women with clinically and urodynamically proven SUI without prolapse before and after anti-incontinence surgery (colposuspension n = 8, tension-free vaginal tape n = 6, tension-free transobturator tape n = 34). They found that preoperative URP did not correlate with SUI in all women, had no predictive value, and did not correlate with the outcome of anti-incontinence surgery. However, they did find a positive correlation between URP and body mass index. [30]

In 2008, Roderick et al reported on URP and established measures of incontinence severity in 100 women with pure USI prior to and 3 months after the insertion of a midurethral tape. [31] They found mean URP bore no relationship to the severity of urine loss assessed by 24-hour pad loss. There was no correlation between URP and other measures of incontinence severity. Pre and postoperative URP was available in 73 women. Although 84.9% were objectively cured after surgery, pre and postoperative URP was not significantly different (62.7 ± 19.4 cm H_2O vs 61.2 ± 20.4 cmH_2O). They concluded that urethral retro-resistance pressure is not a useful measure of urethral function.

Conclusion (level 2/3)

- Urethral retro-resistance pressure measurements do not give any better information about urethral closure function than the urethral pressure profile or valsalva leak point pressure.

Recommendation (grade B/C)

- That urethral retro-resistance pressure measurements should be discouraged because equivalent information can be obtained from urethral pressure measurements made with conventional urodynamic equipment.

5. URETHRAL PRESSURE REFLECTOMETRY

In 2005, Klarskov et al reported on an in vitro study of pressure reflectometry; a novel technique for the simultaneous measurement of cross-sectional area and pressure in a collapsible biological tube. [32] A very thin, highly flexible 6 cm long polyurethane bag with a diameter of 5 mm when expanded was introduced into eight different test model cavities of known cross-sectional areas in the range of 4-16 mm^2. The cross-sectional area was measured by acoustic reflectometry while pressures of 10-200 cm H_2O were applied by a pump. Measurements were reliable from about 1 to 5 cm within the cavity and at pressures from 10 to 200 cm H_2O. The reproducibility was not influenced significantly by change in background noise, temperature, catheters, or geometries of the cavities or new calibration. They concluded that the measurements seem reliable for

clinical use in the range of 4-16 mm^2 and at pressures from 10 to 200 cm H_2O.

In 2007, Klarskov and Lose used the technique of urethral pressure reflectometry (UPR) to assess the female urethra. [33] Cross-sectional area of the urethra was measured during inflation and deflation of the thin bag placed in the urethra using step-wise pressure changes within the range 0 to 200 cm H_2O. They showed that the technique was easy to carry out and that they could obtain measurements of opening and closing pressure, opening and closing elastance and hysteresis. They postulated that these parameters had the potential to provide more physiological information about the urethra than could be obtained from conventional urodynamic studies.

In the same year, Klarskov and Lose compared UPR with urethral pressure profilometry (UPP) in 143 women (105 patients and 38 healthy volunteers). [34] UPR was measured supine both while relaxed and during 'squeeze', and while upright and relaxed. UPP was carried out using the perfusion technique with the patient supine and relaxed. All the women were assessed twice with both UPR and UPP at the same setting (short-term reproducibility) and 17 patients were assessed with both methods on two different days (long-term reproducibility). The authors showed that UPR measured the same pressure as UPP but the UPR was more reproducible. With the patient relaxed the opening and closing pressure, opening and closing elastance and the hysteresis can be measured while supine and upright; while squeezing, the opening pressure and elastance can be measured.

In 2008, Klarskov and Lose measured UPR parameters in healthy and stress urinary incontinent (SUI) women and compared them with urethral pressure parameters obtained by the perfusion technique. [35] The study included 30 SUI women and 30 volunteers (23 "continent" and 7 "nearly continent"). The women were examined in the supine position both while relaxed and during squeezing, and upright position and the following UPR variables were measured; opening and closing pressure, opening and closing elastance, hysteresis (absolute) and hysteresis (percent). UPP was carried out with the women supine while relaxed and during squeezing. The maximum urethral pressure (MUP) and maximum urethral closure pressure (MUCP) were obtained. They showed that all parameters except the hysteresis (percent) were significantly decreased in the SUI group compared to the volunteers. The squeeze opening pressure increased in all women compared to the resting condition, while MUP and MUCP during squeeze increased in 78% and decreased in 22%. The separation between the continent and SUI women was better using the resting and squeezing opening pressure than the corresponding UPP parameters. They concluded that UPR is a clinically reliable technique, which provides sound physiological parameters. The resting and squeezing opening pressures separate SUI from continent women better than the UPP parameters. They also postulated that UPR parameters have the potential to provide a pathophysiologic subdivision of SUI and other dysfunctions.

Conclusion (level 3)

- Measurement of opening pressure from urethral pressure reflectometry appears to have more power to separate women with stress urinary incontinence from those with normal urinary control when compared to continent women.

Recommendation (grade C)

- That further studies are undertaken to investigate the clinical usefulness of this technique.

C. URODYNAMICS: NORMAL VALUES, RELIABILITY AND DIAGNOSTIC PERFORMANCE

I. REPRODUCIBILITY OF FILLING CYSTOMETRY AND AMBULATORY URODYNAMICS

1. INTER-OBSERVER, TEST-RETEST AND PRACTICE VARIATION

When different investigators judge urodynamic traces together with written clinical information in women, there is agreement between them regarding the final clinical diagnosis in about 80% of cases. In other words there is, depending on the diagnosis, some disagreement in 20% of cases when urodynamics is judged in this manner. [36].

A few studies have concluded that there is good inter and (short time) intra–rater reliability. In a single centre series of 621 urodynamic pressure flow tracings of female patients, small average differences between analysis parameters were observed by various investigators, which was interpreted as good interobserver agreement. [37] Inter-observer variability has also been tested in other ways. In a study where 4 experienced practitioners, evaluated 17 pediatric urodynamic datasets, they failed to agree on aspects of detrusor function, including DO, in a quarter of the cases. [38] This result is reminiscent of a similar study of the interpretation of urodynamic recordings of male voiding function. [39]

In a survey to determine the variation in urodynamic

practices in the United Kingdom 100 questionnaires were sent to units known to be performing urodynamic investigations. There was a significant variation in practices with only 51% of units having a protocol for what tests should be performed, under what circumstances and how. [40]

Standardisation of urodynamic variables may result in a greater consistency of diagnosis, allowing easier comparisons of treatment regimes and outcomes, and is the conclusion of studies of this kind and reviews. [41, 42].

In a review to examine the best position during cystometry to demonstrate DO and reproduce the overactive bladder (OAB) symptoms, 16 relevant studies with good consistency were analysed. All but two showed a clear effect, with a higher incidence of DO in the vertical position (sitting or standing) or onset of DO when changing to a vertical position. Performing the UDS in a supine position would have missed a large proportion of DO diagnoses ranging from 33% to 100%. The authors noticed a substantial practice variation in position during urodynamic investigation and demanded standardisation. [43]

2. SHORT-TERM (WITHIN-SESSION) REPRODUCIBILITY

A number of authors have investigated the within-session reproducibility of cystometric measurements. Because such measurements are conducted within a short period of time, the possibility that the first measurement influences the second for example through a direct effect on the mechanical properties of the bladder (hysteresis and/or viscoelasticity) has to be considered.

Brostrom et al [44] examined 30 healthy women with a mean age of 52 years, performing 2 consecutive medium fill rate (50 mL/min) cystometries in a single session. The volumes at first desire to void (FDV) and normal desire to void (NDV) increased significantly from the first to the second measurement, by 34 and 51 mL respectively. The maximum bladder capacity showed no significant change. The proportion of these healthy subjects who showed DO decreased from 4/30 (13%) in the first cystometry to 1/30 (3%) in the second but this was not statistically significant.

In a similar study [45] of short-term repeatability in 31 female patients aged 14-74 years, two consecutive cystometries were performed with body temperature liquid at a rate of 50 mL/min. On the first cystometry, FDV occurred at a median volume of 112 mL (range 26-503 mL). The cystometric capacity had a median value of 150 mL, with a range from 39-633 mL. (These values may be compared with the normal values in **Table 3**). The volume at FDV increased by 46 mL from the first to the second cystometrogram, while the cystometric capacity increased by 35 mL. These changes are similar to those seen in normal volunteers, but, as the authors point out, they are not clinically important because they are much smaller than the random variability within subjects, as measured by the 95% confidence limits of ±130 and ±106 mL respectively.

Chin-Peuckert et al [46] examined the variability between two consecutive cystometries in 32 male and 34 female children with a mean age of 7. Most suffered from spinal dysraphism. A smaller number showed DO on the second study than on the first ($p< 0.05$), and similarly the volume at which DO was first observed was larger on the second study ($p <0.05$). Interestingly, these results are similar to those obtained in children without overt neuropathy.[47]

Hess et al [48] did not perform repeated cystometries, but first measured the bladder pressure “as is” at whatever volume was in the bladder initially, in 21 men and 1 woman with ‘neurogenic bladder’. They then drained the bladder and refilled to the same volume and again measured the pressure. The second “cystometric” pressures were higher than the initial ‘physiological’ ones by approx 6 cm H_2O ($p = 0.01$), although there was a strong correlation between them.

In another study where fifty consecutive individuals with spinal cord injury had 2 trials (trial 1 and trial 2) of UDS done 5 minutes apart, differences in maximum cystometric capacity, opening pressure, maximum detrusor pressure, volume voided, and post void residual (PVR) volume were evaluated. The variation observed was ± 100-150 mL for the volume parameters and ±10-20 cm H_2O for the mentioned pressure parameters. [49]

Sixty men with LUTS and 35 with neurogenic bladders after spinal cord injury (SCI) were assessed. Symptom scores and uroflowmetry were obtained and filling and pressure-flow cystometry were carried out three times in succession. In men with LUTS, a significant decrease in the number and pressure of involuntary detrusor contractions (IDC) in consecutive cystometries resulted in a reduction of observed DO from 72% to 63% and 48%, in the three studies. In men with SCI, cystometric variables and DO remained consistent over sequential studies. [50].

Twenty asymptomatic women with a mean age of 41.8 years (30-55) agreed to undergo a urodynamic evaluation, repeated immediately without removing the catheters (a two-fill and void study). [51] Sixteen women of this cohort returned for an identical assessment 1-5 months later. Immediate and short-term repeatability of UDS parameters was assessed. The short time variation was ± 5 ml/s for Q_{max} and ± 10 cm H_2O for $p_{det}Q_{max}$. Voided volume and first sensation of filling (FSF) differed ±50 mL in the test retest situation. The authors noted that the variation of parameters in these healthy women was larger than observed in other studies with patients.

3. INTERMEDIATE-TERM REPRODUCIBILITY

Homma et al [52] found that, in 30 patients with DO, repeat cystometry carried out 2-4 weeks after initial testing showed a consistent shift toward normal. Bladder volumes increased by 10-13% ($p<0.01$), while DO disappeared in 10% of subjects and decreased in amplitude by an average of 18% in the remaining cases. The random variability of cystometric capacity was ± 57 mL (95% CI).

4. LONG-TERM REPRODUCIBILITY

Sørensen et al [53] investigated 10 healthy females (mean age 34 years), twice at an interval of 2 years. They carried out measurements in both supine and sitting positions. FSF occurred at a mean volume of 378 mL supine and 354 mL sitting, with intra-subject variability over two years as quantified by the standard deviation (SD) of 76 and 100 mL (SD) respectively. Maximum capacity was 512 mL supine and 502 mL seated, with intra-subject SD of approximately 75 mL in both cases. Inter-subject SD's were a little larger: 76-144 mL. No significant differences in volumes or compliance over two years could be demonstrated (**Table 2**).

Summary

In patients and in healthy volunteers, if cystometry is repeated either during the same session or within about 4 weeks, the bladder volumes at which the various sensations are felt and the bladder capacity tend to increase by 30-50 ml, while the proportion of traces showing DO tends to fall. These systematic changes are fairly small in comparison with the random within-subject variability, which has an SD of about 50-60 mL.

Conclusions (evidence level 2)

- A number of studies have reported test retest variation of ±10-15% for various parameters (volume, pressure or flow) and observations; this can be regarded as the physiological variation of urodynamic testing.
- Various studies have demonstrated clinically relevant practice variation and inter-rater/observer variation.

Recommendations (grade B)

- The committee recommends that investigators and clinicians take into account the inherent physiological variability of urodynamic testing
- The committee recommends investigators and clinicians evaluate the 'representativity' of the tests (which is an evaluation based on the patient's perception as to how well the tests have reproduced their usual lower urinary tract function) and the committee recommends that examiners strive towards maximal representativity.

Table 2. Intra-subject variability of cystometric parameters from one test to the next, within-session, intermediate-term (2-4 weeks), and long-term (2 years)

Authors	Population	Period between tests	Systematic change (test 2- test 1)			Within-subject random variation from test 1 to test 2	
Brostrom [44]	Healthy ♀	Same session	ΔFDV = +34	ΔNDV = +51	ΔMCC = ns	ΔDO = -3/30	
Mortensen [45]	Patients ♀	Same session		+46	ΔMCC = +35	NDV: ±130 (95% CI)	MCC: ±106 (95% CI)
Chin-Peuckert [46]	Children, spinal dysraphism	Same session	ΔVDO = + ($p<0.05$)	ΔDO = - ($p<0.05$)			
Hess [48]	Neurogenic bladder	Same session	ΔP = + 6 cm H_2O				
Homma [52]	Patients ♀	2-4 weeks	ΔV = +10% -13%		ΔDO = -10%		MCC: ±57 ml (95% CI)
Sørensen [53]	Healthy ♀	2 years	ΔFSF:ns	ΔMCC:ns		FSF: ±76-100mL (SD)	MCC:±75 mL

(SD) Key to symbols: VDO = volume at which DO occurs; Δ = increase from test 1 to test 2.

- The committee recommends persistent attention to the standardisation of techniques and interpretation of results, especially to reduce inter-practice variation and inter–observer variability.

Topics for research

- The committee suggests further consideration of standardisation of urodynamic tests, procedures and evaluation, especially to reduce inter-practice variation.
- The committee suggests intensive dissemination of up-to-date standards and careful training of urodynamic investigators and suggests evaluation of the effect of these standards and training on health care quality.

5. REPRODUCIBILITY OF AMBULATORY URODYNAMICS

The third ICI reported that there was no published data on the reproducibility of ambulatory urodynamic studies. This continues to be the case.

II. CYSTOMETRY: NORMAL VALUES

1. NORMAL VALUES: FILLING CYSTOMETRY AND AMBULATORY URODYNAMICS

Table 3 shows normal values for cystometric variables reported by a number of authors. This has been updated since the table published in the 3rd ICI. A striking observation is that there is great inter-centre variability, even for nominally similar patients. There

Table 3. Normal values (mean or median) of filling cystometry variables

Authors	population	parameters	FSF	FDV	NDV	SDV	MCC	DO
Brostrom [44]	Healthy ♀	Seated, 50 mL/min		171 43-508	284 182-576		572 338-1016	4/30
Wyndaele [54]	Healthy ♂	Body temp 30 ml/min	222 ± 151	325 ± 140		453 ± 94	453 ± 94	7/50
	Healthy ♀	Body temp 30 mL/min	176 ± 96	272 ± 106		429± 153	429 ± 153	
Van Waalwijk [55]	Healthy ♂ and ♀	Seated 35 mL/min	104 ± 57	172 ± 66	263 ± 93	263 ± 96		3/17
Robertson [56]	Healthy ♂	Room temp 50 mL/min					342 (269-471)	2/12
	Healthy ♀	Room temp 50 mL/min					500 (345-562)	
	Healthy ♂	Room temp 100 mL/min					475 (400-600)	0/12
	Healthy ♀	Room temp 100 mL/min					500 (390-790)	
Sørensen [57, 58]	Healthy ♀	Supine, body temp 60 mL/min	347 ± 101				482 ± 103	0/10
	Healthy ♀	Seated 60 mL/min	357 ± 126				491 ± 147	
	Post-meno ♀	Supine 60 mL/min	396 ± 163				551 ± 223	0/12
	Post-meno ♀	Seated 60 mL/min	331 ± 168				489 ± 196	
Heslington [59]	Healthy ♀	Supine 100 mL/min					420 175-810 (range)	4/22
Walter [60]	Healthy ♀	Supine, body temp 30 mL/min	225 (150-300)				425 (400-490)	0/15
Hosker [61]	Healthy ♀	Supine, body temp 100 mL/min		304 ± 116			543± 94	0/72

Total DO 20/252 = 8% Key to symbols: ± = SD; (xxx-yyy) = interquartile range; xxx-yyy = 95% confidence interval. All volumes are in ml

is no evidence from the table that these variations are associated with differences in filling rate, infusate temperature, or patient position. It appears that the sensations themselves are ill-defined and inadequately standardised.

Wyndaele et al [54] examined 50 volunteers. The bladder was filled at 30 mL/min with body temperature saline. For males (n=18; mean age 22 ± 3 years), FSF occurred at 222 mL ± 151 mL; FDV occurred at 325 mL ± 140 mL; and strong desire to void (SDV) occurred at 453 mL ± 94 mL, and this was taken as maximum capacity. For females (n=32; mean age 21 ± 2 years) FSF occurred at 176 ± 96 mL; FDV at 272 mL ± 106 mL; and SDV at 429 mL ± 153 mL. DO was observed in 7/50 (14%) of these normal volunteers. The group also published a study with symptom free 'middle-aged' female volunteers. Of their volunteers a substantial number was excluded because of asymptomatic abnormalities. The remaining had an average capacity during cystometry of 586 mL (sd 193 m) with 258 mL and 1092 mL as extremes. [63].

In 17 healthy subjects, reported in another study, with a mean age of 24 years, but a wide age range, FSF occurred at a mean volume of 104 ± 57 mL; FDV occurred at 172 ± 66 mL; NDV occurred at 263 ± 93 mL; strong desire occurred at 294 ± 96 mL. [55] DO was observed in 3 of 17 subjects (18%) on conventional cystometry in the seated position. The filling rate was 35 ml/min. On ambulatory monitoring the proportion showing DO rose to 69% (**Table 4**).

Fifty-seven postmenopausal women: 30 continent and 27 with SUI underwent urodynamic investigation in another small study. The incontinent women showed lesser bladder capacity at FDV, as well as decreased urinary volume. MUCP was lower in the patients in relation to the continent women. Other differences between the normals and the incontinent women were not observed. [64].

Robertson [65] reported on 11 male and 6 female healthy asymptomatic volunteers, age range 22-72 years, examined by conventional 20ºC saline filling cystometry and by ambulatory monitoring. In females: the 'filling volume' (presumably equivalent to maximum cystometric capacity) was: 342 mL median (269-471 mL IQR) at 50 mL/min; and 475 mL median (400-600 ml IQR) at 100 mL/min. In males it was: 500 mL median (345-562 ml IQR) at 50 ml/min; and 500 mL median (390-790 ml IQR) at 100 mL/min. DO was observed in 2/12 volunteers (17%) during filling cystometry at 50 mL/min; there was none at a filling rate of 100 mL/min (which preceded the 50 ml/min filling). During ambulatory monitoring DO was seen in 6/16 subjects (38%). The median volume voided during ambulatory monitoring was markedly smaller than the filling volume on conventional cystometry (compare **Tables 3 and 4**).

Sørensen et al [58] examined 10 younger women (mean age 34 years, range 29-46 years) at 3 points of the menstrual cycle, filling the bladder with body temperature fluid at 60 ml/min. Because the variables showed little systematic variation during the cycle, average values are given here. FSF occurred at 347 mL ± 101 mL (SD) supine and 357 mL ± 126 ml seated. MCC was 482 mL ± 103 mL, supine and 491 mL ± 147 mL, seated. No DO was observed. The same authors [57] investigated 12 healthy post-menopausal females, mean age 59 years, using similar parameters. The means of 2 studies showed: FSF, supine, at 396 mL ± 163 mL (SD); and sitting at 331 mL ± 168 ml. MCC, supine, at 551 mL ± 223 mL; and sitting at 489 mL ± 196 mL. They reported no DO.

In 2004, Hosker reported on the urodynamic findings of 72 healthy female volunteers (mean age 41.4 ± SD 10.1 years and mean parity 2.3 ± 1.6) who formed the control group for a study of urethral pressures in women with urodynamic stress incontinence. Cystometry was performed in the supine position with saline at body temperature filling the bladder at a rate of 100 mL/min. The mean PVR on catheterisation was 11 ± 13 mL. The mean FDV was 304 ± 116 mL and the mean MCC was 543 ± 94 mL. He reported no DO. [61]

Twenty-four women without a history of frequent urgency and without DO (mean age 50.2 years, range 22-80 years), including 7 pre- (29.2 years), 7 peri- (48.8 years), and 10 postmenopausal (66.0 years) women were studied with uroflowmetry and video urodynamics to determine normative data for LUT

Table 4. Normal values – ambulatory monitoring

Authors	population	Mean/median voided volume	DO
Van Waalwijk [55]	Healthy ♂ and ♀	200 ± 78 ml (mean ± SD)	11/16
Robertson [56]	Healthy ♂ and ♀	263 ml (201-346) (interquartile range)	6/16
Heslington [59]	Healthy ♀	212 ml 100-550 (range)	15/22
Salvatore [62]	Healthy ♀		2/21
			Total DO 34/75 = 45%

function in asymptomatic continent women without DO across the age span. For all subjects, median maximum single voided volume in bladder diary was 500 mL and median MCC was 580 mL. SDV was reported at 287, 366, and 425 mL for pre-, peri-, and postmenopausal groups, respectively. The maximum flow rate was 25, 32, and 23 mL/sec in uroflowmetry and 23, 24, and 18 mL/sec during the pressure-flow study, respectively. Median PVR was below 20 mL in all groups. At maximum flow rate subjects voided with detrusor pressures of 29, 26, and 24 cm H_2O, respectively and maximum urethral closure pressure was 94, 74, and 42 cm H_2O, respectively. [66].

Heslington and Hilton [59] examined 22 asymptomatic healthy female volunteers, performing conventional cystometry and ambulatory study in a random order. DO was observed in 18% on conventional cystometry and 68% on ambulatory monitoring.

As indicated above, most studies of ambulatory monitoring in healthy subjects have revealed high percentages with DO (typically of modest amplitude [55, 67]). However, Salvatore et al [62] by using 2 bladder catheters simultaneously and only verifying DO if it was shown by both, suggested that some of this apparent overactivity was a measurement artifact, and that 90% of a group of 26 healthy women showed no DO on ambulatory monitoring.

Thirty healthy males aged 21-32 years volunteered for an ambulatory urodynamic 24 h investigation with a suprapubic catheter to study natural fill urodynamics during normal and increased fluid intake. The recorded micturition data were: frequency (f), voided volume (VV), voiding time, maximum flow rate (Q_{max}) and time to Q_{max}. The number of sensed and not-sensed detrusor contractions, and their duration and time in relation to voiding were also recorded. During the recording day subjects were randomised to normal (30 mL/kg body weight per day) or larger (60 mL/kg body weight per day) fluid intake. There was a larger urine production and an increased voiding frequency in the fluid-loaded group ($p<0.0001$). The detrusor pressure ($p_{det}Q_{max}$) was significantly higher in the fluid-loaded group (73 cm H_2O, range 57-94) than in the normal fluid intake group (60 cm H_2O, range 45-86) ($p=0.003$). No other urodynamic data differed significantly between the two groups. Ambulatory urodynamics in normal young men showed a large interindividual variation. Detrusor contractions during filling were frequently recorded, and premicturition contractions were consistently found. The data found in this study were similar to previous home flow recordings in the same group. [68]

In a retrospective study of 186 selected investigations the influence of autologous urine production during filling cystometry on total bladder volume was observed. Mean filled volume (external infusion plus autologous urine production) was 346 ± 152 mL, but mean real bladder capacity (voided volume + residual urine) was 391 ± 170 mL. In all patients, 14% extra urine was produced due to autologous urine production (mean rate, 6.1 mL/min). In 42% of the investigations, the real bladder capacity was more than 110% of the infused volume. In 18% of the patients, the contribution of natural bladder filling was more than 25% of the infused volume. [69]

Urodynamic tests were, in another study, conducted on 39 asymptomatic male volunteers with a mean age of 25.8 years (range 21 to 31) and mean weight of 75.5 kg. (range 63 to 95) to examine the pressure-flow relationship and obtain evidence to support the hypothesis that fluid consumption has a role in detrusor voiding function. Volunteers were divided into 2 groups according to water consumption regimen of 30 mL/kg daily (17 patients, group 1) and 60 mL/kg daily (12, group 2). Bladder pressure was monitored via a suprapubic catheter and abdominal pressure was measured via a rectal balloon using an ambulatory system with an average duration of 20.5 hours Doubling of water consumption increased urethral opening pressure from 51.2 ± 3.2 to 61.5 ± 5.1 cm H_2O ($p<0.05$), maximum detrusor pressure from 58.9 ± 4.5 to 70.0 ± 6.2 cm H_2O ($p<0.01$) and contractility from 15.4 ± 1.4 to 17.7 ± 1.4 W/m^2. There were no significant differences due to water consumption in maximum flow rate (24.4 ± 1.4 to 25.2 ± 1.8 mL/s) or bladder capacity (286 ± 20 to 329 ± 15 mL) but a significant increase in the number of micturitions from 5.8 ± 0.5 to 9.8 ± 0.5 per day ($p<0.001$) proportional to water consumption. [70].

2. COMPLIANCE

Compliance is the ratio of a change in volume measured relative to the corresponding change in pressure. Usually compliance is calculated over the change in volume from an empty bladder to that at MCC.

In 17 healthy subjects, using a filling rate of 35 mL/min, [55] the range of compliance values was very wide (range = 11-150 mL/cm H_2O; mean ± SD = 46 ± 40 mL/cm H_2O). Such a mean value implies only a small rise in pressure on filling (a few cm H_2O), consistent with a high compliance. Sørensen et al [53] reported similar mean values for compliance in a group of healthy females: 62 mL/cm H_2O initially and 58 mL/cm H_2O on re-examination 2 years later. Even higher values of compliance were reported by Hosker (range = 31-800 mL/cm H_2O; mean ± SD = 124± 150 mL/cm H_2O) in 72 healthy females (age 25-75 years) and these reproduced the wide range of values already published. [61]

The results were comparable in elderly, peri and post menopausal women. [66]. In another selected group of healthy, middle aged, volunteers compliance was ‘high’ on average, however with a large variation. [63]

Similarly, Robertson showed that in 17 healthy male and female volunteers, the median detrusor pressure rise on conventional filling cystometry was 5 or 6 cm H_2O at filling rates of 50 and 100 ml/min respectively. [65] On ambulatory monitoring the median pressure rise was 0 cm H_2O however, a significantly smaller value.

Compliance cannot only be quantified in the units of mL/cmH_2O but also as a dimensionless number measured from empty to MCC. Compliance increases with age (because bladder capacity increases with age). The dimensionless value of compliance presents a value of which is independent of age. This is especially relevant in children when intra- and inter-individual test (retest) comparisons are made. [71]

Consistently, among 22 healthy female volunteers, conventional cystometry and ambulatory study performed in random order showed a significantly larger detrusor pressure rise on conventional filling as compared with ambulatory studies. [59]

Although these figures show that conventional filling cystometry provokes higher pressure increase during filling than ambulatory monitoring with natural filling of the bladder, this is not necessarily a disadvantage because it may unmask abnormal compliance.

Robertson [65] reported cystometric variables for 6 patients with "low-compliance bladders" due to neuropathy. Conventional cystometry showed pressure rises of 18 (± 7) and 46 (± 13) cm H_2O during bladder filling at rates of 20 and 100 mL/min respectively, but the pressure rise during natural (ambulatory) filling was much smaller (in fact, hardly distinguishable from normal): 6 (± 4) cm H_2O. The corresponding compliance values were 8 (± 2) and 6 (± 3) mL/cm H_2O for conventional cystometry (abnormally low), but 114 (± 32) mL/cm H_2O for natural filling (a normal value). [67]

3. NORMAL SENSATIONS AND BLADDER CAPACITY - SUMMARY

Table 3 shows the striking variability from centre to centre: FSV for example occurs at about 100 ml in one centre but at about 350 mL in another, a value large enough to provoke a strong desire to void in the first.

The bladder capacity is somewhat less variable from centre to centre, its mean varying from 340 to 570 mL. Apart from this inter-centre variability, the inter-subject variability of all the parameters is also substantial, with an SD of about 100 mL in order of magnitude. Some of this variation represents genuine differences between subjects, but it should be noted that the within-subject variability is also quite large, in order of magnitude 50 mL (**Table 2**).

As a rule of thumb in healthy adult subjects, and omitting some of the more inconsistent values, FSF occurs at about 170-200 ml, FDV or NDV (the ICS makes no distinction [4]) at 250 ml, and strong desire to void at about 400 mL; MCC is about 480 mL. It is interesting that the mean voided volume on ambulatory monitoring falls between FSV (on cystometry) and FDV/NDV.

Thus, in daily life, the bladder is usually emptied long before a strong or even a "normal" desire to void would be felt on cystometry, although much more can be held if voiding has to be postponed. Correspondingly, there is a discrepancy in bladder capacity between daily life and urodynamic study, also depending on the method of measurement (uroflowmetry, voiding diary or cystometry).[72]

4. DETRUSOR OVERACTIVITY IN NORMAL SUBJECTS - SUMMARY

DO is shown during conventional cystometry by up to 17% of normal subjects with a mean percentage of about 8% (**Table 3**). The percentage is much higher (up to 69%, see **Table 4**) on ambulatory studies, although one group disputes this.

DO can be observed during urodynamic testing, in healthy subjects (without the symptoms that are usually associated with OAB) which indicates that the observation of 'detrusor overactivity' should not always be interpreted as 'synonymous with pathology that demands treatment'.

Conclusions (evidence level 2)

- Various studies have been helpful to reveal normal values and test retest variation of urodynamic parameters in healthy volunteers.
- There is some evidence that evaluation of filling sensation may be different between laboratories, (thus: 'may be observer dependent'), making data exchange as well as generalisation and interpretation of published data difficult.

Recommendations (grade B)

- The committee recommends that investigators and clinicians bear in mind the results of urodynamic testing in healthy persons and to recognise 'normal' test-retest variation as well as the differences and/or variations between 'usual LUT behaviour', ambulatory monitoring and office urodynamic testing.
- The committee suggests investigators should be sufficiently aware of the normal variation, and normal values of urodynamic studies.
- The committee recommends further standardisation and a practical objective means of recognising and recording the parameters relevant to sensation during bladder filling.

5. INFLUENCE OF CATHETER ON VOIDING

A urodynamic database of 600 consecutive women referred for the evaluation of voiding symptoms was reviewed to examine the effect of a 7F transurethral catheter on flowrate. Before urodynamics, all patients voided privately using a standard toilet and free flow was recorded. Only 100 patients who voided similar volumes varying by less than 20% on the free and pressure flow studies were included. In each voided volume category and urodynamic diagnosis, pressure-flow parameters were significantly different from the equivalent free flow parameters in all but 4 cases. Specifically the maximum flow rate was significantly less and flow time was significantly longer on pressure versus free flow studies (each $p < 0.01$). An intermittent flow pattern was more common on pressure than in free flow measurements (43% versus 9%). [73]

Women between the ages of 30 and 70 years, without LUT complaints and without a history of surgery for urinary incontinence, were recruited to prospectively examine the effect of a 6F urethral catheter on the urinary flow rate in healthy women without LUT symptoms. After a free flow rate, cystometry and pressure-flow studies were performed twice using a 6F urethral catheter. The maximum flow rates during the first and second studies were compared with one another and with the nonintubated values. In the 20 volunteers (mean age 42 years), the mean nonintubated flow rate was 23 mL/s. With a 6F urethral catheter in place, the women had a mean maximum flow rate of 16 mL/s on the first study and 15 mL/s on the second. A significant difference was demonstrated between the free and intubated maximum flow rates for both the first ($p = 0.0006$) and the second ($p = 0.0001$) study. No significant difference was detected between the two intubated maximum flow rates ($p = 0.262$). [74].

The impact of three different sized (4.5-, 6- and 7F) catheters on pressure-flow studies was studied in 60 women undergoing urodynamic evaluation for LUT symptoms, divided into two groups (A and B) of 30 women each. The patients underwent non-invasive free-flow uroflowmetry with determination of PVR. In group A the two consecutive pressure-flow studies were performed using a 4.5F catheter once and a 6F catheter once; in group B the two consecutive pressure-flow studies were performed using a 4.5F catheter once and a 7F catheter once. The maximum and average flow rate in all pressure-flow studies performed were significantly lower than the equivalent free-flow parameters and the flow time was significantly longer for all pressure-flow versus free-flow studies. Furthermore, there was a significantly larger PVR for pressure-flow than for free-flow measurements. There was no significant difference in maximum flow rate, average flow rate and flow time between 4.5- and 6 F pressure-flow studies (A). However, there was a statistically significant difference between 4.5- and 7F pressure-flow studies (B) in those uroflowmetry parameters. Detrusor pressure at maximum flow ($p_{det}Q_{max}$) and maximum detrusor pressure ($p_{det\ max}$) in group A did not show statistically significant differences between 4.5- and 6F pressure-flow studies whereas in group B, $p_{det.}Q_{max}$ and $p_{det.\ max}$ were significantly different between 4.5- and 7F pressure-flow studies. [75].

Conclusion (evidence level 3):

- There is evidence that, in general, flow is reduced when voiding with a urodynamic catheter in the urethra and that this reduction is partially caused by the size of the catheter.

Conclusion (evidence level 4):

- It is also the opinion of the committee that single catheters 6F incorporating both a filling channel and a pressure-sensing channel should be used for intravesical pressure measurement during cystometry (i.e double lumen catheters in the case of using fluid filled pressure lines). This is because removal of a separate filling catheter just before voiding may displace the pressure sensor and that movement of catheters within the urethra are likely to interfere with the representativity of lower urinary tract function during micturition.

Recommendations (grade B)

- The committee recommends that investigators interpret pressure-flow voiding parameters and the subsequent post void residual together with the uncatheterised (and representative) voiding parameters.
- The committee suggests the 'standard' use of, as thin as possible, 'one-catheter-systems' for filling and pressure recording during urodynamic testing.

III. REPRODUCIBILITY, RELIABILITY AND NORMAL VALUES OF URETHRAL PRESSURE MEASUREMENTS

1. NORMATIVE AND COMPARATIVE DATA FOR MAXIMUM URETHRAL CLOSURE PRESSURE

Table 5 shows values of MUCP that have been obtained by different authors in normal (or, at least, without urodynamic stress urinary incontinence) and abnormal female populations. It has several striking features. The first is the between-centre variability in

Table 5. Maximum urethral closure pressure in stress-incontinent women and women without proven urodynamic stress urinary incontinence, from Weber [126]

First author	SUI	No SUI	p value
Awad [76]	35.9 ± 16.3 n = 20	101 ± 52.0 n = 10	< 0.001
Bunne [77]	21.2 ± 20.9 mm Hg n = 11	44.4 ± 15.2 mm Hg n = 10	< 0.01
Hendriksson [78] ages 30-39	41.1 ± 12.0 mm Hg n = 10	54.4 ± 15.1 mm Hgn = 10	< 0.05
[78] ages 40-49	36.5 ± 11.2 mm Hg n = 33	49.2 ± 13.4 mm Hg n = 12	< 0.01
[78] ages 50-59	32.4 ± 9.6 mm Hg n = 29	40.7 ± 12.8 mm Hg n = 10	< 0.05
[78] ages 60-69	29.4 ± 14.6 mm Hg n = 13	36.2 ± 10.2 mm Hg n = 10	ns
Kaufman [79]	35.9 ± 1.2 (SEM) mm Hg n = 86	46.4 ± 2.5 (SEM) mm Hg n = 32	< 0.001
Godec [80]	42.0 ± 27.0 n = 66	56.0 ± 27.0 n = 31	< 0.05
Rud [81]	37 n = 24	38 n = 6	ns
De Jonge [82] supine, empty [82] standing, full	 45.4 ± 17.6 n = 38 48.8 ± 20.3 n = 38	 61.9 ± 21.0 n = 28 60.6 ± 19.3 n = 28	
Kujansuu [83]	46.3 ± 11.8 mm Hg n = 15	49.5 ± 9.6 mm Hg n = 14	ns
Kach [84]	57.9 ± 20.5 n = 78	93.9 ± 16.9 n = 44	ns
Richardson [85] [85] normal	abnormal 46 ± 30 n = 30 59 ± 28 n = 43	65 ± 35 n = 5 67 ± 35 n = 59	ns ns
Versi [86]	28.1 ± 5.3 (SEM) n = 95	49.2 ± 6.0 (SEM) n = 114	< 0.01
Cadogan [87]	34.1 ± 16 n = 40	49.7 ± 17 n = 16	= 0.0036
Versi [88]	25.4 ± 40.8 n = 70	42.2 ± 24.6 n = 102	< 0.01
Thind [89]	20	45	

Mean values of MUCP are in cm H_2O except where noted. ± = SD, except where noted. SEM = standard error of mean

the values reported, with mean MUCP varying from 36 to 101 cm H_2O in non-stress-incontinent subjects. The second is the large between-subject SD reported in most studies (from 10 to 52 cm H_2O). The third is that, in spite of this variability, in every study the mean MUCP was lower in stress-incontinent patients than in non-stress-incontinent women, sometimes significantly so and sometimes not. Although, some of the variations shown in the table are the result of different patient populations, a weighted averaging of the mean values suggests that a normal MUCP is about 54 ± 25 cm H_2O. In stress-incontinent women the corresponding figures are 39 ± 24 cm H_2O. Clearly there is so much overlap that this test can hardly be useful for diagnosis [90] (see section D.I.2.b - severity of stress urinary incontinence).

Eighty primiparous women with self-reported new stress incontinence 9-12 months postpartum were compared with 80 primiparous continent controls and 80 nulliparous continent controls to identify impairments specific to stress incontinence. MUCP (± SD) in primiparous incontinent women (62.9 ± 25.2 cm H_20) was lower than in primiparous continent women (83.9±21.0) who were similar to nulliparous women (90.3 ± 25.0). This lower MUCP followed by ultrasound assessment of vesical neck mobility on coughing was the measure most associated with de novo stress incontinence after first vaginal birth. [91]

Studies providing normative data for men are scant, but there are some data on the UPP in normal males.[92, 93].

2. RELIABILITY OF URETHRAL PRESSURE VARIABLES

In clinical practice, use of a fluid-perfusion technique to measure resting urethral pressure profile parameters such as MUCP yields an SD that ranges from 3.3 to 8.1 cm H_2O. On average the SD is approximately 5 cm H_2O (95% confidence limits ± 10 cm H_2O) or ± 5%. With a microtip transducer technique the SD varies between 3.3 and 16.5 cm of water, which means that the 95% confidence limits may be as large as ± 33 cm H_2O. The coefficient of variation when using the microtip transducer technique has been reported to be 17% (95% confidence limits ± 34%).

In one study using fluid perfusion the coefficient of variation of MUCP varied from 3% to 11% (95 % confidence limits 6% - 23%). [94]

Another, comparative study between fluid-filled and microtip pressure transducers observed that MUCP obtained from the fluid-filled catheter was significantly higher than that obtained from the microtip catheter. However, the authors also concluded that the use of the double-lumen fluid-filled catheter for the measurement of MUCP can be considered a reliable technique since its reproducibility is as good as that of the microtip catheter. [95]

A significant difference between MUCP values recorded by microtransducer versus fiberoptic catheter systems has also been observed. Significantly lower mean MUCP's were recorded by the fiberoptic system than by the microtransducer system. No significant difference was however observed between these two systems in measurement of VLPP. [96]

As mentioned earlier, the performance of air-charged catheters in measuring MUCP has been shown to be comparable to microtransducers in the measurement of maximum urethral closures pressure in a non-randomised study. [9] However, there was a difference in FUL which was attributed to the different diameters of the two catheters.

In 2008, Zehnder et al carried out a randomised comparison of these air-charged catheters with microtip catheters in 64 women and found that the air-charged catheter was as least as reliable as the microtip for measuring both MUCP and FUL. However, they found that the air-charged catheter gave a higher reading of both parameters compared to the microtip device. [10]

3. AGING

It is well established that in women the UPP changes with age. A recent study of 255 women, ages 20-77 years, without DO, overt neuropathy or pelvic or urinary incontinence surgery, confirmed that the MUCP is negatively associated with age ($r = -0.489$, $P < 0.0001$). [97] This study was not a randomised trial but one that used a convenience sample of patients.

4. OTHER PARAMETERS AFFECTING THE MEASUREMENT OF URETHRAL CLOSURE PRESSURE

The 2002 ICS standardisation report relating to urethral closure pressures shows that the value of MUCP is not only dependent on the type of catheter used but also its orientation within the urethra, the degree of bladder fullness and the position of the patient. [98]

Conclusions (evidence level 2)

- Various studies have shown considerable test-retest variation of all urethral pressure measurements or parameters.
- Various studies have shown that normal and pathological values of urethral pressure parameters are largely overlapping.
- Various studies have shown that urethral pressure(s) (parameters) are affected by age.
- Studies have shown that urethral pressures depend on patient position, volume of fluid in the bladder and position of the patient.
- Studies have shown that urethral pressures depend on the pressure recording catheter used and, sometimes, its orientation within the urethra.

Recommendations (grade B)

- The committee recommends that investigators and clinicians recognise the poor sensitivity and specificity of urethral pressure measurements and their 'normal' test retest variation.
- The committee does **not** recommend urethral pressure measurement as the only urodynamic test in patients with incontinence.
- The committee recommends that the clinical relevance of urethral pressure measurements, when performed, is judged in relation to other urodynamic tests (such as cystometry) and to the clinical examination.

IV. LEAK POINT PRESSURE

1. INTRODUCTION

The detrusor pressure or the intravesical pressure (p_{det} or p_{ves}) at which involuntary expulsion of urine from the urethral meatus is observed is the leak point pressure (LPP). The rise in bladder pressure causing leakage may originate either from the detrusor (caused for example by the filling of a low-compliance bladder) or from an increase in the abdominal pressure. Thus there are two different leak point pressures – the detrusor LPP (DLPP) and the abdominal LPP. The abdominal pressure increase during the latter is produced voluntarily by coughing (CLPP) or by Valsalva (VLPP).

LPP is not consistently defined throughout the reports in literature and we have not found any standardisation (report) of the technique. Any comparison of findings between studies is hindered by this.

The elements which could be standardised include: 1) the basic definition of LPP (baseline value of pressure; route of measurement – urethral or rectal), 2) whether Valsalva or cough is used to produce leakage, 3) the technique to confirm urine loss, 4) location of catheter, and shift in location on cough or strain, 5) calibre of catheter (if transurethral) 6) type

of pressure sensor 7) the volume in bladder, 8) the rate of prior bladder filling and 9) patient position. [90].

2. RELIABILITY OF LEAK POINT PRESSURE MEASUREMENTS

a) Diagnosis

In a study that recruited 168 patients it was seen that women who demonstrate urodynamic SUI at lower bladder volumes do not report greater bother from incontinence than women who leak at higher volumes. The authors concluded that leakage severity 'quantified' by this urodynamic method, is not an adequate reflection of incontinence related quality of life and or subjective incontinence severity. [99] Another study confirms these observations. [100]

A total of 200 women with SUI were clinically evaluated and underwent urodynamic study to determine the correlation between VLPP and the UPP. A progressive correlation of VLPP with MUCP was found when UPP was performed at 50 mL ($r = 0.305$, $p < 0.0001$), at 250 mL ($r = 0.483$, $p < 0.0001$) and at maximum bladder filling ($r = 0.561$, $p < 0.0001$). The authors concluded that there is a significant correlation between MUCP and VLPP. [101] Another prospective study in 109 patients assessed the relationship between CLPP and VLPP with SUI (n=61; 56%), DO (n=21; 19%) or a combination of these (n=27 25%). More women with SUI leaked during CLPP than during the VLPP; fewer women with DO leaked during CLPP and more during the VLPP. [102] LPP's are reported to be dependent on patient position; being lower in the standing position as compared to supine position. [103] Another study with the goal of determining the effect of position on UPP seems to have been troubled by 'poor test retest reproducibility' in the standing position. [104]

Two studies, one with 369 patients including some without incontinence and another study with 65 female patients with incontinence stratified into groups with various LPP's; various grades of urethral (hyper-)mobility and various grades of incontinence severity have been performed. Both studies were unable to find strong 'urodynamic' discriminators for the type or severity of incontinence and concluded that all values overlapped. Patients with SUI can be characterised by LPP and change in the urethral angle and or mobility, although these variables do not always define discrete classes. [105, 106]

The results of these studies basically confirm the earlier conclusion in an expert review: 'It is not apparent that either LPP measurement or UPP can accurately predict which patients will achieve the best outcome of surgical treatment for SUI. Other parameters assessed during urodynamic evaluation might provide prognostic information regarding the risk of voiding dysfunction postoperatively and the possibility of persistent urgency-related leakage following surgery, though not directly predict cure.' [107]

b) Treatment

Can any value of LPP (valsalva or cough) and/or UPP help in the selection of treatment for patients with SUI? This question has been addressed by various investigators.

In a retrospective cohort analysis of 3-month outcomes in 145 subjects (TOT = 85; TVT = 60) it was observed that relative risk of postoperative urodynamic SUI 3 months after surgery in patients with a preoperative MUCP of ≤ 42 cmH_2O was 5.89 (1.02 to 33.90, 95% confidence interval) when TOT was compared with TVT tape. [108]

The value of urethral hypermobility, MUCP and urethral incompetence in the diagnosis of SUI was evaluated in 369 women with clinical symptoms suggestive of SUI without symptoms of bladder overactivity. The cohort was divided into 2 groups according to continence or incontinence status. Continent and incontinent patients differed with regards to urethral incompetence and hypermobility (each $p < 0.0001$). Incontinent patients had a greater probability of a higher grade of each factor. MUCP was significantly lower in the incontinent group ($p < 0.001$). [106]

A prospective study assessed the difference in measured urethral function before and after TVT procedure. Twenty-three (65.7%) of 35 consecutive women had a preoperative diagnosis of intrinsic sphincter deficiency (ISD) as defined by MUCP < 20 cm H_2O and/or VLPP <60 cm H_2O. Subjective and objective success rates were 91% and 83%, respectively. The mean change in MUCP was -1.3 cm H_2O (95% CI -5.9, 3.3), whereas the pressure transmission ratio increased 15.7% (95% CI 5.0%, 26.3%). The mean decrease in straining urethral angle was 16.3 degrees (95% CI -23.9 degrees, -8.7 degrees). Cured subjects, demonstrating hypermobility preoperatively, continued to do so postoperatively. The effectiveness of the TVT did not appear to depend on a clinically significant change in the straining urethral angle. [109]

A total of 221 women 29 to 80 years old (mean age 55.2) were included in a later study to evaluate the outcome of the TVT procedure for SUI with low VLPP. Mean follow-up was 10.5 months (range 6 to 52). Patients were divided into 61 with low (<60 cm H_2O) and 160 with higher (>60 cm H_2O) VLPP. The overall cure rate was significantly lower in patients with low vs higher VLPP (82.0% vs 93.1%, $p = 0.013$). In women with low VLPP, multivariate analysis indicated that urge symptoms and low MUCP were independent factors for treatment failure (OR 15.12, 95% CI 1.90 to 120.61, $p = 0.010$ and OR 0.92, 95% CI 0.86 to 0.99, $p = 0.018$, respectively). [110]

174 consecutive patients who underwent a distal polypropylene sling procedure for the treatment of SUI were prospectively evaluated and reported in a slightly earlier study. The group was divided by VLPP

into group 1: 60 patients who did not leak on urodynamics, group 2: 27 patients with VLPP > 80 cm H_2O, group 3: 71 patients with VLPP 30 to 80 cm H_2O and group 4: 16 patients with VLPP < 30 cm H_2O. Mean follow-up was 14.7 months (range 12 to 30) and mean patient age was 62 years (range 32 to 88). The groups were well matched before surgery with respect to age, number of previous surgeries, and severity of SUI symptoms and urge incontinence. The percentage of patients who were cured or improved was similar among groups. After surgery there was no statistical difference among patient mean self-reported symptoms of or bother from SUI or urge incontinence. The distal urethral polypropylene sling provides similar symptom improvement in all patients regardless of preoperative VLPP. LPP is helpful in the diagnosis of SUI but appears to be of minimal benefit in predicting the outcome of the distal urethral polypropylene sling procedure. [111]

A later study reported that neither MUCP nor LPP were good predictors of post-operative stress incontinence but, because this was not the primary outcome measure of this study, there may not be adequate power to make this a definitive conclusion. [112]

c) Within-patient variability

McGuire and coworkers [113] found a SD of 5.4 cm H_2O yielding a true 95% confidence interval of 89-111 cm H_2O. In another study where the microtip transducer technique was used the true value was found to vary between 72 and 128 cm H_2O in the standing position and between 61 and 139 cm H_2O when semirecumbent. [103]

The committee has found no reports on ***inter-observer*** variability.

Conclusions (evidence level 2/3)

- Different definitions and techniques to determine (urine) leak point pressure exist.
- Various studies have demonstrated a weak association of abdominal leak point pressures and the patient experienced or measured severity of incontinence.
- Studies have shown that the 'isolated' parameters from abdominal leak point pressure measurements are not extremely helpful as predictors of success for TVT, TOT or suburethal sling treatment of patients with stress urinary incontinence.

Recommendations (grade B/C)

- The committee does **not** recommend leak point pressure measurement as a single urodynamic test in patients with urinary incontinence.
- The committee recommends that the result of abdominal leak point pressure measurements, when performed on patients with urinary incontinence, should be judged in relation to other urodynamic tests such as cystometry and to the clinical examination.
- The committee considers detrusor leak point pressure in patients with neurogenic lower urinary tract dysfunction a relevant parameter. This is discussed in section III (neurogenic lower urinary tract dysfunction) and in section IV (patient evaluation: children).

V. DIAGNOSTIC PERFORMANCE OF FILLING CYSTOMETRY AND AMBULATORY MONITORING

1. SENSITIVITY AND SPECIFICITY OF FILLING CYSTOMETRY IN OVERACTIVE BLADDER SYNDROME WITH OR WITHOUT URGENCY INCONTINENCE

a) Detrusor overactivity incontinence

Table 6, reproduced from the second Consultation[2] shows that some authors have found quite high positive sensitivity, specificity and predictive value of symptoms for urodynamic SUI. Specificity, sensitivity and predictive value of symptoms were less for detrusor overactivity incontinence (DOI) or 'mixed symptoms' of urinary incontinence.

Van Waalwijk van Doorn et al [122] made careful tests of the sensitivity and specificity of non-ambulatory urodynamic observations (a) for any urinary incontinence and (b) for urgency urinary incontinence (UUI). Among 348 women of mean age 41 years with symptomatic urimary incontinence, urodynamics demonstrated incontinence in only 164, a sensitivity of only 164/348 = 47%. For a similar group of men of mean age 44 years the corresponding figures were 31/83 = 37%. In a similar group of 102 female patients with voiding complaints but without symptoms of urinary incontinence, urodynamics revealed no incontinence in 96/102, a specificity of 94%. For men the corresponding figures were 71/75 = 95%.

Among 154 female patients (in the same study [122]) in whom urodynamics reproduced urinary incontinence, the observation of pure DOI had a sensitivity of 25/28 = 89% for symptomatic pure urgency incontinence; its specificity was 103/126 = 82%; and its negative predictive value was 97%. However, the positive predictive value was only 25/48 = 52%. In large part this low value was due to a group with mixed symptoms who revealed DOI on urodynamics.

Table 6. Value of patient history for predicting urodynamic findings, evaluated by various methods and in various female patient populations, from Homma et al [2]

Author	Year	Sample size	USI STV	SPT	PPV	DOI STV	SPT	Mixed incontinence STV	SPT
Jensen [114]	1994	Review	0.91	0.51	0.75	0.74	0.55	0.48	0.66
Handa* [115]	1995	101	0.77	0.44	0.52				
Handa* [115]	1995	101	0.82	0.59	0.70				
Haeusler [116]	1995	1938	0.56	0.45	0.88	0.62	0.56		
Cundiff [117]	1997	535	0.44	0.87	0.87	0.71	0.41	0.68	0.48
Videla [118]	1998	72		0.82					
Diokno* [119]	1999	76	0.83	1.0	1.0				
James [120]	1999	555			0.81				
Lemack* [121]	2000	174			0.92				

STV = sensitivity, SPT = specificity, PPV = positive predictive value

* = predictive values are for type II SUI (i.e. with hypermobility)

Taking account of the patients with mixed symptoms does not however improve the overall agreement between symptoms and urodynamic findings, because nearly half of them proved to have isolated urodynamic stress urinary incontinence on urodynamics. Similar findings for stress urinary incontinence are discussed in section D.I.2.

Griffiths et al [123] examined 100 older men and women, median age 79.5 years, with urinary incontinence proven on 24-hour monitoring. The type of urinary incontinence was believed to be DO in the majority. During filling cystometry (room temperature fluid, filling rate 60 mL/min, supine and seated) urinary incontinence was not demonstrated in 32%; i.e. the sensitivity of conventional urodynamics for DO with incontinence was 67% in this study.

b) Detrusor overactivity alone

The sensitivity, specificity and predictive value of *symptoms* for *DO*, given in a review of papers quoted in the third ICI [124] are shown in **Table 7**. (Note that this sensitivity and specificity are equal to the positive and negative predictive values of *DO* for corresponding *symptoms.*)

In spite of the wide variations shown in **Table 7**, all authors agree that the correlation between symptoms and DO is modest; underlining the necessity of urodynamic testing to obtain an objective diagnosis.

Van Brummen et al [143] examined the sensitivity of DO*,* observed during conventional cystometry, for UUI. They examined 95 women, with OAB, symptomatic stress urinary incontinence, and/or prolapse. Symptoms were assessed by a bladder diary and conventional filling cystometry was performed (sitting, fill rate 60 mL/min). Urinary frequency, urgency and UUI had similar associations with the cystometric observation of DO (**Table 8**). Among patients with one of these symptoms, DO was <u>not</u> observed in 77-81%: i.e., there were large numbers of 'false positive symptoms'.

In another study 171women were recruited. These women were assessed with an OAB scoring system to help discriminate between USI and DO. The scoring system had a sensitivity of 79%, a specificity of 78% and a positive predictive value of 73% to identify DO. Investigators suggested that the scoring system could be applicable in primary care. [144]

In a similar study the accuracy of a urinary incontinence questionnaire in the diagnosis of various types of urinary incontinence was classified according to the results of multichannel urodynamic testing. Using a urinary incontinence questionnaire consisting of 12 urinary symptoms questions 129 women with symptoms of urinary incontinence were interviewed. Of the 12 questions, only three questions (two SUI symptoms and one OAB symptom) were significantly associated with the urodynamic diagnoses of urodynamic SUI or DO. The sensitivity and specificity of the questions was relatively low leading to the author's conclusion that symptoms of urinary incontinence were not sufficient to predict types of urinary incontinence and the suggestion that urodynamic testing is essential in the diagnosis and management of female urinary incontinence. [145]

In a study to determine the prevalence and associations of 'sensory urgency' in comparison with DO 592 women, attending for an initial urogynecological / urodynamic assessment, took part. The group was separated into those having 'sensory urgency'; relevant symptoms, without urodynamic DO

Table 7. Sensitivity, specificity and predictive value of symptoms obtained on patient history for the urodynamic observation of detrusor overactivity

First author	No. of patients	Sensitivity	Specificity	Predictive value	
				Positive	Negative
Awad [125]	108	0.96	0.25	0.82	0.67
Bent [126]	81	0.83	0.49	0.32	0.91
Cantor [127]	214	0.91	0.45	0.80	0.79
De Muylder [128]	408	0.62	0.47	0.62	0.48
Glezerman [129]	128	0.40	0.86	0.27	0.92
Hilton [130]	100	0.77	0.38	0.44	0.72
Jarvis [131]	100	0.91	0.45	0.54	0.87
Korda [132]	537	0.47	0.63	0.44	0.66
Lagro-Janssen [133]	103	0.84	0.77	0.67	0.90
Ouslander [134]	135	0.89	0.21	0.49	0.68
Phua [135]	84	0.84	0.31	0.82	0.84
Sand [136]	218	0.78	0.39	0.80	0.78
Summitt [137]	79	0.46	0.76	0.57	0.46
Thiede [138]	196	0.88	0.39	0.86	0.88
Valente [139]	102	0.74	0.97	0.88	0.74
Walters [140]	106	0.35	0.91	0.67	0.35
Sandvik [141]	40	0.56	0.96	-	-
Cundiff [117]	102	0.71	0.87	0.41	-
Haeusler [51]	130	0.62	0.56	0.64	0.39
Fantl [142]	17	-	0.64	0.57	-

or those wíth DO. The only difference in the clinical profile between to groups was increased prevalence of the symptom of UUI. The authors concluded that sensory urgency and DO appear to be part of the same clinical spectrum of bladder dysfunction. [146]

Looking just at the association between DO and UUI [44, 143], there was again a substantial number of 'false positive symptoms' – subjects with UUI but no DO. Correspondingly the specificity and negative predictive value of DO were found to be low, in these studies (15/67 = 22%; 27/79 = 34%).

To determine and compare the urodynamic characteristics in patients with OAB and patients with OAB plus SUI (OAB+SUI), 120 patients (60 each in OAB and OAB+SUI groups) underwent detailed history, physical examination, complete urodynamic investigation and 20-minute pad test. FDV, SDV, urgency, and the percentage of urodynamic SUI were larger in the OAB+SUI group and FUL, MUP and MUCP were significantly lower in the OAB-SUI group than those in the OAB group (P <0.03). [147]

c) Detrusor overactivity and overactive bladder syndrome

Digesu et al [148] reported a retrospective review of 4500 women aged 22-73 years. Neurological disorders were excluded. As shown in **Table 8**, this study highlights that there are not only a substantial proportion of 'false positive symptoms', but also a large number of 'false negative symptoms'; patients with DO but without OAB symptoms. The sensitivity and specificity of DO for OAB (symptoms) were 457/843 (54%) and 2473/3657 (68%) respectively, while its positive and negative predictive values -with symptoms referred to as the 'golden' standard- were 28% and 86% respectively.

Sekido et al [149] retrospectively reviewed the urodynamic examination of 139 adult patients (12 males and 38 females) and looked into the correlation between detrusor function (FSF, MCC, compliance) and DO versus symptoms of uncomplicated OAB. 75% of male patients with OAB symptoms had DO on cystometrogram in supine position and only 36.8% female patients.

Table 8. Overactive bladder symptoms and detrusor overactivity, from reference [148]

	Detrusor overactivity	No detrusor overactivity	Totals
OAB symptoms	457	386	843
No OAB symptoms	1184	2473	3657
Totals	**1641**	**2859**	**4500**

Hyman et al [150] examined 160 men, mean age 61 ± 15 years, without neuropathy but with symptoms "suggestive of DO." They observed DO in 68, suggesting a sensitivity of 43% for OAB symptoms. DO was seen more often with UUI than with symptoms of frequency, urgency, nocturia, suggesting a rather higher sensitivity for UUI.

In a retrospective study with 1,626 women with symptoms of mixed urinary incontinence were divided into stress predominant or urgency predominant symptoms; or equal severity of stress and urgency on the basis of the most severe symptom scored on the King's Health Questionnaire. The frequency of different urodynamic diagnoses for the all women in each of the above groups was calculated. In this study 29% (464/1,626) had stress predominant symptoms, 15% (248/1,626) had urgency predominant symptoms and 56% (912/1,626) had equal severity of urgency and stress symptoms. On urodynamics 42% (665/1,626) had pure urodynamic stress incontinence (USI), 25% (414/1,626) had pure DO, 18% (299/1,626) had both DO and urodynamic SI and 15% (248/1,626) had normal urodynamic studies. In those with stress predominant symptoms, 82% had USI; in those with urge predominant symptoms, 64% had DO. The urodynamic diagnoses were significantly different for the different balance of symptoms ($p<0.05$). In women with equal severity of urgency and SUI, 46% had DO while 54% had USI. The relative severity of symptoms from a symptom questionnaire distinguishes between different urodynamic diagnoses. [151]

In a study 1457 adult males and females were retrospectively selected based on OAB syndrome symptoms to determine how well the symptoms of OAB syndrome correlated with urodynamic DO using ICS definitions. A better correlation in results between OAB symptoms and the urodynamic diagnosis of DO was observed in men than in women. Of men 69% and 44% of women with urgency (OAB dry) had DO, while 90% of men and 58% of women with urgency and UUI (or OAB wet) had DO. SUI seems to have accounted for the decreased rates in women since 87% of women with UUI also had the symptom of SUI. The ICS definition does not specify what constitutes abnormal voiding frequency. Analysis of results showed that increasing voiding frequency did not have any effect on increasing the accuracy of diagnosis of DO except in women with 10 or more daytime micturition episodes. The authors concluded that the bladder is a better and more reliable witness in men than in women. [152]

The association between urinary symptoms and the urodynamic diagnoses of DO and USI was calculated to describe the relationship between symptoms reported in a self-completed postal questionnaire and urinary disorders based on urodynamic investigation. The study population was selected from women aged 40 years or over living in the community, who responded to a postal questionnaire. Four hundred eighty-eight women completed urodynamic investigation; 29.1% (142/488) were found to have DO, 33.6% (164/488) USI, 20.7% (101/488) mixed incontinence, and 16.6% (81/488) no urodynamic abnormality. SUI and UUI were included in the risk model for USI. SUI reported monthly or more was associated with more frequent diagnosis of USI, and UUI reported weekly or more with less frequent diagnosis of USI (STV: 76.9%; SPT: 56.3%; PPV: 67.8%). Strong or overwhelming urgency, urinary incontinence monthly or more, and nocturia once a night or more were all significantly associated with an increased diagnosis of DO. Reporting of SUI monthly or more reduced the risk of DO (STV 63.1%; SPT 65.1%; PPV 63.1%). The conclusion was that a postal urinary symptoms questionnaire was able to predict urodynamic diagnoses with moderate accuracy. [153]

One hundred and fourteen women attending a tertiary urogynaecology clinic were included in a randomised crossover study to either an initial interview-assisted questionnaire in the clinic with a follow up postal questionnaire or an initial pre-outpatient questionnaire followed by an interview-assisted questionnaire at the clinic visit. Question responses were compared with urodynamic diagnoses. With an interview method, only severity of incontinence was significantly associated with DO ($p = 0.012$). With self-completion, severity of nocturia ($p < 0.05$), urgency ($p = 0.003$), UUI ($p = 0.003$), leakage without warning ($p = 0.035$) and incomplete voiding ($p = 0.01$) were significantly associated with detrusor activity. On interview the symptom of SUI ($p = 0.002$) and use of pads ($p = 0.011$) were significantly associated with a diagnosis of USI. Severity of SUI ($p < 0.001$), frequency of leakage ($p = 0.004$), use of protection ($p < 0.018$), nocturnal incontinence ($p = 0.002$) and quantity of leakage ($p < 0.05$) on self-completion were strongly associated with diagnosed USI. There was no

association between the symptoms of urgency or UUI, and USI. No symptom had a high enough specificity and sensitivity to replace urodynamic testing however, postal questionnaire responses had a better relationship with urodynamics, for USI and for DO, than interview-assisted questionnaire responses. [154]

Conclusions (evidence level 2)

- Many studies have shown the weak correlation between symptoms and the result of urodynamic investigation, especially cystometry, in patients with incontinence.
- The correlation of the symptom 'stress incontinence' (expressed, or questioned) with the result of urodynamic investigation is somewhat better than the correlation of urgency or urgency incontinence (expressed, or questioned) with urodynamic investigation.
- The committee concludes that especially when frequent voiding, urgency and/or urgency incontinence is part of the symptom complex of patients with incontinence, urodynamic investigation is of value to obtain an objective diagnosis.
- Taking into account the variation between various institutes and the test-retest variation, the committee considers it relevant that investigators and clinicians judge the individual representativity of the results of the performed tests by comparison with the patients' symptoms.

Recommendations (grade B)

- The committee recommends urodynamic testing in patients with incontinence when an objective diagnosis is warranted. This is commonly the case when symptoms do not exclusively direct to stress incontinence, or when (for all types of incontinence) conservative measures have not been successful, or when relevant comorbidity exists or relevant previous surgery is performed.
- The committee recommends interpretation of the results of the complete urodynamic testing in relation with the symptoms, the clinical (or other) examinations and with the voiding diary in all patients.

d) Distinguishing or defining characteristics of detrusor overactivity

Several groups have attempted to find characteristics of DO that may distinguish incontinence with different aetiologies, or incontinence of different severity.

One group [155, 156] examined 132 patients with OAB symptoms (with and without neurological disease) by videourodynamics. Based on the characteristics of their involuntary contractions, patients were divided into 4 categories: *type 1*- no evidence of involuntary detrusor contractions on videourodynamics; *type 2* - involuntary detrusor contractions present, and patient aware and able to abort them; *type 3* - contractions present, patient aware and able to contract the sphincter (judged from the videourodynamics) but not to abort contractions; and *type 4* - contractions present and patient unaware but unable to contract the sphincter or abort contractions. There was no significant relationship between category and severity of symptoms as judged by voiding frequency, functional bladder capacity, or pad test. The authors concluded that the characteristics of the involuntary contractions were not distinct enough to aid in differential diagnosis, but that the ability to abort DO and stop incontinent flow might have prognostic implications, especially for the response to behaviour modification, biofeedback training, and pelvic floor exercises.

Cucchi et al [157] looked into detrusor contraction strength, detrusor contraction velocity and contraction sustainability. In this retrospective review the authors separated male patient into three groups; Group 1 had no neurogenic DO, with urgency and UUI. Group 2 was similar to group 1 but did not have urgency before involuntary contractions and Group 3 consists of "normal" men. They found that detrusor contraction velocity was different in the group with urgency versus no urgency or normal, implying that this may be an underlying mechanism for urgency.

Defreitas and coworkers [158] examined three groups of patients: group 1, men with LUTS and no known neurological condition with DO (n = 22); group 2, men with Parkinson's disease and LUTS (n = 39); and group 3, women with Parkinson's disease and LUTS (n = 18). Patients with Parkinson's disease had a significantly lower median volume at first detrusor contraction than those with non-neurogenic DO. The percentage of group-1 patients with UUI was significantly lower than that found in the other two groups (9% versus 54% and 56%, $p < 0.001$ and 0.002, respectively). No statistically significant correlation between the duration or severity of Parkinson's disease and urodynamic parameters was found. The distinction between Parkinson's disease proper and multiple system atrophy, which appears to be important with regard to bladder dysfunction,[159] was not made in this study.

In the study cited above, [150] 160 older men without neuropathy but with symptoms "suggestive of DO" were examined. DO was seen more often with UUI than with symptoms of frequency, urgency and nocturia. The bladder volume at which DO was observed tended to be lower in those with UUI and frequency and/or urgency than in the rest ($p = 0.07$). The prevalence of DO was similar in men with and without bladder outlet obstruction (BOO).

Ockrim at al [50] compared the variability of DO in men with LUTS to that in men with SCI by sequentially repeating urodynamic studies three times. They observed a significant decrease in the number and amplitude of involuntary detrusor contractions in the 60 patients with non-neurogenic LUTS whilst in the 35 SCI patients, the urodynamic variables remained the same over the subsequent studies.

The urodynamic characteristics of DO in women with multiple sclerosis (MS) (n = 54) were compared with the involuntary contractions found in women with LUTS and DO (n = 42) in a retrospective study. Among other parameters, the amplitude of the first involuntary contraction, maximum detrusor contraction, and threshold volume for the first involuntary contraction were evaluated. The amplitude of the first involuntary contraction was statistically greater in the patients with MS and DO compared with patients with DO (28.3 versus 20.5 cm H_2O, p = 0.003), as was the maximum detrusor contraction (46.4 versus 30.8 cm H_2O, p = 0.002). The threshold volume for DO was greater among patients with neurogenic DO (186.8 versus 150.5 mL, p = 0.037), which was likely to be secondary to the elevated PVR volume noted among patients with MS (p = 0.049).

The authors concluded that additional investigation is required to determine whether these differences are due to neurogenic influences directly on the detrusor muscle through aberrant innervation or by other mechanisms. [160]

Miller et al [161] suggested that functional bladder capacity was smaller in those with more severe incontinence as judged from the voiding diary in a study to evaluate quantification of DO.

Conclusions (evidence level 2)

- Studies have not been able to show relevant differences in patterns or characteristics of detrusor overactivity when the cause of overactivity is neurogenic or idiopathic.
- Various studies have not been unable to reliably quantify the severity of detrusor overactivity, in a clinically or scientifically applicable way.

Recommendation (grade C)

- The committee recommends that neither the cause (neurogenic or idiopathic) nor the severity of detrusor overactivity is diagnosed on the basis of parameters from urodynamic investigation (cystometry).

Topics for research

- The committee recommends further evaluation and development of objective parameters for assessing the treatment outcome of detrusor overactivity.
- The committee recommends the development of an objective and cystometry-based detrusor overactivity severity scale.

e) Provocative manoeuvres

Some studies have shown that 50% of DO occurs during supine cystometry without provocation and that the remaining 50% is revealed by posture change, standing cystometry, on provocation by cough, or on catheter removal. [162-164].

Awad and McGinis [125] observed DO in 30% of female patients in the supine position versus 61% in the standing position. A systematic review of the literature by Al-Hayek et al [43] concluded that supine cystometry failed to detect a significant percentage of patients with DO.

Webster et al [165] found that in 52% of women with DO, provocation by fast filling in the standing position, and with exercises such as coughing, was required to reveal it. Investigative technique, in particular the inflation of a balloon in the proximal urethra [166] or the instructions given to the patient,[167] affects the frequency of the observation of DO.

Choe et al [168] systematically examined which manoeuvres were most provocative of DO. In 134 women with symptomatic UUI they performed gas (CO_2) cystometry. Six provocative manoeuvres were performed consecutively to evoke DO, including lying supine, rising to a seated position, walking toward the bathroom, handwashing, coughing and sitting on the toilet with instructions not to void. By filling to maximum capacity and performing these manoeuvres in 2 different orders, they were able to demonstrate DO in 76/134 subjects (67%). Sitting on a toilet with a full bladder and with the instruction not to void was the most provocative manoeuvre, responsible for revealing DO in 52 of the 76 (68%). Handwashing was a distant second, revealing overactivity in 15 of the 76 (20%). Other manoeuvres revealed very little DO.

An extreme provocative manoeuvre is the bladder cooling (ice water) test advocated by Geirsson et al.[169]. The empty bladder is filled with water at a temperature of less than 10 ºC. This stimulates C-fibers that normally carry afferents from receptors sensitive to temperature and pain. In infants, stimulation of these receptors can initiate a detrusor contraction, but this response is normally lost at ages over 5 years. The bladder cooling test stimulated detrusor contraction (neurogenic DO) in 91-97% of patients with traumatic upper motor neuron lesion, but in only 47% of those with presumed idiopathic DO. Detrusor contraction was not observed in any patient with a lower motor neuron lesion or pure (urodynamic) SUI. Thus the bladder cooling test is highly sensitive for neurogenic DO, and highly specific for DO in general.

The bladder cooling reflex, elicited by the ice water test (IWT) was performed in patients with painful bladder syndrome (PBS, n = 17), idiopathic DO (IDO, n = 22), neurogenic DO (NDO, n = 4) and SUI (as controls, n = 21). The IWT was performed by intravesical instillation of cold saline (0 - 4 degrees C). A positive IWT was observed in IDO (27.3%) and NDO (100%) patients, but was negative in all PBS and all control patients. Thirteen (76.5%) PBS patients reported pain during the IWT, with significantly higher pain scores during ice water instillation compared to the baseline (p = 0.0002), or equivalent amount of bladder filling (100 mL) with saline at room temperature (p = 0.015). [170]

A total of 114 patients >50 years, with an International Prostate Symptom Score (IPSS) >8 and Quality of Life (QoL) >2, were evaluated by complete urodynamic workup and IWT to investigate whether DO and/or the response to the IWT were related to nighttime urinary frequency. The DO-positive IWT responders had a significantly higher bladder outlet obstruction index (BOOI) than did the DO-positive IWT nonresponders and the DO-negative IWT nonresponders. The DO-positive IWT responders had significantly more frequent nocturia and smaller nighttime maximal and minimal voided volumes than did the DO-negative IWT nonresponders without any difference in the nocturnal voided volume. The patients with nocturia two or more times had a significantly larger nocturnal voided volume and smaller nighttime minimal voided volume than the patients with nocturia less than two times. The incidence of DO-positive IWT responders was significantly greater among the patients with nocturia three or more times than that among those with nocturia less than three times. The authors concluded that high grade BOO leads to development of C-fibre reflex activity. [171]

Conclusions (evidence level 2)

- A systematic review concludes that more detrusor overactivity is seen when the patient is in the sitting position during cystometry, when compared to the supine position.
- There is some evidence that moving to a toilet, and also handwashing, is a strong provocative of detrusor overactivity.
- Evidence suggests that ice water cystometry can be applied to elicit detrusor overactivity in patients with neurogenic lower urinary tract dysfunction and that a detrusor contraction during filling with ice water can be interpreted as a sign of pathologic (existing only in patients with relevant neurology) C-fibre reflex activity. It has however also been shown in this regard that false-negative tests do occur.

Recommendations (grade B)

- The committee recommends that the results of provocative cystometry are interpretated in view of patients' symptoms and to bear in mind the representativity of the results obtained
- The committee recommends that the position of the patient during filling cystometry is taken into account because it can influence the demonstration of detrusor overactivity. Repeating the cystometry in a different position can be helpful when it is deemed clinically necessary.

2. AMBULATORY URODYNAMICS: SENSITIVITY AND SPECIFICITY

Ambulatory urodynamics is performed in an effort to capture more realistic or more physiological observations, especially of incontinence episodes. Thus, similar to provocative manoeuvres, it is an attempt to increase sensitivity by providing a longer time for overactivity to manifest itself. The authors of a review article [172] concluded that ambulatory monitoring detects more actual incontinence than conventional cystometry.

Radley et al. [173] found that ambulatory monitoring revealed DO in 70/106 women with symptoms suggestive of DO (twice as many as conventional cystometry with provocation by handwashing), and that it detected DOI in 40 of the 70. The observation of DOI was correlated with symptom severity, but it was not clear how many women complaining of UUI showed DOI. Therefore the sensitivity is unknown.

3. THE ADJUNCT USE OF IMAGING AND EMG

Videourodynamics is an investigation where cystometry is carried out simultaneously with imaging (usually x-rays) of the lower urinary tract. This can be useful in the management of some patients; particularly children and neurogenic patients and is briefly discussed in the relevant sections. There is a fuller discussion of videourodynamics in the chapter on Imaging, Neurophysiology and other tests.

Another adjunct to cystometry is the simultaneous measurement of muscle activity using EMG. Most frequently this is used in the investigation of neurogenic patients and often surface electrodes are placed on the perineum to detect general striated muscle activity. Amongst other uses, failure of the urethra/pelvic floor to relax and detrusor sphincter dyssynergia can be theoretically detected during voiding using this technique. Unfortunately, it is technically difficult to ensure a good quality EMG signal from the appropriate muscle during this procedure and there have been no publications in at least the last 20 years investigating the benefits of combining EMG with cystometry.

VI. THERAPEUTIC PERFORMANCE OF FILLING CYSTOMETRY AND AMBULATORY MONITORING

1. PREDICTION OF TREATMENT RESPONSE

a) Filling cystometry

The authors of a review of papers from 1980-2000 [124] (see **Table 9**), concluded that "it is not possible to correlate the results of urodynamic tests with the effects of non-invasive therapy."

Consistent with the table, Malone-Lee et al [177] reported on 356 female patients with OAB symptoms. On urodynamics, 266 showed DO. There was no significant difference (between those with and without DO) in treatment outcome after 6-8 weeks of oxybutynin and bladder retraining.

On the other hand, previous reviews have concluded that women with incontinence and DO respond less well to *surgery* for SUI than those without DO. [2] Friis et al [178] conducted a blinded prospective study to evaluate the usefulness of urodynamic examination compared to clinical diagnosis. The study showed that when urodynamic examination was added to the preoperative planning of treatment for female urinary incontinence a more beneficial cure rate was found if the patient was treated in accordance with the urodynamic findings. However, the patient material is small and the power of the study is weak.

A retrospective study has shown that a careful minimal evaluation may be adequate to identify ISD, predict postoperative voiding difficulties and maximise surgical outcomes. [179]. A Cochrane review concluded that current evidence is insufficient to demonstrate a clear improvement in clinical outcomes as a result of performing urodynamic studies.[180].

In men, fewer studies have been done. Golomb et al [181] examined whether preoperative urodynamic examination allows us to predict the risk of incontinence after radical prostatectomy. A small group of 20 patients underwent radical retropubic prostatectomy for prostate cancer. Urodynamics showed DO in 12/20 pre-operatively. 5 of these 12 suffered from UUI post-operatively. The positive predictive value of preoperative DO for post-operative incontinence was thus only 42%.

In a literature overview of the diagnostic and therapeutic value of urodynamic investigations in patients undergoing prolapse surgery, the reviewers found a large heterogeneity of results. 'Occult' SUI showed large variation between studies and de novo DO after TVT as adjunct to prolapse surgery was observed in inconsistent and unpredictable percentages. It was impossible to estimate the predictive value of urodynamic testing on the basis of this review and prospective studies were demanded. [182] A later clinical study confirmed this view. [183]

A study presented a decision-analytic model that evaluated the cost-effectiveness of basic office evaluation before surgery in women with prolapse and SUI symptoms and contrasted it with that of urodynamic testing. Costs were obtained from the Federal Register; effectiveness of treatment for urinary incontinence was based on the published literature. The strategies of basic office evaluation and urodynamic testing had the same cure rate of urinary incontinence (96%) after initial and secondary treatment. Under baseline assumptions incremental cost-effectiveness (cost for single extra cure of urinary incontinence) of urodynamic testing was $328,601.

According to sensitivity analyses, basic office evaluation was more cost-effective than urodynamic testing when the prevalence of pure DO was <8% or when the cost of urodynamic testing was >$103. The analysis concluded that urodynamic testing before surgery in women with prolapse and SUI symptoms is not cost-effective relative to basic office evaluation. [184]

Table 9. Response to medical treatment for urinary incontinence in subjects with negative or positive results of urodynamic tests, from reference [124]

First author	# patients	Treatment	Urodynamics	Results
Wagg [174]	290	Oxybutynin and retraining	Cystometry	No relationship between urodynamic variables and response to treatment
Hashimoto [175]	77	Oxybutynin 6 mg/day for 4 weeks	Cystometry	No difference in effect of oxybutynin in motor and sensory urge
Holtedahl [176]	87	Estriol and pelvic floor exercise and bladder training + electrical stimulation if requested	Cystometry + urethral pressure profile	Outcome similar in subjects with/without urodynamically confirmed diagnosis

b) Ambulatory monitoring

Brown and Hilton [185] used conventional and ambulatory urodynamic monitoring to study the incidence of DO before and after colposuspension. They showed that preoperative ambulatory monitoring was unable significantly to predict which patients would suffer from urgency postoperatively, or even which women would demonstrate DO post-surgery. Another paper addressed specifically the effect on clinical management of doing ambulatory urodynamics.[186] In this retrospective chart review of 71 women there were technical difficulties in 30/71 ambulatory studies although only 2 were not interpretable. 32/71 women showed DO and were nearly all treated with medication. Among the remainder without DO fewer received medication. However, fewer than half of those who received medication improved. The authors concluded that ambulatory urodynamics was not very helpful in deciding on management.

Conclusions (evidence level 2/3)

- Various studies have shown that the result of urodynamic investigation does not perfectly predict the outcome of relevant treatment in all patients; neither in patients with urodynamic detrusor overactivity nor in patients with urodynamic stress incontinence and also not in patients with a 'double' urodynamic diagnosis.
- A retrospective study with subsequent health economic modelling has shown that in patients with 'pure symptoms of stress incontinence' urodynamic testing might not be cost effective.

Recommendations (grade B/C)

- The committee recommends that the result of urodynamic investigation is applied to 'optimise' treatment strategy without attributing perfect specificity to the result of treatment, in an individual patient.
- The committee recommends that the cost effectivity of urodynamic testing is taken into account when discussing the necessity of urodynamic investigation.

Topics for research

- The committee suggests that large multicentre ('national') prospective studies might be of help to better understand the cost-effectiveness of high quality urodynamic testing in health care quality for patients with incontinence.

D. CLINICAL APPLICATIONS OF URODYNAMIC STUDIES

I. PATIENT EVALUATION: WOMEN

1. INTRODUCTION

The clinical evaluation of an incontinent woman is based on the combination of the medical history, physical examination and, when appropriate, selected urodynamic tests.

The patient's symptom SUI is clearly defined and the sign often can be objectively demonstrated as 'the observation of urine leakage from the urethra synchronous with exertion/effort, or sneezing or coughing' without any urodynamic measurement. Traditionally, provocative cystometry has been the core test for the urodynamic diagnosis of urodynamic stress incontinence (USI). Videourodynamics, dynamic urethral closure pressure profilometry, leak point pressure testing and ambulatory urodynamics have also been used.

Previous studies have found significant variation of the predictive value of symptoms in identifying 3 urodynamic observations i.e USI, DO and mixed urinary incontinence.[187, 188] This variation can at least partly be explained by inhomogeneous patient materials and lack of consistency in the clinical and the urodynamic diagnosis of USI between the studies and methodology (UDS). A carefully performed study [122] showed that, in a group of 154 females with both complaints and urodynamic demonstration of incontinence, the observation of pure USI had a sensitivity and specificity of 90% and 65% respectively for the isolated symptom of SUI. The positive and negative predictive values were 60% and 91%. The relatively low values were due to a substantial number of patients with mixed symptoms that showed pure USI.

The figures given in a review [188] are slightly different: the isolated symptom of SUI had a PPV of 56% for the observation of pure USI and 79% for USI with additional urodynamic abnormalities. The corresponding negative predictive values were 66% and 42% respectively. The PPV of SUI in association with other symptoms was 77% in detecting USI (with or without additional urodynamic abnormalities). A positive cough stress test had a PPV of 55% for detecting USI and 91% for the "mixed condition" (USI and additional abnormalities). These predictive values were based on an average prevalence of isolated USI of 41%.

In view of these discrepancies between symptoms and urodynamic findings, the soundest basis for the clinical diagnosis and evaluation of stress urinary

incontinence and urgency urinary incontinence remains to be established, as does the significance of the corresponding urodynamic observations such as USI, DOI and DO. However it should be noted that besides their diagnostic potential, urodynamic investigations can contribute qualitative and quantitative information about the underlying or coexisting pathophysiology.

In the following paragraphs the committee discusses clinical application of urodynamic tests in patients with signs or symptoms of incontinence. Firstly women with stress incontinence, followed by women with overactive bladder symptoms with incontinence

2. STRESS URINARY INCONTINENCE

a) Pathophysiology of stress urinary incontinence

There is a clear need to better understand the pathophysiology of stress urinary incontinence. Neither the clinical nor the pathophysiological value of classification into types 0-III,[189] or of distinguishing between hypermobility and ISD, has ever been documented in prospective studies. Clinically, ISD has been defined as "... sphincter weakness..." because "...the urethral sphincter is unable to coapt and generate enough resistance to retain urine..." .[190] However, this clinical term has never been conceptualised into sound urodynamic parameters. Conventional static urethral parameters such as MUP or MUCP, or cough profile parameters such as pressure transmission ratio and LPP have been shown to be of limited value to characterise the extent and the type of urethral dysfunction. [90, 191] Thus conventional urethral pressure profile parameters do not consistently provide reliable pathophysiological information. One study suggests that urethral elastance may be a more useful variable to characterise intrinsic sphincter deficiency. [192]

b) Severity of stress urinary incontinence

There is no consensus on how to measure the severity of SUI clinically or urodynamically. Severity can be expressed on the basis of simple clinical measures such as questionnaires, or on a bladder diary or on pad weighing tests. A review concludes that static urethral pressure profilometry parameters such as MUCP or cough profile parameters such as pressure transmission ratio cannot be used to characterise the severity of incontinence.[90]. One review suggested that abdominal LPP measurement might be a useful tool to quantify urethral dysfunction associated with SUI. [191]

However, other studies have found no correlation between leak point pressures and the severity of urinary incontinence as measured by bladder diaries and quality of life instruments. [100, 193-195] Leak point pressures are also limited as a diagnostic tool by the lack of standardisation of the technique. [196]

A total of 221 women, 29 to 80 years old (mean age 55.2), were included in a prospective TVT treatment study, performed mostly using local anesthesia with a mean follow-up of 10.5 months. Patients were divided into 61 with low (less than 60 cm H_2O) and 160 with higher (60 cm H_2O or greater) VLPP. Cure of incontinence was defined as an absent subjective complaint of leakage and absent objective leakage on stress testing. The overall cure rate was significantly lower in patients with low vs higher VLPP (82.0% vs 93.1%, p = 0.013) and, in women with low VLPP, multivariate analysis indicated that urgency symptoms and low MUCP were independent factors for treatment failure (OR 15.12, 95% CI 1.90 to 120.61, p = 0.010 and OR 0.92, 95% CI 0.86 to 0.99, p = 0.018, respectively). This led to the conclusion that women with urgency symptoms and low MUCP should be considered to be at high risk for failure after the TVT procedure. [110]

The role of preoperative VLPP in predicting the outcome of the distal polypropylene sling procedure for the treatment of SUI was prospectively evaluated in 174 consecutive patients, divided by VLPP into group 1 (60 patients who did not leak on urodynamics), group 2 (27 patients with VLPP >80 cm H_2O), group 3 (71 patients with VLPP 30 to 80 cm H_2O) and group 4 (16 patients with VLPP <30 cm H_2O). Mean followup was 14.7 months and mean patient age was 62 years. The distal urethral polypropylene sling provides similar symptom improvement in all patients regardless of preoperative VLPP. VLPP is helpful in the diagnosis of SUI but appears to be of minimal benefit in predicting the outcome of the distal urethral polypropylene sling procedure. [111]

In a review of recent reports and controversies concerning the use of LPP testing and urethral pressure profilometry prior to surgical treatment for SUI, it was concluded that there remains no clear consensus as to whether this testing enhances surgical outcome of SUI treatments by improving case selection or altering the surgical approach based on study findings. The reviewer found little evidence to suggest that patients with more severe forms of USI on urodynamic testing fare more poorly after the most commonly offered surgical treatment than those with less severe forms. However urodynamic testing may aid in identifying the group of women who appear to be at higher risk of voiding dysfunction following incontinence surgery. [107]

A total of 200 prospectively selected women with stress urinary incontinence (SUI) were clinically evaluated and underwent urodynamic study to determine the correlation, as well as the influence of bladder volume, between VLPP and UPP in urody-namically selected patients with USI. A progressive correlation of VLPP with MUCP was found when UPP was performed at 50 mL (r = 0.305, p <0.0001), at 250 mL (r = 0.483, p <0.0001) and at maximum bladder filling (r = 0.561,

p <0.0001). Urethral functional length did not show a correlation with LPP at a bladder distention of 50 mL (r = 0.117, p = 0.100) or 200 mL (r = 0.167, p = 0.019) but there was a minor correlation at bladder capacity (r = 0.234, p = 0.002). The authors found a significant correlation between MUCP and VLPP. Patients with SUI had a more remarkable correlation between UPP and VLPP when UPP was determined after filling the bladder to more than 200 mL. [101]

In a prospective study to assess the relationship between cough LPP and VLPP in women with SUI and/or DO, all 109 women with SUI demonstrated leak at CLPP but 40 women (66%) did not leak with VLPP. Of the 21 patients who had DO, 16 (76%) did not leak at CLPP whereas 17 (81%) leaked with VLPP. In the group of 27 women with mixed incontinence all leaked with cough at CLPP but only 17 (63%) leaked with VLPP. Women with SUI diagnosed with urodynamics leaked more at CLPP than the VLPP, and women with DO leaked less at CLPP and more with the VLPP. [102]

A total of 655 women with stress predominant symptoms underwent a standardised assessment before sling or Burch procedure. Weak to moderate correlations were observed between Medical, Epidemiological and Social Aspects of Aging Questionnaire, incontinence episode frequency, pad weight, Incontinence Impact Questionnaire and Urogenital Distress Inventory. On the other hand, VLPP correlated poorly with all variables measured. The sensitivity and specificity of the supine empty bladder stress test to predict intrinsic sphincter dysfunction were 49% and 60%, respectively. Urinary incontinence severity measures correlated moderately with each other at best. VLPP did not correlate with measures of severity and quality of life. The supine empty bladder stress test did not demonstrate a clinically significant association with other severity measures. [100]

From a total of 168 women, the 31% that demonstrated SUI at lower bladder volumes (100 ml) did not report greater bother from incontinence than the 35% women who leak at higher volumes (>400 ml). The Urogenital Distress Inventory, Incontinence Impact Questionnaire, and also the MUCP and VLPP were similar in the groups. Among the 116 patients who had a sling procedure, USI persistence did not differ according to the volume at which USI occurred (p=0.72). The authors concluded that 'bladder volume when leaking' during a urodynamic study is not an adequate reflection of incontinence related quality of life. [99]

Most retrospective studies show higher failure rates after surgery in women with low MUCP (often defined as MUCP ≤ 20 cm H_2O at MCC [90]). Other urethral closure pressure cut-points have been suggested as predictive of failure with transobturator versus retropubic midurethral slings in recent retrospective trials, but no prospective, randomised studies have been done to validate these observations.[108, 197] However, other investigators have shown that a low MUCP is not an efficient predictor of surgical failure.[187] In a recent prospective, randomised trial of women undergoing either Burch retropubic urethropexy or bladder neck slings, LPPs were not found to be predictive of surgical outcome for SUI. [198] Nevertheless, there are data to suggest that LPP may be a sensitive indicator of changes in incontinence status, reflecting treatment effect.[191]

The value of urethral hypermobility, MUCP and urethral incompetence was analysed in a study with 369 women with symptoms suggestive of SUI without symptoms of DO. Continent and incontinent patients differed with regards to urethral incompetence and hypermobility (each p <0.0001).

Incontinent patients had a greater probability of a higher grade of each factor. Even after adjusting for the older age of incontinent patients by ANCOVA, MUCP was significantly lower in the incontinent group (p <0.001). The best univariate optimised cutoff point for discriminating continence from incontinence was obtained with urethral incompetence greater than grade I. [106]

To compare the success rates of Burch colposuspension in relation to a VLPP cutoff level of 60 cm H_2O and to examine other predictive factors for ISD, such as MUCP and FUL, in an attempt to define the urodynamic contraindications to Burch colposuspension 79 patients eligible for continuous postoperative follow-up were enrolled in a prospective study. The mean age was 58 ± 10 years, mean parity was 3.71 ± 4.

The success rates in 2 groups, VLPP ≥ 60 cm H_2O (n=55) and < 60 cm H_2O (n=24) were 94.55% and 91.67%, respectively, demonstrating no statistical significance (p > 0.05). On post-hoc analysis a VLPP level <60 cm H_2O was not found to represent an absolute contraindication to Burch colposuspension, provided that other parameters, such as MUCP and FUL, are within acceptable ranges. [199]

Conclusions (evidence level 2/3)

- Various studies have shown conflicting results regarding the association of incontinence severity and urethral function tests (leak point pressures and urethral closure pressures)
- It is the opinion of the committee that contemporary urethral function tests are only modestly suited to judge the severity of incontinence or to further 'subcategorise' patients with stress (predominant) incontinence.

Recommendations (grade B/C)

- The committee recommends that urethral function measurements of leak point pressures and urethral closure pressures are not used as a single factor to grade the severity of incontinence.
- The committee recommends caution with the prediction of the outcome of any surgical treatment on the basis of contemporary urethral function tests.

Topics for research

- The committee suggests further studies with the aim to better understand urethral closure function and dysfunction, in relation to treatment for stress incontinence or stress predominant symptoms.

c) Aspects of urodynamic studies relevant to therapy for stress urinary incontinence

In a systematic meta analysis (only) 129 (out of 6009) studies were relevant for inclusion using the Quality Assessment of Diagnostic Studies (QUADAS) tool to identify and synthesise studies of diagnostic processes of urinary incontinence and to construct an economic model to examine the cost-effectiveness of simple, commonly used primary care tests. A clinical history for diagnosing USI in women was found to have a sensitivity of 0.92 and specificity of 0.56 and for DO a sensitivity of 0.61 and specificity of 0.87. For validated scales, question 3 of the Urogenital Distress Inventory was found to have a sensitivity of 0.88 and specificity of 0.60. Seven studies compared a pad test with multichannel urodynamics; however, four different pad tests were studied and therefore it was difficult to draw any conclusions about diagnostic accuracy. Of the four studies comparing urinary diary with multichannel urodynamics, only one presented data in a format that allowed sensitivity and specificity to be calculated. Their reported values of 0.88 and 0.83 suggest that a urinary diary may be effective in the diagnosis of DO in women.

Examination of the incremental cost-effectiveness of three primary care tests used in addition to history found that the diary had the lowest (best) cost-effectiveness ratio of between £35 and £77 per extra unit of effectiveness (or case diagnosed). Imaging by ultrasound to determine leakage was found to be effective in the diagnosis of USI in women, with a sensitivity of 0.94 and specificity of 0.83. The report found that a large proportion of women with USI can be correctly diagnosed in primary care from clinical history alone. On the basis of diagnosis, the diary appears to be the most cost-effective of the three primary care tests (diary, pad test and validated scales) used in addition to clinical history. The authors thought that ultrasound imaging may offer a valuable alternative to urodynamic investigation and that the clinical stress test is effective in the diagnosis of USI. However, they also conceded that if a patient is to undergo an invasive urodynamic procedure, multichannel urodynamics is likely to give the most accurate result in a secondary care setting. [200]

In 2006 in the UK, the National Institute of Health and Clinical Excellence (NICE) issued guidelines that urodynamics was recommended before surgery for urinary incontinence only if there is a clinical suspicion of DO or, if there has been previous surgery for stress incontinence or anterior compartment prolapse or, if there are symptoms suggestive of voiding dysfunction. [201] In other words, urodynamics is not routinely recommended for women before surgery for a 'clearly defined clinical diagnosis of stress urinary incontinence'. This was a recommendation founded on expert opinion collated by a modified Delphi process.

However, a study in 2008 by Agur et al casts some doubt on the wisdom of this recommendation. [202] In their tertiary centre, patients are referred with lower urinary tract symptoms. Information is collected and entered into a computer database at the time of history taking and before conducting urodynamic tests. The database was used retrospectively to identify women aged 18-80 years who had multichannel cystometry for urinary incontinence over a 17-year period (1 January 1990 to 31 December 2006). To apply the NICE criterion of a 'clearly defined clinical diagnosis of pure SUI', strict selection criteria were used to identify patients with pure SUI. The reliability of the patients' history in predicting 'pure' USI in patients with 'pure' SUI was investigated. They found that only 324/6276 (5.2%) women had pure SUI; moreover, a quarter of those with pure SUI symptoms ultimately had urodynamic diagnoses other than USI, that could affect the outcome of continence surgery. They concluded that only a small group of women fulfil the NICE criteria of pure SUI and it seems inevitable that even with these strict criteria, a woman can go forward to a surgical procedure with potentially important urodynamic findings unaddressed.

Conclusion (evidence level 1)

- It is concluded in a model study, based on a selected retrospective cohort, that urodynamic testing is not cost effective in the primary health care setting for women with predominant stress incontinence symptoms. It is also shown that in the referred population, urodynamic investigation is the most accurate way to obtain an objective diagnosis in patients with predominant stress urinary incontinence symptoms.

Conclusion (evidence level 3)

- Symptoms of pure stress urinary incontinence do not always exclude other abnormalities of lower urinary tract function.

Recommendation (grade A)

- The committee recommends that the cost effectiveness of urodynamic testing is kept in mind when discussing 'cost and gain' of the various methods of diagnosis for urinary incontinence, in relation to the method of treatment.

Recommendation (grade B)

- The committee recommends urodynamic studies are carried out in all women prior to surgical intervention for stress urinary incontinence.

Topic for research

- The committee suggests that a well-designed, multicentre study should address the question as to whether women with symptoms of pure stress urinary incontinence are more at risk of failure from surgical treatment of their incontinence without pre-operative urodynamics or have more adverse events following surgery without pre-operative urodynamics than women who have pre-operative urodynamic studies.

d) Prediction of failure of surgery

Most retrospective studies show higher failure rates after surgery in women with low maximum urethral closure pressure (often defined as MUCP ≤ 20 cm H_2O at maximum cystometric capacity). [90] Other urethral closure pressure cut-points have been suggested as predictive of failure with transobturator versus retropubic midurethral slings or pubovaginal slings in recent retrospective trials, but no prospective, randomised studies have been done to validate these observations. [108, 197, 203] When used together, Kilcarsian and colleagues found low urethral closure pressure and low leak point pressures to be predictive of failure after in situ vaginal wall slings in 58 women. The success rate was 65% in women with VLPP < 50 cm H_20 and MUCP < 30 cm H_20 but it was 91% in those with VLPP ? 50 cm H_20 and MUCP ? 30 cm H_20 ($p< 0.05$). [204] Clemons and LaSala showed that combining low urethral closure pressure and the absence of urethral hypermobility was predictive of surgical failure after a tension-free vaginal tape procedure. They found that an MUCP ≤ 15 cm H_20 resulted in only a 60% cure rate after TVT with an odds ratio of 6.3 for failure ($p= 0.03$). The absence of urethral hypermobility, defined as a straining angle of ≤ 35°, was associated with a cure rate of 50% with an odds ratio of 7.7 ($p= 0.02$). When the 2 factors were combined the cure rate was only 17% ($p< 0.001$). [205]

However, other investigators have shown that a low MUCP is not an efficient predictor of surgical failure. [187, 206] In a recent prospective, randomised trial of women undergoing either Burch retropubic urethropexy or bladder neck slings, leak point pressures were not found to be predictive of surgical outcome for stress urinary incontinence. [198]

Leak point pressures have not been found to be predictive of surgical outcomes following bone-anchored suburethral slings, transobturator and retropubic midurethral slings. [111, 193, 207-209]

Urethral retro-resistance pressure has also been studied as a potential predictor of surgical success. However, Tunn et al failed to show any predictive value of this measurement for surgical success with colposuspension, retropubic midurethral slings and transobturator midurethral slings. [30]

Ward and colleagues carefully examined the impact of urodynamic testing on decision-making and treatment recommendations in incontinent women. They found that the probability that urodynamics would alter recommendations for medical treatments was 27% and 46% for surgical treatment. Clinicians believe that there is value to adding multichannel urodynamics studies to history, physical examination, bladder diary, assessment of urethral hypermobility,cough stress test and post-void residual urine measurement. [210]

Conclusion (evidence level 2)

- Leak point pressures do not appear to correlate with success rates of colposuspensions, transobturator and retropubic midurethral, bone-anchored suburethral slings

Conclusion (evidence level 3)

- There is some evidence that low urethral closure pressures are associated with poorer success rates of retropubic and transobturator midurethral, vaginal wall and transvaginal bone-anchored slings.

Recommendation (grade B/C)

- The committee recommends that measurements of urethral function (leak point pressures and urethral closure pressures) are not used to reliably predict the likelihood of success after surgical treatment for stress incontinence. However, the values of urethral closure pressure may provide some guidance in this respect.

e) Voiding difficulties after surgery

Surgery for SUI may lead to voiding difficulties.[211] At this time risk factors (including urodynamic risk factors) for delayed resumption of voiding are not well defined. The type of surgery clearly plays a role: retropubic midurethral slings have been found to be less obstructive than Burch colposuspensions [212]

and transobturator midurethral slings appear to be less obstructive than the retropubic midurethral slings [213]. One major problem is that at the moment there is no clear urodynamic definition of obstruction or detrusor underactivity in women. It has been reported that low maximum flow rates (< 20 mL/s) [214] or "inadequate contraction strength" defined as p_{det} <15 cm H_2O during voiding (but note that this low p_{det} frequently signifies a low urethral resistance, and not necessarily a weak detrusor contraction), or significant use of the Valsalva manoeuvre when voiding, are associated with postoperative voiding difficulties.[215-217] Wheeler et al found that maximum flow rates were the best predictor of passing an initial voiding trial after retropubic and transobturator midurethral slings in multivariate analysis of 89 women (p=0.0002). [218] Similar findings were noted by Gravina and colleagues. [219] The possibility exists that, in women who do not use their detrusor during voiding, detrusor contractility may be assessed preoperatively by mechanically interrupting the flow ("Stop test"). [220, 221]

Shukla and colleagues found no urodynamic factors that were predictive of postoperative voiding difficulty following tension-free vaginal tape procedures despite a trend toward long term voiding difficulties in those with lower average flow rates in a multivariate regression analysis of 411 patients (p= 0.12). [222]

Dawson et al showed a significant relationship between the centile score for average flow rates and the risk of voiding dysfunction and the need for intermittent self-catheterisation on multivariate analysis after tension-free vaginal tape procedures in 267 women (p=0.029). [223]

Conclusion (evidence level 3)

- Current test methods have not been unable to reliably predict patients who will develop voiding difficulties after surgery for stress incontinence.
- However, average and maximum flow rates may be useful in predicting post-operative voiding dysfunction and retention following retropubic and transobturator midurethral slings.

Recommendation (grade C)

- The committee recommends that patients are informed that it is difficult to predict who will develop voiding difficulty following surgery for stress incontinence. However, poor pre-operative maximum and average flow rates are more likely to result in voiding problems following retropubic and transobturator midurethral slings.

f) Postoperative urgency

The preoperative symptoms of UUI and urgency, and the urodynamic observation of DO, have each consistently been shown to be associated with poorer surgical outcome in patients with mixed urinary incontinence. Several studies where the amplitude of DO was graded have shown that the risk of persistent urgency was more closely associated with high-pressure DO (p_{det} ≥ 25 cm H_2O) than low-pressure DO.[224-226] Consequently cystometry may allow a more precise selection of patients who respond well to surgery despite concurrent urge symptoms. The success rate after anti-incontinence surgery in patients with low-pressure contractions seems to be similar to the success rate in those without DO, [224-227] but the success rate in women with high-pressure contraction is less than 50%.[224-227]

On the other hand preoperative urgency symptoms resolve in a substantial proportion of patients (50-65%).[228-230] One untested hypothesis is that surgical correction of the bladder outlet may prevent ingress of urine into the proximal urethra (which if it occurs, may induce DO in some patients).[231-234]

De novo UUI has been reported to occur in 10-20% of patients after surgery.[211] There is scant information on clinical or urodynamic risk factors; possibly the type of surgery plays a role. A recent retrospective trial suggested that the incidence of de novo UUI was higher in bladder neck slings than in retropubic midurethral slings which were also associated with more de novo UUI than transobturator midurethral slings [213]. It should be remembered however that de novo DO may merely represent DO that was missed preoperatively.

Conclusions (evidence level 2)

- Current test methods have been unable to reliably predict which patients will develop de-novo urinary urgency (OAB syndrome) after surgery for stress incontinence.
- Post hoc evidence suggests that procedures which are more 'obstructive' produce a higher chance of de novo urinary urgency (OAB-syndrome).

Recommendation (grade C)

- The committee recommends that patients with stress incontinence are informed that the chance of developing urinary urgency (OAB-syndrome) following surgery is largely unpredictable

Topics for research

- The committee suggests further work to evaluate predictors of voiding difficulties or urinary urgency after contemporary (moderately invasive) treatments of stress incontinence (e.g. trans-obturator or trans-vaginal tapes).

g) The role of urodynamic studies in predicting occult stress urinary incontinence in women due to be treated for pelvic organ prolapse

Because 11 to 22% of continent women undergoing vaginal repair for a large cystocoele develop SUI following surgical repair,[235, 236] it would be helpful to devise methods to evaluate patients who are at risk for this complication.[237] Women with severe pelvic organ prolapse may develop incontinence symptoms when the prolapse is reduced; this is frequently named 'occult' SUI. Voiding difficulty and bladder outlet obstruction may coexist with occult SUI; all may be associated with pelvic organ prolapse, and all may be altered if the prolapse is reduced during urodynamic testing.

The overall incidence of occult SUI was 25% when videourodynamic testing was performed with and without pessary support of the bladder base during stress manoeuvres.[238]

In a small group of patients with severe genitourinary prolapse, occult incontinence was found in 59%, and about 20% (4/22) were reported to demonstrate stress pressure profiles suspect for SUI after pessary placement. [239] However, it should be remembered that stress UPPs are not particularly reliable measurements. A special technique (Scopette, Birchwood Lab) for reducing prolapse during multichannel urodynamics revealed a 56% incidence of low-pressure urethra (possibly related to ISD, but see caveats regarding UPPs above) and an overall incidence of occult SUI of 83% in women with massive pelvic organ prolapse but without clinical urinary incontinence.[240]

As expected, urethral hypermobility is correlated with the degree of prolapse. [241] Surprisingly, so too is DO (revealed by prolapse reduction), although impaired detrusor contractility and ISD were not significantly associated with prolapse in this one study.

The literature thus emphasises the importance of urodynamic assessment with prolapse reduction to assess potential occult SUI and possibly DO. [184, 237, 238, 242] However, although occult SUI is revealed in a high proportion of cases with severe prolapse, there seem to be no studies assessing reproducibility, a particularly important point since the technique of reduction is variable and non-standardised.

Many different tests (e.g. pessary test, speculum test) have been used to document occult SUI. In many studies they are positive in 50-77% of patients (which, arguably might be overestimating the risk). In various papers the Pereyra and Kelly procedures have been used prophylactically but there is no documentation that they reduce the risk of postoperative incontinence. [243-245] A prospective controlled study [246]showed that the pessary test was positive only in 50% of incontinent women and was falsely positive in 72%. Another study [219] concluded that urodynamic testing before a pelvic organ prolapse operation was not cost-effective.

More recently in 2008, the CARE trial in the United States examined 322 stress-continent women with stages II-IV prolapse who underwent standardised urodynamics. Five prolapse reduction methods were tested: two at each site and both were performed in each subject. Clinicians were masked to urodynamic results. At sacrocolpopexy, participants were randomised to Burch colposuspension or no Burch colposuspension (control). Preoperatively, only 12 of 313 (3.7%) subjects demonstrated USI without prolapse reduction. More women leaked after the second method than after the first (22% vs. 16%; p = 0.012). Preoperative detection of USI with prolapse reduction at 300ml was found with a pessary in 6% (5 of 88); with manual vaginal elevation in 16% (19 of 122); with forceps in 21% (21 of 98); proctoswabs in 20% (32 of 158); and with a speculum in 30% (35 of 118). Women who demonstrated preoperative USI during prolapse reduction were more likely to report postoperative SUI, regardless of concomitant colposuspension (controls 58% vs. 38% (p = 0.04) and Burch 32% vs. 21% (p = 0.19). [247]

Conclusions (Evidence level 1)

- Various studies have shown that symptoms of stress incontinence can appear after surgery for prolapse.
- There are a variety of methods to uncover 'occult stress urinary incontinence' in women with vaginal prolapse. However, they all have different sensitivities and this makes comparison of results difficult. Standardisation of these tests in clinical practice may be beneficial
- Various studies have shown that concomitant procedures to address possible stress incontinence developing after prolapse surgery (with or without simultaneous urodynamic testing) are not reliable in preventing its occurrence.

Recommendation (Grade B)

- The committee recommends that patients with vaginal prolapse are informed about the relative unpredictable chance of developing stress incontinence after surgery for that prolapse.

3. URGENCY URINARY INCONTINENCE

a) Pathophysiology and severity of urgency urinary incontinence

It remains unclear if the chronological sequence of bladder and urethral pressure changes may distinguish between 'true' (idiopathic?; originating in the detrusor?)

DO and 'secondary' DO. Secondary DO might be due to bladder outlet relaxation and ingress of urine into the proximal urethra followed by a micturition reflex. [248]

No statistically significant relationship between the various cystometric variables and reported symptom severity has been established.

b) Prediction of treatment response

Urgency and UUI or OAB syndrome are poorly associated with the urodynamic observation of DO, as discussed previously. The positive predictive value of OAB (urgency usually accompanied by frequency and nocturia with or without UUI) for urodynamically determined DO is only around 50%.[148] On the other hand DO is reported in 10-69% of asymptomatic female volunteers, depending on the definition and type of cystometry. [55, 59, 65, 162, 187, 249] This makes it impossible to use urodynamic investigation (cystometry) to predict the outcome of treatment for UUI.

Studies on voiding difficulties or de novo SUI or combined incontinence (as a consequence of increased capacity because of treatment for UUI) have not been published.

Conclusions (level 2/3)

- Various studies have concluded that the association between overactive bladder symptoms and detrusor overactivity during urodynamic investigation is weak.
- Various studies have concluded that the prediction of treatment -for overactive bladder symptoms - response on the basis of the characterisation or quantification of detrusor overactivity during urodynamic investigation is impossible.

Recommendation (Grade B/C)

- The committee recommends that investigators and clinicians discuss with patients with detrusor overactivity that neither quantity nor specific characteristics of detrusor overactivity predicts the response of any of the therapeutic approaches.

Topics for research

- The committee suggests further studies to find predictors of response on treatment for patients with overactive bladder syndrome.
- The committee suggests further studies to find urodynamic predictors of response for patients with overactive bladder without detrusor overactivity.

4. RECOMMENDATIONS FOR URODYNAMIC STUDIES IN WOMEN WITH URINARY INCONTINENCE

a) Recommendations for clinical practice:

1) The committee recommends non-invasive urodynamics (voiding and incontinence diary, PVR, and possibly uroflowmetry) for all patients with incontinence.

2) The committee finds that invasive urodynamic studies are not necessary prior to treatment in situations where the type of urinary incontinence is clear and there are no complicating factors and planned treatment is reversible. The committee provides the following examples:

- uncomplicated symptoms of SUI with normal bladder diary, normal flowmetry and without relevant PVR. (Symptomatic pure SUI with no symptoms or signs of voiding difficulties), for treatment by, for example, pelvic floor muscle training.
- uncomplicated symptoms of UUI with a bladder diary in accordance with these symptoms, with normal flowmetry and without relevant PVR. (symptomatic pure UUI with no symptoms or signs of voiding difficulties), for treatment by, for example, bladder training.

3) The committee recommends that, whenever surgical intervention is planned, whenever there is doubt about the pathophysiology, or about whether the incontinence is uncomplicated or not, then invasive urodynamics should be performed in order to provide the knowledge on which rational treatment decisions or prognosis can be based. The investigation should be tailored to the individual patient; typically this means that it will be a comprehensive examination of multiple aspects of storage and voiding function, and not just of the incontinence itself.

4) The committee suggests for research:

- to study new or existing urodynamic tests and parameters which have a sound technical and physiological basis

b) Recommendations for research:

1) The committee recommends research programs:

- to more clearly establish the technical and physiological basis of the urodynamic observations that are made in women with incontinence
- to design and conduct randomised studies that may provide objective documentation of the utility of soundly based tests
- to conduct studies that may provide objective evidence of the utility of performing urodynamics in near-normal subjects and in defined patient groups
  - note that the more complex and morbid the pathophysiological situation, the greater the differences between patients, and thus the more important it is to do urodynamics in order to obtain knowledge of what is to be treated
- to develop new tests, for example tests of urethral properties, which have a sound technical and physiological basis

2) The committee recommends that no new therapy should be introduced without extensive urodynamic testing of all accessible aspects of its effect on LUT function and dysfunction.

II. PATIENT EVALUATION: MEN

1. INTRODUCTION

Although the incidence of urinary incontinence in men is generally regarded as much lower than in women, this is not necessarily true for all patient groups, especially when dealing with the elderly (see section D.V, Patient evaluation: Frail elderly). In both sexes those who lose urine, whatever the cause may be, increase in number with advancing age.[250] In this section the characteristic pathologies that lead to incontinence in men are discussed from the point of view of urodynamic testing. Although urinary incontinence related to benign prostatic obstruction (BPO), BOO or to (radical) prostatic surgery is most frequently encountered, other important pathological conditions such as nocturnal enuresis and post-micturition dribbling are also clinically relevant.[2, 251]

This section is organised according to the suspected origin or cause of incontinence or related LUTS, reflecting the very varied aetiologies responsible for the condition in men.

2. LOWER URINARY TRACT SYMPTOMS RELATED TO BLADDER DYSFUNCTION MAINLY DETRUSOR OVERACTIVITY AND BLADDER OUTLET OBSTRUCTION

LUTS are fairly common among men of 50 years and over. Incontinence is not usually prominent but, if it is present, urodynamics can be helpful to establish the underlying vesical/urethral dysfunction, in particular, DO and/or BOO. Coexistence of BOO and DO increases with age and with the degree of BOO. [252, 253]

Non-invasive investigations such as uroflowmetry and measurement of PVR are easy to perform, but even in simple situations can only give clues to the underlying pathology. Low Q_{max} on uroflowmetry cannot distinguish BOO from the poor detrusor contractility. [254] There is also a significant variation in Q_{max} in repeated tests [255]. Moreover, since elderly people often suffer from co morbidities – e.g. insidious neurogenic ailments such as Parkinson's disease, multiple sclerosis, cerebrovascular disease or diabetes mellitus – invasive urodynamic tests are frequently necessary to finalise the diagnosis and plan any intervention, especially if surgical treatment is considered.

The role of urodynamics and DO in predicting treatment outcome still remains controversial. Aboseif et al compared 92 men with and without DO on pre-operative urodynamics before radical prostatectomy.

They found, after one year, a significantly higher incidence of incontinence (39% v/s 3%) in patients with pre-operative DO compared to those without pre-operative DO. [256]

Similarly, Seki at al in a retrospective study of 384 patients who had undergone transurethral resection of the prostate (TURP) for symptomatic benign prostatic enlargement (BPE), showed after one year from IPSS and QoL that the baseline DO negatively affected outcome. [257]

Monoski at al found in 40 men who underwent photoselective laser vaporisation prostatectomy (PVP) for 'BPH' and retention that the presence of DO in patients on pre- surgery urodynamics is associated with significantly more storage symptoms requiring twice as likely anticholinergics treatment than the patient without DO. No specific distinction was given to incontinence. [258]

On the other hand, Kleinhans et al concluded (44 patients) that preoperative DO did not correlate to any of the post surgical incontinence eight months after radical prostatectomy. [259]

In 1999, Golomb et al also concluded that there was no significant association between pre-operative DO and post-operative incontinence. [181]

Urodynamics may also be useful for selecting candidates for new, emerging treatments. For example, Vandoninck et al. [260] used urodynamics to evaluate patients with OAB symptoms who were to be treated with percutaneous tibial nerve stimulation. Overall, the objective and subjective success rates of stimulation were 56% and 64%.

The treatment abolished DO only in a few cases and subjects without DO at baseline were 1.7 times more likely to preferably respond to percutaneous tibial nerve stimulation than those with DO.

a) Recommendations for urodynamic investigation in those with LUTS with incontinence related to bladder dysfunction mainly detrusor overactivity and bladder outlet obstruction

Patients with symptoms suggestive of non-complicated bladder outflow obstruction (BOO) on the basis of prostate enlargement without incontinence, need prostate size assessment, urinary flow study, PVR measurements, (International Prostate) Symptom Score and 24 hour frequency-volume charts prior to intervention, but do not always need to be investigated with invasive urodynamic study. [261-263]

Men with incontinence and a suspicion of other LUT dysfunction form a much more restricted group with complicated, disparate, and uncertain diagnoses. In some the incontinence may be an initial symptom; in others it may follow treatment (see the following section on post-prostatectomy incontinence).

Recommendation (Grade C)

- Evidence that urodynamics improves outcome is limited, but nevertheless the committee recommends that all such patients should receive a complete urodynamic evaluation in order to understand the problem that is to be treated and that surgeons should plan surgical interventions only after scrutinising the lower urinary tract by urodynamics.

3. POST-PROSTATECTOMY INCONTINENCE

a) General

After prostatectomy a noticeable number of patients suffer from urinary incontinence. The reported incidence following surgery varies widely depending on patient age, bladder function, definition or degree of urinary incontinence, benign or malignant prostatic disease and the type of surgery. Approximately 10-14% of patients, 2-5 years after radical prostatectomy complain of incontinence. [264] A prospective survey study on 1201 patients and 625 partners on outcome after treatment for prostate cancer showed that urinary incontinence was at its worst by 2 months after surgery and then improved in most patients. Factors that were associated with worse incontinence were an older age, black race, and a high PSA score at diagnosis. Patients in the brachytherapy group reported significant deterioration in 'urinary irritation' or obstruction and incontinence as compared with baseline ($p<0.001$). Incontinence after brachytherapy was reported by 4 to 6% of patients at 1 to 2 years after treatment. [265]

Understanding of prostato-vesical anatomy and the pelvic floor, and meticulous surgical technique, are of prime importance in preventing these distressing symptoms. Urodynamic studies can establish the aetiology and provide a rational basis for treatment by determination of the type of LUT dysfunction(s).

Kondo et al [251] have analysed the aetiology of urinary incontinence following surgery for 'benign prostatic hyperplasia (BPH)' or prostatic cancer using accumulated data from 573 patients reported in 8 articles from 1978 to 1997. Urodynamic studies suggested that the most common aetiology was sphincter weakness (causing USI), present in 34% of patients, followed by sphincter weakness plus DO in 33%, and DOI alone in 26%. Other aetiologies including low compliance and urethral stricture were responsible for the remaining 7% of patients with incontinence after surgery for BPH. *Thus, although sphincter weakness was present in two-thirds of patients, a blanket assumption that it is the only cause of incontinence would be wrong in two-thirds. Clearly urodynamic testing is needed for diagnosis, and perhaps to choose treatment.*

b) TURP, Open Prostatectomy and Thermal Treatments

Approximately 1% of patients who have undergone TURP suffer from post-prostatectomy incontinence.[266] Is urodynamics required prior to treatment? Das et al. [263] performed holmium laser resection of the prostate in 100 men patients for management of LUTS without performing any urodynamic studies except for a urinary flow rate. Their follow-up study 2 years later revealed that persistent incontinence remained in only 1, who required pads, and that the IPSS and maximum flow rates improved from 21.6 to 6.8 points and from 7.5 to 21.6 mL/s, respectively. This report does suggest that if patients are appropriately selected, post-operative urinary control is quite satisfactory, leaving only about 1% of cases with urinary incontinence. This implies that the role of urodynamic investigation in preventing post-operative incontinence before laser resection of the prostate may be marginal.

Kuo [267] urodynamically evaluated 185 men aged from 55 to 91 with a mean of 75 years who had had variable LUTS after TURP and had been refractory to conventional treatments. He found that urinary incontinence was present in 74 patients (40%) and that BOO and DO with impaired contractility (DHIC) were the most common findings associated with post-prostatectomy incontinence, followed by DO. Since these diagnoses imply quite different treatments, urodynamic investigation has an important role.

Conclusions (evidence level 3)

- Retrospective studies have shown that urodynamic tests cannot predict stress urinary incontinence or detrusor overactivity (with or without incontinence) after surgical treatment for benign prostatic obstruction.
- Studies have shown that urodynamic tests *clearly identify the aetiology* of urinary tract dysfunction after surgical treatment for benign prostatic obstruction however the predictive value towards the effects of subsequent treatment is unknown.

Recommendations (Grade C)

- The committee recommends urodynamic testing when patients have signs and/or symptoms of lower urinary tract dysfunction after surgical treatment for benign prostatic obstruction; particularly if further surgical or invasive treatment is planned.

c) Radical Prostatectomy and Radiotherapy

i) Is (invasive) urodynamic investigation of incontinence after radical prostatectomy necessary?

Radical retropubic prostatectomy for prostatic cancer results in much higher incidence of post-prostatectomy incontinence than TURP. In physician-reported studies, the incidence of total incontinence is a few percent and the incidence of SUI requiring some degree of protection is about 10%.[268] In studies based on patient self-report, however, the incidence of any degree of incontinence is 66% and the incidence of pad use is 33%.[269] One of the main determinants of prevalence is the time following surgery, since continence is regained after radical prostatectomy over the first year in many patients.[270] Continence after radical prostatectomy depends on minimizing the injury to the striated urethral sphincter and the use of well-designed surgical techniques. [271] Patients who undergo a nerve-sparing radical prostatectomy appear to have a better chance of achieving continence than those undergoing standard radical prostatectomy. [272] Recent enhancements to the nerve-sparing prostatectomy may preserve external sphincter function and shorten the time to achieve post-operative continence. [272]

Castille et al prospectively assessed 229 men who were scheduled to undergo radical retropubic prostatectomy with preoperative urodynamics in an attempt to help physiotherapists predict postoperative incontinence. [273] They observed that all men diagnosed as having DO or BOO were incontinent 6 weeks after operation but had improved 4 months later. They stressed that DO and BOO in those undergoing radical retropubic prostatectomy are significant risk factors for postoperative incontinence, although only for a short period of time. Thus the role of pre-operative urodynamics is limited.

Groutz et al [274] evaluated 83 men of mean age 68 years, who were consecutively referred for persistent urinary incontinence following radical retropubic prostatectomy. They reported that USI was the most common urodynamic finding (73 patients, 88%), followed by DO in 6, BOO in 1, impaired detrusor contractility in 1, and normal findings in 2. Of 73 men diagnosed as having USI, 27 suffered from pure urodynamic USI, and the remaining 46 had concomitant bladder disorders such as impaired detrusor contractility (22 men), BOO (14 men) or DO (10 men). The authors reported that 25 of the 83 men had what they called “low urethral compliance”. This non-standard term expressed the fact that there was a difference of more than 10 mL/s between maximum free uroflow and maximum invasive (pressure-flow) uroflow. This term is not recommended, however, as it implies a cause for these observations that may not be correct.

Huckabay et al suggested a urodynamic protocol with video-urodynamics for patients with persistent incontinence after radical prostatectomy. They evaluated 60 men and found that twenty-four (40%) men had DO with 8 (13%) also having DOI. Only one patient had impaired bladder compliance. All men had USI, but 21 (35%) men demonstrated it only after removal of the urethral catheter. For men leaking with and without the urethral catheter, the respective abdominal leak point pressure (ALPP) was significantly different, 86.3 and 67 cmH_2O, respectively ($p = 0.002$). The men who leaked only in the absence of the urethral catheter had significantly higher ALPP measurements, $p < 0.001$. After reclassification using the fluoroscopic images of the bladder outlet and free Qmax, only 13.3% patients were obstructed. [275]

McCallum et al [276] reported that 21 of 180 men who had been treated for incontinence following radical prostatectomy still remained incontinent 2 years later. Sixteen of the 21 were evaluated, and half had USI together with UUI or decreased bladder compliance. The authors emphasised that SUI was one of the predominant symptoms but that co-morbid detrusor dysfunction had to be taken into consideration, as well as ISD, in order to properly treat persistent post-prostatectomy incontinence.

There was a very interesting study reported by Noguchi et al in 2006.[277] They evaluated a standard versus modification technique of radical prostatectomy in which the anterior attachment of the puboprostatic ligament to the pubic bone is preserved, to which the newly created vesico-urethral anastomosis is suspended. Three months after surgery ALPP, functional urethral length (FUL) and maximal urethral pressure were measured. The “suspension” group had a significant better continence rate and significantly higher ALPP.

On the other hand Twiss et al. based on study 29 men with incontinence after radical prostatectomy, concluded that ALPP is a relatively poor predictor of incontinence severity and, therefore, has limited clinical value in the urodynamic evaluation of post-prostatectomy incontinence. [278]

i) Is (invasive) urodynamic investigation of incontinence after radiotherapy necessary?

There are few manuscripts reporting the effects of radiotherapy in those with prostatic cancer, and even fewer discussing the place of urodynamics.[279, 280]

Henderson et al. [281] assessed the clinical role of urodynamics in the selection of prostate cancer patients for brachytherapy with a minimum dose of 145 Gy. One hundred consecutive patients were assessed after implantation. Prior to the treatment an unselected group of 57 of the 100 patients had been evaluated urodynamically: normal detrusor function (no DO) was found in 48 and DO in 9. No patients had

permanent urinary incontinence and 2 required surgery for BOO. Acute urinary retention developed in 7 patients, clean intermittent catheterisation was utilised by 27, and 89% of patients had a deterioration in their LUTS with the worst symptoms 6 weeks after implantation. They found that those who post-operatively had acute retention or preferred to utilise clean intermittent catheterisation had either larger prostatic volumes (> 35 mL) or were urodynamically obstructed. Consequently they concluded that urodynamics might have an important role in the selection of treatment for men with early prostate cancer, in particular to improve the outcome of brachytherapy.

In another study Beekman et al found in 204 patients that high PVR (> 100 mL) is associated with slower resolution of voiding symptoms, prolonged (more than 3 days) catheter dependency, and increased postbrachytherapy surgical intervention for BOO. [282]

Also Wehle et al suggested that the combination of urinary flow rate, prostate volume, postvoid residual urinary volume, and the American Urological Association symptom score can help identify patients with underlying voiding dysfunction. Urinary flow rate was a statistically significant predictor of genitourinary tract morbidity after brachytherapy for localised prostate adenocarcinoma. [283]

Overall there is a weak evidence to support urodynamic evaluation before radiotherapy for cancer of the prostate

iii) Artificial urinary sphincter and male sling

Gomha and Boone [284] treated 86 patients who were incontinent following prostatectomy with implantation of an artificial urinary sphincter (AUS) and assessed whether or not prior radiation affected surgical outcomes in those who had or had not had radiotherapy. The aetiology of the urinary incontinence in group I (without radiation) was radical prostatectomy in 55 patients, TURP in 2, orthotopic ileal reservoir in 1; in group II (with radiation) the aetiology was radiation with salvage prostatectomy in 5, adjuvant radiotherapy after radical prostatectomy in 20, and radiotherapy and TURP in 3. Urodynamic study prior to artificial sphincter implantation revealed that DO was much more prevalent in group II (radiation, 26%) than in group I (no radiation, 5%), a significant difference ($p = 0.04$). In spite of this, post-operative urgency with or without urgency incontinence was found in similar proportions of the 2 groups (47% of group I and 43% of group II), and similar proportions wore 0 to 1 pad a day to protect against their incontinence (60% and 64% respectively). Thus pre-operative urodynamics did not predict outcome.

Similarly, Thiel and co workers concluded that patients with incontinence post RP and DO, low compliance, decreased MCC and FSF have the same outcome after AUS implantation. [285] This was a retrospective review of 86 patients. Obviously, there could have been a selection bias in the study and the more severe cases could have been excluded from surgery.

However Ullrich & Comiter evaluated urodynamically 22 patients at a mean of 25 months after a male sling procedure and found that patients with postoperative retrograde leak point pressure < 50 cm H_2O and DO are associated with increased pad use and bother. [286]

d) Recommendations for urodynamics in those having post-prostatectomy incontinence

Sphincter weakness, BOO, DO and mixed incontinence are significant aetiological factors contributing to post-prostatectomy incontinence.[251, 267, 276] These parameters can be only identified by urodynamics, which is considered by most,[284, 287, 288] but not all, [289] to be one of the main tools for investigating this type of incontinence. In brachytherapy for prostate cancer, urodynamics may have some value for predicting which men might develop acute urinary retention or might require intermittent catheterisation after treatment.[281]

Conclusions (evidence level 3)

- Retrospective studies have shown that urodynamic tests cannot predict lower urinary tract dysfunction after surgical treatment for prostatic carcinoma.
- There is weak evidence to support urodynamic evaluation before radiotherapy for cancer of the prostate
- Studies have shown that urodynamic tests clearly identify the aetiology of urinary tract dysfunction after surgical or radiotherapeutic treatment of prostatic carcinoma however the predictive value towards effect of subsequent treatment is unknown.

Recommendations (grade C)

- The committee recommends urodynamic evaluation before radiotherapy for cancer of the prostate.
- The committee recommends urodynamic testing when patients have signs and/or symptoms of lower urinary tract dysfunction after treatment of prostatic carcinoma; particularly if surgical or invasive treatment is planned

Topics for research

- The committee suggests research to find predictors for lower urinary tract dysfunction after treatment for benign prostatic obstruction or for prostatic carcinoma.
- The committee suggests research to improve

prediction of success (whether or not on the basis of urodynamic testing) of treatment for lower urinary tract problems following on to treatment of benign prostatic obstruction or prostatic carcinoma.

4. NOCTURNAL ENURESIS AND PARKINSON'S DISEASE RELATED TO MALE INCONTINENCE

Several ailments or pathological conditions have been reported to be closely associated with male incontinence, e.g., neurological diseases, prior radiotherapy, neurogenic DO, diminished bladder compliance, nocturnal enuresis, post-micturition dribble and terminal dribbling.[251]

a) Nocturnal enuresis

Nocturnal enuresis in adult males is rather rare. Sakamoto and Blaivas reported important and interesting observations based on data of over 3000 patients referred for the evaluation of LUTS.[288] They found that 8 of 3277 patients (0.02%) had adult onset nocturnal enuresis without daytime enuresis. All these patients were male, with a mean age of 63 years (48 to 80 years) and all suffered from BOO with mean maximum urinary flow rate 8.5 mL/s, mean IPSS 12.6, and mean PVR urine 350 ml (50 to 489 ml). The authors identified hydronephrosis in 5 of the 8 patients, a bladder diverticulum in 3/8, VUR in 4/8 and low bladder compliance in 4/8. Five of the 8 underwent TURP resulting in improved symptoms. Thus BOO is one of the distinct pathologies that can provoke nocturnal enuresis with variable LUTS, but it is not the only pathological factor. For example, Hunsballe [290] found more delta activity in electroencephalography among adult primary enuretics compared to normal controls. Therefore, invasive urodynamics may be justified in such patients, because it is the only way of reliably identifying BOO.

Another factor contributing to nocturnal enuresis is the presence of a neobladder. Nocturnal enuresis plagues nearly 28% of such patients. Indeed, 25 of 30 patients (83%) who underwent the Stanford pouch ileal neobladder had nocturnal enuresis 1 year later.[291] Patients older than 65 years are at greater risk because of the physiological increase in LUTD nocturnal diuresis associated with aging. An orthotopic neobladder produces variable LUTD including both failure to empty the bladder and failure to store urine. The urodynamic behavior depends on the type, length, and configuration of the bowel segment used.[292] There may be overdistension, elevated PVR, lack of sensation, reduced MUCP, or more frequent and higher-pressure DO. [293] The intestinal overactivity in a neobladder resembles bowel peristalsis. [294]

el-Bahnasawy et al studied urodynamically 50 enuretic men at least 1 year after a radical cystoprostatectomy and ileal neobladder and compared them to 17 men with only occasional enuresis and 50 men without enuresis after similar surgery. Both enuretic groups had significantly higher residual urine volumes, pressure at mid-capacity and at maximum enterocystometric capacity, amplitude of involuntary contractions, and lower compliance than continent men. Men with occasional enuresis also had a significantly higher frequency and duration of involuntary contractions than continent men. Men with persistent enuresis had significantly lower average and maximum urinary flow rates than continent men, and significantly lower functional urethral length and maximum urethral pressure. [295]

Urodynamic investigation is important to establish the diagnosis and select treatment, although one group suggested that bed wetting could be simply alleviated by waking up at least twice per night to void.[291]

Stroke is a common and well-known cause of enuresis and LUTD in the older population. The predominant symptoms are urinary frequency, urgency and UUI (including night-time incontinence) while DO is the most common finding on urodynamics. [296] In patients after a stroke, incontinence (or LUTD in general) is a serious threat for quality of life. [297] Because DO in patients with LUTD is so prevalent, conservative or pharmacologic treatment is often instituted without prior urodynamic investigation, even though the size and the site of the stroke do have an influence on urological findings.[298] Simple tests such as uroflowmetry and, especially, PVR urine assessment (by ultrasound) are however useful since elevated residual urine is to be expected in a significant amount of these patients and its evaluation can improve care-giving and quality of life. [299, 300] Cystometry has limited value: the prevalence of DO in older people is quite high even in the absence of stroke (perhaps 10% in women and 25 to 35% in men). Therefore the observation of DO alone is not definitive, while the observation of DOI merely confirms what one would suspect in any case.

b) Parkinson's disease

Parkinsonian diseases are known to significantly influence bladder function (see section D.V.6). LUTS may be the first sign, especially nocturia in male patients. Large capacity bladder (when discovered during urodynamic testing for LUTS) may also be a sign of Parkinsonism. [301-304]

DOI is common in patients with Parkinsonism,[158] but urodynamic findings differ in different diseases of this group.[305] In multiple system atrophy for example – as opposed to Parkinson's disease – PVR urine volume >100mL, detrusor-sphincter dyssynergia, or EMG evidence of internal or striated sphincter denervation are common. Such findings, especially (large) residual urine, may influence the choice of treatment. If there is residual urine, invasive pressure-flow studies may be indicated, particularly to diagnose

or rule out BOO and or to confirm detrusor underactivity or dyssynergy.

Defreitas et al carried out a retrospective review of the urodynamic results in men with DO due to BOO (22 patients) and compared them to men (39 patients) and women (18 patients) with Parkinson's disease. Patients with Parkinson's disease had a significantly lower median volume at first detrusor contraction than those with non-neurogenic DO. The percentage of urgency incontinence was significantly lower in patient without Parkinson's disease than in men and women with it (9.1% vs 53.8% and 55.6%). No statistically significant correlation between the duration or severity of Parkinson's disease and UDS parameters was found. [158]

c) Recommendations for urodynamic investigation for men suffering from nocturnal enuresis or Parkinson's disease

Conclusions (level of evidence 2/3)

- Nocturnal enuresis in adult males is rare but problematic, and it is associated with many possible aetiologies.
- Nocturia, nocturnal enuresis or lower urinary tract symptoms may be a first or an early sign of Parkinsonism in elderly male patients.
- Lower urinary tract dysfunction in patients with Parkinsonism can be the result of detrusor overactivity, (benign prostatic) bladder outlet obstruction, dyssynergic voiding or post void residual urine or any combination thereof.

Recommendations (grade B/C)

- The committee recommends that urodynamic evaluation should be conducted in all cases of nocturnal enuresis in adult males
- The committee recommends that urodynamic evaluation should be performed in patients with Parkinsonism. There should be flowmetry and postvoid residual assessment in all cases and invasive testing when abnormalities are observed in flowmetry and postvoid residual assessment.
- The committee suggests that investigators should be alert for large capacity bladder and/or detrusor underactivity (or large residual without significant bladder outlet obstruction) because it is a first or early sign of Parkinsonism.

5. POST-MICTURITION OR TERMINAL DRIBBLING

There are no recent manuscripts on post-micturition dribble or terminal dribbling involving urodynamics.

In 1996, Reynard et al determined the prevalence of the symptom of terminal dribbling from a symptom questionnaire completed by 165 men presenting with LUTS. Objective evidence of terminal dribbling during voiding was assessed from uroflow recordings and prostate volume was measured by transrectal ultrasonography. Combined pressure-flow studies were performed to determine the presence or absence of BOO. They found that there was relatively poor agreement between the symptom of terminal dribbling and objective evidence of its presence; 48% of the patients who reported terminal dribbling most or all of the time showed no objective evidence of terminal dribbling on uroflowmetry.

The symptom of terminal dribbling was not significantly related to the presence of BOO ($p = 0.74$). However, objective evidence of terminal dribbling on uroflow traces was significantly related to BOO ($p < 0.001$) and those patients with objective evidence of terminal dribbling had higher values of URA (median 39 compared with 28 cmH_2O). Objective terminal dribbling had a specificity of 92% and positive predictive value of 88% for the presence of BOO. Neither the symptom of terminal dribbling nor objective evidence of its presence were significantly related to prostatic enlargement. The authors concluded that while the symptom of terminal dribbling is probably not related to BOO or prostatic enlar-gement, objective evidence of terminal dribbling on flow curve recording is fairly specific for BOO and as such, its presence could potentially be of value in the assessment of men with LUTS. [306]

Recommendation (grade C)

- When a complaint of terminal dribbling is objectively identified in the urinary flow curve, urodynamic studies may be indicated to verify or rule out the presence of bladder outlet obstruction or urethral pathology.

III. NEUROGENIC LOWER URINARY TRACT DYSFUNCTION

1. INTRODUCTION

Neurogenic incontinence may express itself as UUI, 'reflex incontinence', 'overflow incontinence' or SUI. UUI and SUI have already been reviewed in this present chapter. 'Reflex' and 'overflow incontinence' are terms not currently recommended by the International Continence Society but they will be discussed below, together with other relevant topics for this group of patients which are not covered elsewhere in this chapter.

2. WHAT IS USUALLY EVALUATED?

Because not all patients with neurogenic conditions develop typical urinary symptoms or urodynamic findings, a specific understanding of the dysfunction in each individual is an absolute prerequisite for the correct choice of therapy. [307-309] The aim is to describe the (dys)function of the bladder, the urethra and the pelvic floor, their coordination during filling and voiding, and their influence on other pathological conditions (e.g. autonomic dysreflexia) or organ systems (e.g. renal function). Except in a few diseases where empirical, conservative therapy can safely be instituted, or where LUT dysfunction is predictable (e.g. post-stroke), urodynamic investigation is required to provide the understanding of the situation on which rational treatment must be based. Even when empirical therapy is instituted without urodynamics, the progress of the patient must be carefully reviewed to determine whether urodynamics is needed after all.

Because many patients with neurological conditions show anatomical abnormalities that involve the LUT, or detrusor-sphincter dyssynergia (lack of coordination) that can be demonstrated easily by imaging, comprehensive videourodynamics is the test of choice. [307-311]

3. SPECIAL TESTS

The ***ice water (bladder cooling) test*** is sometimes used in an attempt to identify neurogenic DO (see section C.V.1.e: provocative manoeuvres).

The ***carbachol test*** is intended to reveal supersensitivity to muscarinic agents following neurological decentralization, typically in bladders in which a voiding reflex cannot be demonstrated.[312] A subcutaneous injection of a muscarinic agonist (0.25 mg carbachol or bethanechol) is given and the detrusor pressure is monitored for 30 min or until it rises to over 20 cm H_2O. The test is considered positive if the detrusor pressure increases above 20 cm H_2O.[313] Results published more than 20 years ago report detrusor decentralisation in a variable proportion of patients with a positive carbachol test (from as few as 50% up to as many as 98%).[312, 314, 315] Thus in some hands (though not in all) it does not have a very good diagnostic performance and as a result it has fallen out of favour. An attempt to use it to help predict the results of sacral neuromodulation proved unsuccessful.[316]

4. NEUROGENIC DETRUSOR OVERACTIVITY INCONTINENCE ('REFLEX INCONTINENCE')

DO of neurogenic origin is frequently observation in association with neurological disease, and often leads to actual leakage, i.e. incontinence. Observed on urodynamics, this type of incontinence should be termed *neurogenic DOI*. The corresponding symptom is variable: if the DO is accompanied by sensation (desire to void) it might be termed UUI; frequently however any sensation is absent and so the term *urgency incontinence* is misleading. For this reason the term '*reflex incontinence'* was introduced,[4] implying automatic filling and emptying of the bladder without sensation or control. This term is no longer recommended.[5]

5. DETRUSOR-SPHINCTER DYSSYNERGIA

Neurogenic DO is often accompanied by detrusor-sphincter dyssynergia: a neurogenically determined failure of coordination of detrusor and urethra. The failure of the urethral sphincter to relax, when the detrusor contracts, causes a functional urethral obstruction which may not only hinder bladder emptying, but may also permit the development of high detrusor pressures. If high pressures are present for prolonged periods in daily life, renal function may be endangered (see the following subsection on "overflow incontinence").

6. 'OVERFLOW INCONTINENCE'

'Overflow incontinence' is another term that is no longer recommended.[4] It means continual leakage from a constantly overdistended bladder.[4] The presenting symptom is usually characterised by continual small amounts of incontinence, exacerbated by increased abdominal pressure, together with an inability to empty the bladder by voiding.

On urodynamics the usual corresponding observation is a bladder with low compliance and little or no detrusor activity; as the bladder is filled the detrusor pressure rises because of the poor compliance, until it reaches a value sufficient to open the urethral sphincter. Dribbling leakage then ensues. Clinically, the most important variable is believed to be the detrusor pressure at which leakage occurs, the detrusor leak point pressure (DLPP). If this pressure is elevated, and if similar pressures are attained during continual leakage in daily life, then renal function is endangered because the constantly high detrusor pressure hinders outflow from the ureters. Conventionally, DLPPs of 40 cm H_2O or more are believed to be unacceptable. There is evidence (mostly from pediatric studies) that upper urinary-tract deterioration is more probable when DLPP is elevated. [317-319] However, the evidence for a cut-off at 40 cm H_2O seems less clear.

7. REPRODUCIBILITY AND RELIABILITY OF TESTS

Since many patients with neurogenic dysfunction of the LUT have severe subpontine neuropathy, the influence of the emotional (limbic) nervous system on lower-tract function is reduced or eliminated; thus, urodynamic observations may be less variable and more reliable than those made in individuals with an intact nervous system. Nevertheless, the test

conditions (e.g. the rate of filling the bladder) do influence the results, and should be chosen carefully.[2]

8. DOES URODYNAMIC TESTING IMPROVE CLINICAL OUTCOME?

The aims of therapy for neurogenic lower urinary tract dysfunction are to achieve the most nearly physiological filling and voiding conditions [307-309] as well as a management situation acceptable to the patient in daily life. Long periods of elevated detrusor pressure during bladder filling or (abnormally prolonged) voiding put the upper urinary tract at risk [317-319] (Level of evidence 3). The primary aim of therapy in patients with such problems is conversion to a low pressure bladder during filling,[307, 309] even if this leads to incomplete emptying. Adequate therapy depends on whether the detrusor is overactive or has reduced compliance, and only urodynamics can answer those questions unequivocally. Timely and adequate diagnosis is of paramount importance for the patient's quality of life.[308, 309, 320, 321] Urodynamic investigation is essential for checking the efficacy of treatment and in following up any sequelae of the disease and its management. Kabay et al [322] used urodynamics to evaluate acute Posterior Tibial Nerve Stimulation in patients with MS. Stimulation improved volume at the first involuntary detrusor contraction and MCC. It remains however unclear if this translates to clinical improvement

Conclusions (evidence level 3)

- Urodynamic testing improves clinical outcome in patients with continually elevated detrusor pressures.
- In many other types of neurogenic dysfunction rational treatment is impossible without the knowledge that invasive urodynamic testing provides.

Recommendations (grade B/C)

- The committee recommends that patients with suspected neurogenic dysfunction of the LUT should receive comprehensive urodynamic evaluation, including videourodynamics if possible, to establish the state and function of the lower tract
- The committee recommends that anorectal function should be evaluated in addition to urinary function (see section F on Anorectal physiology studies)
- The committee recommends that urodynamic testing in this group of patients should be done in specialised centres by trained and certified personnel

Recommendations for research:

1. Comprehensive urodynamic testing should form an essential part of the evaluation of new therapies such as botulinum toxin injection or intravesical instillation of capsaicin analogs.
2. New types of urodynamic study need to be developed to delineate more precisely the types of neurogenic dysfunction that arise from supraspinal abnormalities of the lower urinary-tract control system, which up to the present have been neglected.

IV. PATIENT EVALUATION: CHILDREN

1. INTRODUCTION

The indications for urodynamic evaluation in children in this section have been set out on neurological, anatomical and functional lines, with the types of studies to be performed being based on the underlying pathological conditions rather than on the presenting symptoms. The findings, efficacy and reliability of urodynamic studies for each of these conditions will be discussed.

Many of the conditions for which urodynamics is employed in children involve anatomical and neurological abnormalities, in which LUT dysfunction is variable, complicated, and unpredictable. Urodynamic testing is used to establish as clearly as possible the baseline situation, so that changes as a result of treatment and/or growth can be assessed, and some guidance is obtained in the choice of treatment (although the result of urodynamic testing may not necessarily be the deciding factor). Here, therefore, perhaps more clearly than in any other patient group, the aim of urodynamic studies is surely to provide objective knowledge about LUT function and dysfunction as well as to provide understanding to the care-giver and to the patient (and her or his parents).

Of course, it is still important that the tests used should be relevant, reliable and reproducible in the patient population considered, and the evidence for this will be discussed in the following paragraphs

2. NEUROGENIC BLADDER DYSFUNCTION

a) Myelodysplasia

For the last 20 years initial urodynamic studies very early in the neonatal period have been recommended for children with myelodysplasia, the basis being that they help identify children at risk for subsequent urinary tract deterioration or a changing neurological picture.[323]. DO on cystometry, detrusor underactivity during voiding, detrusor-sphincter dyssynergia (usually established on the basis of surface EMG), DLPP, and

PVR are the key elements of a detailed urodynamic study that need to be considered.[324, 325]

In an exhaustive review of the efficacy and reliability of urodynamic studies in newborns with myelodysplasia [326], of 24 studies analysed, 13 focused on EMG activity of the striated urethral sphincter or pelvic floor, 7 on bladder compliance and 2 on cystometric technique. Twenty-one studies were at level of evidence 4, 2 were at level 3 and 1 was at level 1. Nine of the 24 studies were performed at international sites and the remainder within the United States. The urodynamic patterns of normal detrusor function (66%), acontractile detrusor (33%), DO (57%), and detrusor compliance, as well as detrusor-sphincter synergia (21%), dyssynergia (37%) and sphincter denervation (60%) were similar, with little variability across comparable studies.

van Meel et al have shown that repeating the Ice Water Test (IWT) will increase its positivity. Combining the IWT and electrical perception threshold (EPT) will reinforce the results of both tests and can indicate more clearly the possibility of an unsuspected neurological cause of the dysfunction in children with idiopathic DO. The IWT was positive in 46% patients with relevant neurological abnormalities if used once, this percentage became 86% when the IWT was repeated. In patients without neurological abnormalities, one IWT was positive in only 7% and when repeated, the positive test rate increased to 24%. The EPTs were not significantly different between the neurologic and nonneurologic patients with a positive IWT, except after the third instillation. In those with negative IWTs, the EPTs were significantly different between the neurologic and nonneurologic patients, independent of the number of IWTs done. [327]

Bladder capacity was studied in a group of 506 myelodysplastic children [328] and found to conform to the formula: capacity in mL = 24.5 x (age in years) + 62. This formula for the increase in bladder size with age is 20% less steep than published age-related bladder capacities in neurologically normal children [329, 330] (e.g. 30 x age + 30). However, those children who did not have DO had a bladder capacity similar to normals. Because neurological impairment affects detrusor compliance, cystometric filling rates also influence measured capacity and compliance as noted in 3 studies that addressed this issue.[328, 331, 332]. The lower the filling rate the greater the compliance and the larger the capacity.

Bladder augmentation alone without simultaneous antireflux repair is usually sufficient for the resolution of pre-existing vesico-ureteral reflux (VUR) in children with neurogenic dysfunction. A retrospective study by Juhasz et al in 2008 suggested that the various GI segments used for augmentation have no effect on the urodynamic results and the resolution of VUR. [333]

On the basis of a retrospective review of single centre data, that also included results from other centres and multicentre studies, intravesical electrotherapy was considered effective in improving bladder capacity without deterioration of compliance and without 'new onset' DO. Of the 372 patients 77% had a 20% or greater increase in bladder capacity after treatment. In this subset of patients, bladder storage pressure at capacity was below the 'critical level' of 40 cm H_2O in 75%. Of the 17% of patients who had no change in bladder capacity 81% had normal bladder storage pressures after treatment. Bladder sensation developed and was sustained in 62% of patients. [334].

Rendeli et al retrospectively assessed the usefulness of urodynamic testing to determine the optimal timing of neurosurgery and to evaluate the evolution of bladder function in children with lipomeningocele. All patients underwent urodynamic testing preoperatively and during extended followup (mean 6.5 years, range 3 to 12). Bladder capacity and mean DLPP improved in all groups but particularly in children who had had neurosurgical treatment within the first year of life. At the end of the study mean bladder capacity was 420 cc in patients operated before the age of 12 months, 300 cc in those operated between 2 to 36 months old and 260 cc in those who were older than 36 months at the time of surgery ($p < 0.01$). Mean DLPP was 37, 54 and 55 cm H_2O in these groups respectively ($p < 0.01$). At the latest followup, 65% of patients in the youngest group had improved urodynamic parameters compared to 33% of those 12 to 36 months old and 28% of those older than 36 months. Urodynamic evaluation and the presence of neurological impairment were considered to have had crucial roles in determining the optimal timing of surgery in patients with lipomeningocele, and in diagnosing the onset of tethered cord. [335]

Six studies evaluated the relationship between level of the neurological lesion (on clinical examination) and LUT function but none could predict a specific urodynamic pattern based on the level of the lesion. Sacral level lesions can be associated with an upper motor neuron urinary tract 'urodynamic pattern' just as readily as the expected lower motor neuron findings.[336] Similar findings have been noted for children with thoracic or high lumbar level lesions where the incidence of sacral reflex sparing is 54%.[337]

Approximately 90% of children born with spina bifida will have a normal upper urinary tract at birth. Over time many children who have not received proactive urological care develop upper and/or LUT deterioration. The deterioration is an acquired phenomenon secondary to the development or progression of various LUT hostility factors such as neurogenic DO, poor bladder compliance, detrusor-sphincter dyssynergia and/or high LPP from denervation fibrosis.

[323-325, 338] Despite the fact that only one study was at level 1, all urodynamic studies corroborated their reliability by reporting that the prediction of upper urinary tract deterioration on the basis of urodynamic testing is possible with 90% accuracy.

In 2006, Wang et al calculated a urodynamic risk score including a DLPP of >40 cmH_2O, a bladder compliance of <9 mL/cmH_2O and evidence of acontractile detrusor. They postulated that the selective use of urodynamic variables might be valuable for predicting the risk of upper urinary tract dilatation in children with neurogenic bladder-sphincter dysfunction. They found that decreased bladder compliance, increased DLPP and acontractile detrusor are the main urodynamic risk factors, and they reciprocally increase the occurrence and grades of upper urinary tract dilatation. The grades of renal dilatation are compatible with increases in relative unsafe cystometric capacity and the calculated urodynamic risk score [338] Severe bladder trabeculation in incontinent children with neurogenic LUT dysfunction is reported to be associated with bladder outlet obstruction. [339]

Not all authors consider that prophylactic (high pressure prevention) treatment is beneficial, but all recommend periodic cystometry when new onset hydronephrosis, VUR or urinary incontinence develops, the latter in children on a continence program already (i.e. clean intermittent catheterisation and/or drug therapy).[340, 341] When new onset urinary incontinence not related to urinary infection nor easily treated by increasing current treatment regimens occurs, one study has shown that repetition of cystometry, urethral pressure profilometry, and EMG measurements, is helpful in management [342].

When incontinence develops in spite of strict adherence to bladder and bowel continence programs, or when changes occur in leg function or sensation, or when the child experiences back pain or increasing scoliosis, a change in neurological impairment might be expected. If striated urethral sphincter EMG is asssessed periodically during the first 3 to 6 years of life and then periodically throughout puberty, changes in pelvic floor or urethral sphincter innervation can indicate changes in neurological and LUT function. Bearing this in mind, 4 studies, noted that a considerable number of myelodysplastic children (40% to 61%) regardless of their neurological level have progressive neurological deficits as they grow up and reach puberty.[336, 343-345]. Two of these studies noted changes particularly early in infancy, while a third study noted changes throughout childhood. Thus, most clinicians agree that myelodysplasia is a dynamic disease process which changes as the child grows and that warrants constant vigilance of both the neurological picture and lower urinary tract function. Although its efficacy has not been proven, it is recommended that a cystometrogram/EMG be repeated 3 months following any neurosurgical intervention to correct a tethered cord, or spinal surgery to repair increasing scoliosis, for this provides a new baseline for comparison should further spinal cord tethering take place after corrective surgery.

In 2006, Schulte-Baukloh et al evaluated prospectively the efficacy and tolerability of propiverine for treating neurogenic DO in children. Twenty children with neurogenic DO due to an upper motor neurone lesion were enrolled (17 had myelomeningocele). In the urodynamic examination, the mean (SEM) volume at first detrusor activity increased from 103.8 (21.3) to 174.5 (33.7) mL ($p<0.005$) after 3-6 months of propiverine treatment, maximum detrusor pressure decreased from 52.5 (7.9) to 40.1 (6.2) cmH_2O ($p<0.05$), maximum cystometric bladder capacity increased from 166 (28.8) to 231.9 (34.8) mL ($p<0.005$), and bladder compliance improved from 11.2 (2.8) to 30.6 (9.7) mL/cmH_2O $p<0.01$). The incontinence score (scale 0-3) improved from 2.4 (0.2) to 1.6 (0.3) ($p<0.05$). [346]

Several studies that evaluated the urodynamic result of bladder augmentation have been published. Significant increase in bladder capacity and compliance were achieved and maintained in the long term. Median preoperative compliance was 1.6 mL/cm H_2O and an increase of 762.5% was observed during followup. [347]

Renal transplantation in patients with myelodysplasia is a challenging issue. LUT dysfunction carries increased risks for the grafted kidney. Careful diagnosis and surveillance of LUT function by urodynamic evaluation is essential to optimise these outcomes. Recent publications suggested that renal transplantation is a safe and effective treatment modality in patient with myelodysplasia. Videourodynamic tests were performed on all patients preoperatively as well as postoperatively. Augmentation cystoplasty was required in a proportion of children to achieve a low-pressure reservoir with adequate capacity.[348-350]

b) Occult spinal dysraphism

Several series characterising the preoperative urodynamic evaluation of children with occult spinal dysraphisms have documented abnormalities in striated urethral sphincter function (denervation and/or detrusor-sphincter dyssynergia) in 20 - 35% of babies under 2 years of age with normal neurological examinations; thus emphasising the need for urodynamic testing in these children.[351-356]. Six reports in older children revealed a greater correlation (70 – 90%) between an abnormal neurological examination and the likelihood of finding an abnormality on urodynamics. [351, 355-359] A few studies demonstrated that between 10% and 20% of patients experience a loss in function immediately postoperatively (most of whom had abnormal LUT

function preoperatively), and a variable number, usually inversely related to age, have improved sacral cord function on postoperative assessment 3 or more months after surgery. [351, 353, 357-359] Two studies, both retrospective, revealed an efficacious response in EMG activity, with stabilisation or improvement in up to 60%, on postoperative urodynamic assessment when the dysraphic state was corrected before 2 years of age.[351, 357] When children were first operated on after 2 years of age, 2 urodynamic reports documented an additional 25 to 35% with progressive changes in urethral sphincter function with axial growth, very few of whom had a detectable change on physical examination.[352, 357]

In a small prospective study in 2008, it was observed that children with open spina bifida, as compared to closed dysraphism, tended to have more bladder dysfunction as exemplified on clinical history and urodynamic assessment. Before neurosurgical closure of the defect, history indicated that the bladder was involved in 14 of the 25 children. Six of the 10 cases with an open spina bifida showed clinical involvement of the bladder as compared to 8 of 15 with a closed pattern. Urodynamic studies showed evidence of bladder dysfunction in 19 children. Of 10 with a meningomyelocele, there were abnormal urodynamics in 9 as compared to 10 of 15 with closed dysraphism. Follow up urodynamic studies showed improvement in 9 of 20 children 3 of 7 with a meningomyelocele and 6 of 13 with closed dysraphism. The authors concluded that a preoperative urodynamic study helps to identify severity of bladder dysfunction in clinically overt cases and also identifies subtle bladder dysfunction in clinically silent cases. Evaluation after operation tends to shows better outcome in children with closed dysraphism. The study also identifies deterioration in some patients with seeming clinical improvement. [356]

In 2007, Abrahamson et al studied the urodynamic findings in a consecutively treated population of children with myelomeningocele after untethering of the spinal cord. Severe bladder dysfunction was defined as detrusor pressure at MCC > 40 cm H_2O and/or amplitude of DO > 60 cm H_2O, moderate dysfunction as detrusor pressure at MCC in the range 20 - 40 cm H_2O and/or amplitude of DO in the range 20 - 60 cm H_2O, and mild dysfunction as detrusor pressure at MCC < 20 cm H_2O. After untethering, 35% of the patients experienced improved bladder function and 5% deteriorated. All of the patients who deteriorated before untethering improved afterward, and 90% of those who were stable preoperatively continued to be stable postoperatively. Therefore, regular evaluation of bladder function in children with myelomeningocele should be performed. [360]

Conclusions (evidence level 2/3)

- Retrospective and prospective studies have shown that the urodynamic diagnosis of DO and/or reduced detrusor compliance in patients with myelodysplasia or (occult) spinal dysraphism is not predictable on the basis of clinical signs or symptoms.
- Many retrospective and prospective studies have shown that urodynamic testing in patients (children) with meningomyelocele or (occult) spinal dysraphism reveals clinical relevant results with regard to detrusor storage function.
- On the basis of expert opinion, videourodynamic testing is preferable above urodynamic testing without video, however the exact advantage (eg in repeated investigation) is not substantiated.
- Various studies have shown that LUT function in children with myelodysplasia or (occult) spinal dysraphism may change over time (and physical growth)
- No studies have been published that are a help to determine the optimum of timing and frequency of urodynamic follow-up.

Recommendations (grade B/C)

- Comprehensive urodynamic testing is advised in all patients with myelodysplasia or (occult) spinal dysraphism.

Recommendations (grade C)

- Videourodynamic testing should be considered in children with myelodysplasia or (occult) spinal dysraphism.
- Timing and technique of urodynamic testing in patients with myelodysplasia or (occult) spinal dysraphism should be selected on an individual basis.
- To help identify children at risk for subsequent urinary tract deterioration or a changing neurological picture initial urodynamic studies very early in the neonatal period are recommended for children with myelodysplasia or (occult) spinal dysraphism.
- The committee recommends that anorectal function or dysfunction is simultaneously evaluated with urinary tract function in children with myelodysplasia or (occult) spinal dysraphism (see section F on faecal incontinence).

c) Sacral agenesis

Sacral agenesis, absence of the lowermost vertebral bony segments, is a lesion that can be missed in infancy because of its subtle clinical manifestations,

with generally no loss of lower extremity motor and sensory function, and the non-progressive nature of its pathophysiology.[361, 362] Urinary and/or faecal incontinence usually manifest themselves at an older age when the child fails to toilet train on time. A careful physical examination noting flattened buttocks and a short gluteal crease is pathognomonic for the diagnosis. In 8 reports that provided enough data, urodynamic studies had been 90% accurate in delineating the neurological deficit, which cannot be predicted by the level of absent vertebrae,[354, 363-369] and in managing the incontinence and/or upper urinary tract abnormalities (i.e., hydronephrosis, VUR). These studies reveal that between 30 and 40% of these patients have an upper motor neuron type lesion with DO and an intact but dyssynergic sphincter, while 25 to 50% have signs of a lower motor neuron deficit with acontractile detrusor and denervation in the sphincter, and 15 to 20% have normal LUT function.[361, 363, 364] Tethered cord occurs in children without sacral anomalies as well as in those with low anorectal malformation. Mosiello et al [370] recommend evaluation of all patients using MRI. When MRI shows sacral or spinal cord anomalies, UDS should be performed. They recommend a noninvasive evaluation for all other children and urodynamics when neurogenic dysfunction is suspected. It is presumed that the neurological deficit associated with this entity is fixed because no study showed any progression of the neurological disorder with increasing age.

Various studies have shown that a proportion of children with sacral agenesis have dysfunction of the LUT and that the proportion of patients is the highest in the patients with concomitant relevant neurological abnormalities.

Conclusion (evidence level 3)

- Case series have shown that evaluation of lower urinary tract function in children with (partial) sacral agenesis reveals a substantial incidence of dysfunction.
- There is a small, however unknown, proportion of children with lower urinary tract symptoms where (otherwise subclinical) sacral abnormalities were ultimately discovered to be the cause of the problems.

Recommendation (grade C)

- Clinicians should consider urodynamic testing in children with sacral agenesis when clinical signs of LUT dysfunction or relevant neurological abnormalities exist.
- Clinicians must be aware that in children with lower urinary tract dysfunction, otherwise clinically silent sacral abnormalities might also exist.

d) Spinal cord injury

The rarity and variability of spinal cord injuries in children makes it difficult to propose any one treatment program unless the specific type of LUT function is known. [49, 371-373]. Even if the individual regains the ability to void spontaneously and empty his/her bladder, it is imperative to know the detrusor filling and emptying pressures. Even if the child is continent on clean intermittent catheterisation, it is important to measure detrusor compliance in order to determine the potential risk for hydroureteronephrosis and VUR. [374] A poorly compliant bladder with or without elevated voiding pressures from detrusor-sphincter dyssynergia often leads to the development of hydroureteronephrosis and VUR; when combined with urinary tract infection progressive renal failure is often the result. [375] Four studies extol the need for urodynamic studies once spinal shock from the initial injury wears off, to determine the presence of low filling and voiding pressures and the ability for complete emptying, for the reasons cited above. [376-379] All studies are retrospective and use historical controls for comparison.

A thoracic or cervical level injury may produce an upper motor neuron deficit leading to DO, poor compliance, high voiding pressures and incomplete emptying over time, secondary to detrusor-sphincter dyssynergia. [380-382] In the presence of elevated filling and voiding pressures, there is a 30% incidence of upper urinary tract deterioration. [318] Balanced voiding with pressures below 40 cm H_2O in the absence of detrusor-sphincter dyssynergia ensures a stable upper urinary tract. [378]

Generao retrospectively studied 42 children with spinal cord injury. Patients were divided into 3 groups based on level of injury-cervical (10), thoracic (26) and lumbar (6). In the cervical group, safe bladder capacity was less than the expected capacity in 80% of patients but all patients undergoing multiple urodynamics had increasing capacity with time. In the thoracic group, 58% of patients had a safe bladder capacity less than expected and 76% of those undergoing multiple urodynamics had increasing capacity. In the lumbar group 50% of patients had a safe bladder capacity less than expected and 67% of those undergoing multiple urodynamics had increasing capacity. [373]

A cauda equina injury often leads to a lower motor neuron deficit of the striated sphincter that may not require any treatment whatsoever because the bladder empties readily at low pressure, but it probably necessitates medical and/or surgical therapy to achieve continence. Urodynamic studies are considered invaluable in describing LUT function and in efficaciously managing any dysfunction to maintain a healthy upper urinary tract and long-term survival with minimal morbidity. [375, 379, 383]

Urodynamic studies should be undertaken no earlier than 6 weeks after injury, to allow for the manifestation of the extent of the neurologic injury. [377]

Periodic reassessment of the bladder and sphincter function is appropriate up to 2 years after injury, due to the potential for change during that time

Conclusion (evidence level 2/3)

- Retrospective studies have shown that urodynamic testing of all children with spinal cord injury is relevant.
- Retrospective studies have shown that urodynamic testing of children with spinal cord injury results in diagnoses and treatment similar to adults with spinal cord injury.

Recommendations (grade C)

- The committee recommends that urodynamic testing in children with spinal cord injury is planned on an individual basis, but no earlier than 6 weeks after injury.

e) Cerebral palsy

Only a few published studies describe the urodynamic findings in children with cerebral palsy.[384-387] The vast majority of the children with cerebral palsy tend to toilet train completely, but often at an age that is later than expected for normal individuals.[384] Any incontinence is usually secondary to urinary urgency from DO associated with an inability to be toiletted on time.[386] A meta-analysis of urodynamic studies performed in children with either persistent incontinence despite frequent toileting, or urinary tract infection, revealed either normal function (15%) or DO (73%; 85 of 117 patients); [384-386] very rarely is dyssynergia between the detrusor and urethral sphincter noted during voiding (5%; 12 of 249 patients). [336, 385, 387] In some recent studies, detrusor-sphincter dyssynergia was present in higher prevalance then earlier reports (11% / 5%).[388-390] Normal function was less prevalent (only 15%) in the more recent case series.[389, 390]

Therefore, it has been suggested but not proven that cystometry and sphincter EMG are obligatory only when frequent toileting or anticholinergic therapy fails to control incontinent episodes, the child develops urinary infection from an inability to empty the bladder completely during voiding, or ultrasonography reveals hydronephrosis.

However, videourodynamic assessment should be performed in all patients with infantile cerebral palsy. The decision should not be based on clinical symptoms because at least half of the children with spastic cerebral palsy have clinically silent bladder dysfunction. 100% of children had neurological improvement postoperatively (selective dorsal rhizotomy), 71% who were incontinent preoperatively became continent and none had deterioration on urodynamics [389-391]

Conclusion (evidence level 3)

- Some studies (with 'historical'/ 'literature' -control groups) have shown that clinically unexpected lower urinary tract dysfunction – predominantly dysfunctional voiding - can occur in children with cerebral palsy.

Recommendation (grade C)

- Clinicians should carefully evaluate voiding in children with cerebral palsy and should consider complete urodynamic testing when dysfunction is suspected
- Urodynamic testing is necessary in all patients with spastic cerebral palsy. Undiagnosed and untreated patient's bladder function remains pathological, and may damage the upper urinary tract.

3. IMPERFORATE ANUS

Imperforate anus is classified as high, intermediate or low depending on whether or not the rectum ends above, at or below the levator ani muscle. In the past, imperforate anus repair for high lesions frequently resulted in urinary incontinence due to a pudendal nerve injury that often occurs from a perineal approach to bringing the rectum down to the anal verge.[392] With the advent of the posterior sagittal anoplasty this complication has been eliminated as a cause for subsequent urinary incontinence, although bladder neck incompetence may be a consequence of extensive mobilisation of the sigmoid colon which helps transfer the rectum to its final location. However, recent reports of spinal MRIs reveal a 35% incidence of distal spinal cord abnormalities in children with an imperforate anus.[393-395]

Wetting after definitive repair may be the result of stress incontinence through ineffective emptying ('overflow incontinence') and bladder underactivity or acontractility rather than sphincter injury. In 2005, Shimada et al reported on the reconstruction of cloacal anomaly in a consecutive series of 11 girls. The main clinical characteristic of bladder dysfunction was a failure to empty. [396] They could not define the exact aetiology, but iatrogenic injury from extensive dissection can lead to the higher risks of peripheral nerve damage.

In 2004, Warne et al prospectively studied the effect of surgical reconstruction by posterior sagittal approach and total urogenital mobilisation in either causing or worsening bladder dysfunction in new patients with cloacal anomalies. A comparable group of patients

with anorectal malformation (ARM) were studied as comparative controls to assess the effect of posterior sagittal approach without urogenital surgery. Natural filling urodynamics via suprapubic catheter were performed in all infants at 0.2 to 9 months (mean 3) before surgical reconstruction. This assessment was repeated 6 to 24 months (mean 14.8) after surgery. A total of 10 patients with cloacal anomalies (5 with short [less than 3 cm] and 5 with long common channel [greater than 3 cm]) and 20 patients with anorectal malformation (ARM) were consecutively studied. At presentation bladder dysfunction was present in 9 of 10 patients with cloacal anomalies and in 12 of 20 patients with ARM. After surgery there was significant deterioration in bladder function in half of the cloacal group (5 of 10 patients, $p = 0.04$) and in 1 of 20 patients with ARM ($p = 0.7$). Of the 5 patients with cloacal anomalies who had deterioration of bladder function a urodynamic pattern of DO changed to detrusor underactivity in 4, all of whom had a long common channel at presentation. The authors concluded that patients with cloacal malformation have a high incidence of innate bladder dysfunction. However, surgical reconstruction by total urogenital mobilisation can cause further deterioration of bladder function, particularly in the group with a long common channel and urodynamic assessment is necessary to detect bladder dysfunction in these patients. [397]

The VATER or VACTERL association is a group of diverse abnormalities that include Vertebral bony, Anal atresia, Cardiac, Tracheo-Esophageal fistula, Renal and Limb anomalies. [321] Imperforate anus may occur as an isolated lesion or in conjunction with this association. Spinal cord pathology occurs in 38% of cases producing a picture of upper and/or lower motor neuron deficits to the LUT. [368, 394, 398-400] By combining the incidences in 3 studies it was found that the presence of an abnormal sacrum increases the likelihood of neurogenic LUT dysfunction to as high as 76% (38 of 50 children).[368, 398, 399] When the rectum ends above the levator ani muscle there is a much greater chance of neurogenic bladder dysfunction than when it ends below the pelvic floor [370, 398] and the older the child is at the time of urodynamic assessment the more likely he/she is to have abnormal LUT function. [400, 401]

In 2006, a prospective study was carried out on children with ARM prior to and following definitive procedure, using urodynamic evaluation. Among these 19 children 13 underwent re-evaluation after definitive surgery for ARM. Of the 19 children, 14 (73.7%) were cases of high ARM and 5 (26.3%) were cases of low ARM. Baseline evaluation done in 19 children revealed seven urodynamic patterns: Normal capacity, compliant without DO (21.1%) or with DO (5.3%); Normal capacity, poorly compliant without DO (5.3%) or with DO (10.5%); small capacity, compliant with DO (5.3%) or poorly compliant with DO (26.3%) and large capacity, complaint with DO (26.3%). Thirteen patients were evaluated post operatively also and in only 23% (3 of 13) was no change in urodynamic pattern observed. In the remaining 76.9% (10 of 13) some changes in urodynamics pattern were observed. The deleterious changes observed were appearance of DO in 30.8% (4 of 13), decrease in the bladder capacity in 23% (3 of 13) and decrease in bladder compliance in 15.4% (2 of 13). Only 9 of the 19 patients had normal urodynamics pre-operatively and post-operatively, and 3 more patients worsened. [402]

Mosiello et al recommends evaluation of all patients with ARM using MRI. When MRI shows sacral or spinal cord anomalies, urodynamics should be performed. They recommend a noninvasive evaluation for all other children and urodynamics when neurogenic dysfunction is suspected. [370]

The reliability and reproducibility of these findings among the various studies analysed confers an important role on videourodynamic studies as an integral part of the evaluation and management of these children: it has diagnostic accuracy; it provides a reason to explore any intraspinal abnormality to improve the child's chances of achieving urinary and faecal continence; and it is useful as a basis for future comparison if incontinence should subsequently become a problem in children not undergoing early spinal cord exploration.

Conclusions (evidence level 3)

- Various studies have shown that a proportion of children with imperforate anus have primary or secondary dysfunction of the LUT, lower urinary tract innervation abnormalities or pelvic floor dysfunction.

Recommendation (grade C)

- Clinicians should consider urodynamic testing in children with imperforate anus when clinical signs of LUT dysfunction or relevant neurological abnormalities exist, before and or after reconstructive surgery.

4. ANATOMIC ABNORMALITIES

The use of urodynamics for evaluating anatomic lesions that affect the lower and, consequently, the upper urinary tract in children is still somewhat controversial. Essentially, the evidence consists of uncontrolled case series and expert opinions.

Although many clinicians now feel its usefulness is beyond question.

a) Posterior urethral valves

Nowhere is the above controversy more obvious than in boys with posterior urethral valves.[403-405] Prior to the ready availability of urodynamics, persistent

upper urinary tract dilation was managed with bladder neck resection and/or striated urethral sphincter resection. By demonstrating the presence of detrusor underactivity or DO, urodynamic studies have helped explain the radiological findings of hydroureteronephrosis that many of the children exhibited over time despite adequate valve ablation. These studies changed the focus from increased bladder outlet resistance to altered bladder function as the aetiology.

There are only two urodynamic reports prior to valve ablation. In one, DO was seen in 60%, poor compliance in 10% and normal function in 30%. [406] In the other, all 46 patients had 'bladder hypercontracility' and comparable high maximum voiding detrusor pressures. At the end of followup (mean 4.5 years) in this second study, no patient in group 1 (22 patients who underwent simultaneous valve ablation and bladder neck incision at the 6 o'clock position) had 'bladder hypercontractility' or DO, and the mean maximum voiding detrusor pressure was 53 ± 15 cm H_2O. In comparison, 9 patients in group 2 (24 patients who underwent simple valve ablation) had 'bladder hypercontractility', 6 had DO and the mean maximum voiding detrusor pressure was 87 ± 45 cm H_2O ($p < 0.01$). [407]

In a series of urodynamic studies after valve ablation, the type of bladder function found correlates with the time elapsed from surgery; DO is the predominant pattern initially [403] but improvement is noted in both DO and compliance over time. [406, 408-413] In 2005, a series of 30 patients showed DO with single or multiple involuntary detrusor contractions in 60 %, and small capacity, reduced bladder compliance in 40%. [414]

Myogenic failure in conjunction with increasing capacity and poor emptying are primarily a later phenomenon, most likely secondary to increased urine production and decreased frequency of voiding with advancing age.[409] Despite early valve ablation, a large proportion of boys treated for PUV have gradual detrusor decompensation and/or secondary bladder neck obstruction leading to obstructive voiding and finally detrusor underactivity or acontractility. [415] VUR was, in a small and selected series, most commonly noted in boys with DO whereas hydronephrosis is most frequently seen with a poorly compliant bladder. [406, 416, 417] The persistence of upper urinary tract changes is related to the bladder's unresponsiveness to medical therapy for the DO and/or underactivity. Several studies have shown the predictability of the development of renal failure based on specific detrusor patterns seen on urodynamic evaluation; persistent poor compliance, high detrusor pressures and failure to adequately contract during voiding with increased PVR are the most likely causes of this progressive deterioration.[403, 404, 408, 409, 416, 418]

b) Bladder exstrophy

Once the exstrophied bladder is closed it may be difficult to determine how best to manage persistent incontinence, upper urinary tract dilation or VUR, whether to further improve bladder outlet continence function or whether to perform augmentation cystoplasty for a small capacity, poorly compliant bladder. In addition, as more children undergo complete primary repair of the exstrophic bladder in the neonatal period the most concrete assessment of bladder function is via urodynamics. Only a few studies characterise the change in function following bladder neck reconstruction in patients with persistent incontinence; 20% show DO preoperatively versus 37% postoperatively, and compliance worsens in up to 50% after surgery.[419-423] No studies are extant that have correlated incontinence with bladder capacity, compliance, DO and/or LPP.

c) Ectopic ureterocele

Urodynamic studies in babies with an ectopic ureterocele have shown that LUT function may be altered in as many as half the affected patients; 2 reports revealed that between 55 and 70% had a larger than normal capacity bladder for age with high compliance, and poor bladder emptying due to detrusor underactivity.[424, 425] In another multicentre analysis of 616 children with a variety of ureterocele types, investigators found only a 6% incidence of bladder dysfunction (all in children with an ectopic ureterocele) consisting of primarily DO; less than 1% had poor bladder emptying whereas the remainder had normal bladder storage function and complete emptying.[426] In a recent study in 2007, voiding dysfunction was suspected in 23% of patients.[427] Urinary incontinence and/or infection following surgical incision or excision of a ureterocele is likely to be secondary to the obstructive effects of the ureterocele directly on the bladder outlet and not to any surgical complication.[424-426]. Patients undergoing bilateral ectopic ureterocele repair are at increased risk for postoperative voiding dysfunction. Whether this risk is present preoperatively or is a result of trigonal surgery is unclear.

d) Vesicoureteral reflux

Recent evidence has confirmed that VUR may be a secondary phenomenon resulting from DO and not a primary anatomic abnormality at the ureterovesical junction in a significant proportion of children.[428-433] There is growing evidence that DO may lead to VUR in a marginally competent ureterovesical junction mechanism.[399, 434, 435]

This DO may be a natural phenomenon in the infant bladder, especially males (due to the presence of high voiding pressures [433, 436-440] and/or a learned dysfunction in older children who try to withhold voiding throughout the day.[431] Several investigators have

shown that DO tends to resolve with increasing age. [434, 438, 441]

The bladder pressure at the onset of VUR, as determined by nuclear cystometrography, is a significant independent predictor of VUR resolution in children. The pressure at the onset of VUR was also highly predictive of spontaneous resolution ($p = 0.0005$). VUR occurring at greater pressures was more likely to resolve spontaneously, independent of the VUR grade or bladder volume at the onset of VUR. [442] VUR occurring at greater than 75% of predicted bladder capacity had a significantly higher resolution rate ($p = 0.0005$). In addition to grade, bladder volume relative to predicted bladder capacity at the onset of VUR appears to provide additional prognostic information regarding the likelihood of spontaneous resolution of primary VUR. [443]

Despite this finding, there is ample evidence in 4 studies to show that treating the DO and/or voiding dysfunction with anticholinergic agents leads to a faster rate of resolution of VUR (63 - 92% within 1 year) [444-446] than it might when the child is treated with antibiotics alone to prevent recurrent infection (25 - 54%). [447]

In this setting, history-taking about voiding habits [448] and urodynamics with cystometry and uroflowmetry to confirm the abnormal bladder and possibly sphincter function, become paramount to just treating the child with antibiotics and getting yearly voiding or nuclear cystograms. Urodynamic studies have confirmed the presence of DO and/or high voiding pressures in at least half the babies studied with high grades of VUR, whereas only 38% had totally normal function [436, 440, 449-452] Upper urinary tract damage is more apt to occur in children with abnormal bladder function as reported in 4 retrospective reviews.[441, 445, 451, 453].

In 2006, videourodynamic studies were performed in 40 patients. Dysfunctional voiding was present in 76% of the children with DO, in 73% of the children with VUR, in 63% of the children with urinary incontinence, in 77% of the children with episodic urinary tract infection, and in all of the children with diurnal enuresis. Compared to children without dysfunctional voiding, the voiding pressure was significantly higher in children with dysfunctional voiding (with VUR, 61 ± 30 vs. 25 ± 16 cm H_2O, $p = 0.004$; without VUR, 53 ± 24 vs. 25 ± 16 cm H_2O, $p = 0.010$). [454] In the 5 patients who had post-treatment urodynamic studies, biofeedback pelvic floor muscle training and treatment with an antimuscarinic agent effectively decreased detrusor pressure, increased bladder capacity and maximum flow rate, and reduced the grade of VUR

Many clinicians treating patients with VUR advocate urodynamics to assess the LUT in children with high grade VUR, especially those who have incontinence, renal damage, or who are about to undergo surgery for VUR.[445, 455-457]

e) Urethral stricture

Urethral stricture disease in boys is rare, usually arising from a previously unsuspected straddle injury. Uroflowmetry can accurately predict the presence of a urethral stricture in 88% of affected males.[458-461] In a prospective study the voided volumes at first sensation of bladder fullness were significantly greater in hypospadias patients with urethral stenosis. They had bladder outflow obstruction and had decreased sensation of bladder fullness. The significantly decreased quotient of Qmax at greater and at smaller voided volumes could demonstrate a mild outflow obstruction. [462]

Because recurrence of a stricture is often both frequent and insidious, periodic urinary flow rates, analysing the maximum flow rate in relation to volume voided, may alert the clinician to early signs of renarrowing but efficacy of periodic flow rates has not been corroborated. [463] Uroflowmetry should be integral in the management of urethral stricture and complete urodynamic investigation is repeatedly required. [464]

Conclusions (evidence level 3)

- Many studies (case series) have demonstrated frequent urodynamic abnormalities - predominantly DO and reduced bladder compliance or large capacity bladder with impaired filling sensation - in children with posterior urethral valves, urethral stricture, ectopic ureterocele, VUR or bladder extrophy.

Recommendation (grade C)

- Clinicians should consider complete urodynamic testing, at least once, in children with posterior urethral valves, urethral stricture, ectopic ureterocele, VUR or bladder extrophy.
- Clinicians should consider regular uroflowmetry and postvoid residual urine in the management and follow –up of children with posterior urethral valves, urethral stricture, ectopic ureterocele, VUR or bladder extrophy.

5. FUNCTIONAL DISORDERS OF THE LUT

When assessing functional disorders involving the LUT in children, one must take into account the dynamics of the maturing nervous system, learned habits of elimination for bladder and bowel function and social influences that might modulate the child's behaviour in a negative or in a positive manner.[465, 466]

a) Diurnal incontinence

Urodynamics has a limited place in diurnal (day and

night) incontinence. This condition is not considered worrisome before age 5 or 6. When older, most children without an (until then unsuspected) anatomic or neurological lesion should be dry.[467] Urinary incontinence in children can have many causes and history and clinical investigation are very important in this regard. Urinary incontinence can also coincide with dysfunctional voiding and or bowel elimination problems. [468, 469] Treating these elimination dysfunctions with behavioural modification, biofeedback training, drug therapy or intermittent catheterisation (CIC) [470] and/or antibiotics to prevent further urinary infection is necessary before considering urodynamics. [471] Uroflowmetry with a PVR urine determination and cystometry are however indicated; especially if the incontinence persists despite medical therapy.

In one study of girls with recurrent infection without VUR two distinct patterns of dysfunction emerged in 80% of those studied, either DO with a normal urinary flow pattern and complete emptying, or a normal detrusor with an intermittent flow pattern and incomplete emptying. [472]

In boys with persistent day and night-time incontinence, voiding cystourethrography is warranted to determine the presence of different forms of bladder outlet obstruction that may be contributing to or coincide with the DO.[473]

Faecal incontinence in the absence of any anatomical or neurological deficit often affects LUT function and contributes to urinary incontinence in a number of ways. Constipation and faecal impaction have been shown to cause DO and a reduced functional bladder capacity.[474] Understanding and eliminating this possible aetiology can normalise LUT function. There is no need for urodynamic testing, before starting treatment for faecal impaction, in these cases. [468]

Persistent daytime and night-time incontinence in the absence of urinary infection and a normal bladder and bowel emptying regimen warrants cystometry, pressure-flow studies and a urinary flow rate. A meta-analysis, over 20 years, of 460 children with daytime incontinence evaluated with urodynamic studies reveals DO in 57% (261 of 460), dysfunctional voiding (failure to relax the sphincter mechanism) in 22% (34 of 152) and normal findings in only 14% (64 of 460). [436, 475-479] In recent studies, dysfunctional voiding was present in 76% of 40 children with DO. [454, 480] These findings are not gender-specific but are age-dependent, with most children outgrowing the abnormal findings by puberty. [476] Presumably normal children without day or night-time wetting do not have a pronounced degree of DO or dyssynergia but the evidence for this is lacking due to the paucity of studies in normal children.

Urodynamic testing has clearly improved our understanding of the aetiology of diurnal incontinence but no study has shown that urodynamic characterisation of any abnormality has improved the efficiency of treatment for these children.

b) Enuresis (nocturnal)

Night-time wetting (enuresis) is a condition that is common in children aged 5 years but which improves with time, so that less than 15% of pubertal boys and 5% of pubertal girls continue to be affected.[465-467, 481] Multiple causes for the persistent wetting, ranging from genetic factors, to maturational delays, to sleep disturbances, to social causes, to attention deficit disorders, to bladder and urethral dysfunction, to excess fluid intake, to abnormal vasopressin secretion and/or to constipation, have been implicated. [468, 482-489] Although in various cultures there may be social and familial pressures to resolve the condition before puberty, in western societies it is generally not necessary to conduct urodynamics until adolescence, to determine why the wetting has not abated. Urodynamic testing in 615 enuretic children with and without daytime symptoms has identified DO in 61%.[370, 490-494] In a prospective study, bladder volume and wall thickness index was calculated based on ultrasound studies and classified as thick (less than 70), normal (70 to 130) or thin (more than 130). 96% of the patients with an index of less than 70 exhibited DO on cystometry. [495, 496] In another prospective study 116 children with primary enuresis were evaluated and urodynamic abnormalities were seen in 80/116 (69%) patients namely DO 50/116 (43%), small bladder capacity 20/116 (17%), large bladder capacity 4/116 (3%), decreased bladder compliance 3/116 (3%) and detrusor sphincter dyssynergia 3/116 (3%). The combination of abnormal micturition history stating daytime urinary urgency or frequency or dysfunctional voiding symptoms like squatting and/or abnormal voiding charts could predict abnormal results of urodynamics correctly with sensitivity of 81% and specificity of 86%. [497]

When the children are divided into those with day and night-time incontinence (non monosymptomatic) versus those with just nocturnal wetting (monosymptomatic), the incidence of DO decreases from 64% to 35% in the latter group.[492, 493] In another prospective study comparing enuretics to age-matched non-enuretic controls, bladder capacity at night (enuretic capacity) was significantly less in those who wet versus those who did not.[498] Although the authors did not speculate on aetiology they felt that enuretics were less able to hold their urination than non-enuretics. Management should be directed at improving the child's ability to withhold urination. Treating the non monosymptomatic child using antimuscarinic agents can be very effective (as high as 77% cure) with low recidivism rates when based on the findings of urodynamic testing.[484, 488, 499-503]

Conclusions (evidence level 2/3)

- Various studies show that treatment for children with functional incontinence (and of the, frequently associated, bowel elimination problems) can be initiated on the basis of history, clinical exam and uroflowmetry and postvoid urine assessment.
- Various studies, reviews and guidelines agree on the relevance of urodynamic testing in children with incontinence and nocturnal enuresis resistant to initial (conservative) treatment.

Recommendations (grade B/C)

- The committee recommends uroflowmetry and postvoid residual urine assessment (until -for the individual child- representative values are obtained) as screening and evaluation in all children with incontinence and nocturnal enuresis.
- The committee recommends complete urodynamic testing in children with incontinence and nocturnal enuresis resistant to conservative treatment, if invasive treatments are contemplated

6. TECHNICAL CONCERNS: RELIABILITY AND REPRODUCIBILITY OF TESTS

Often, differences in urodynamic parameters exist from one study to another or one year to the next. Chou et al provided reference ranges for "normal" variability in urodynamic parameters that can be considered as "no real change" from one study to the next. It was a retrospective chart review. Fifty consecutive individuals with spinal cord injury had 2 trials of urodynamic studies done 5 minutes apart. They established percentile ranges. Knowing these ranges of variability can be helpful in determining whether differences between filling trial 1 and filling trial 2 in a single study or year-to-year changes in urodynamic studies are significant or simply the normal variability of the urodynamic study. [49]

A reduced rate of filling, e.g. 10% of the expected bladder volume per minute, has been recommended in children to accurately determine detrusor compliance and functional bladder volume. [504] Some investigators advocate that infants should be assessed with much lower rates of filling or with natural filling cystometry. [505, 506] Several studies do show lower detrusor pressures under natural filling versus even slow filling rates during cystometry. [331, 332, 507] Even though the practicality of time management plays a role in a busy urodynamic laboratory, it is essential to perform urodynamic testing in a way that reveals what one considers clinically important. One study in particular [331, 332, 507] demonstrated that the intravesical pressure was lower when it was measured initially by catheterisation (before emptying the bladder) and then compared to the pressure at the same volume during the subsequent cystometrogram. Except for determining bladder volumes at specific pressures,[332] no study has shown that these differences are crucial in the management of children with LUT dysfunction. One study looked at the effect of the temperature of the instillate (25^{o} versus 37.5^{o} C) on measured detrusor pressures and found no significant differences in compliance. [46] van Meel et al have shown that repeating the Ice Water Test (IWT) will increase its positivity. [327]

The smallest dual-channel urethral catheter available should be used in children for the same reasons as specified for adults, although the measuring lumen must be large enough to measure pressures in a technically adequate manner. Although urethral catheters of moderate size do not always obstruct the urethra,[508, 509] or produce higher than the normal voiding pressures as measured with suprapubic tubes, it is prudent to employ the smallest calibre catheters that are practical when doing a cystometrogram that measures filling as well as voiding pressures. For very young infants it may be better to insert a suprapubic catheter placed under anaesthesia the day before the test to make the subsequent investigations more accurate [510, 511] but this has not been assessed with any precision.

Most children can undergo urodynamic studies without pre-medication; only the most agitated may require some degree of sedation. Even then, children should not be so heavily sedated that they cannot void around the catheter. However, there are no studies that show a difference in bladder filling pressure (whether related to compliance or to DO) in awake versus anaesthetised children.

In the previous consultation the recommendation was made that children should receive comprehensive urodynamic testing in a laboratory that is specialised in pediatric urodynamic testing with appropriately trained personnel.

Conclusions (evidence level 3/4)

- The committee concludes (on the basis of various studies to determine normal and test retest values for urodynamic testing in children) that within the limits also provided for adults, urodynamic testing in children is reliable and reproducible.
- Although it is plausible and considered useful to reduce filling speed and catheter size in relation to patient size. the exact values cannot be given and the influence of the transurethral catheter size on voiding is unknown.

Recommendations (grade C)

- The committee recommends that the specific demands of children, physically as well as psychologically are taken into account when urodynamic testing is carried out. The committee advises specialised units and equipment to ensure this.
- The committee recommends that clinicians take into account the variability and test retest differences of urodynamic testing in children and also take into account the effect of the (apparent psychologically stressing) laboratory-situation on the child's behaviour.

Suggestions for research:

- The committee suggests that additional work is undertaken to establish normative values and reproducibility of urodynamic data, especially on voiding and voiding abnormalities, both in normal children and in well-defined groups of pediatric patients.
- The committee suggests that further integrated approaches to the diagnosis (and management) of children with anorectal (elimination) dysfunction in combination with lower urinary tract dysfunction are undertaken.

V. PATIENT EVALUATION: FRAIL ELDERLY

1. INTRODUCTION

Frail older patients are poorly represented in all studies, but especially those involving invasive interventions or medications, as they suffer from multiple impairments (eg poor mobility, cognitive impairment, renal failure) or conditions (heart failure, multiple medications) which tend to exclude them from research.

Elderly patients should not be considered differently from younger subjects simply because of their chronological age. LUT symptoms, especially storage symptoms, showed age-related alterations in the two sexes in the absence of any overt underlying disease, and bladder function in both sexes may be subject to a gender-independent aging process.[512] Urodynamic findings in the elderly tend to demonstrate DO, [513, 514] even in asymptomatic individuals. There may also be a reduction in bladder capacity, urinary flow rate and detrusor contractility.[515] Because of these changes the utility of urodynamics has to be judged against a different background in the elderly.

Older people age at different rates, with some developing a clinically recognised pattern of frailty [516, 517] characterised by impairments in a number of functions including physical activity, mobility, balance, cognition, nutrition and endurance. Such individuals tend to suffer multiple chronic medical conditions, take multiple medications, and are at risk of admission to hospital or a care home. [518, 519] They are also at greater risk of developing incontinence. As a group they are poorly represented in research studies. [519] These features need to be born in mind when considering the contributors to and investigation of incontinence. Limitations to care may also be appropriate in a frail older person who is nearing the end of their life [520] but appropriate intervention should not be denied on the basis of age. This is covered more fully in chapter on the Frail Elderly produced by committee 11.

Firstly, the invasive nature of conventional urodynamics becomes a more important factor in the old-old or frail elderly, who may be more vulnerable to any insult than younger people. For example, one study [521] showed that there was a significant association between age and the presence of asymptomatic bacteriuria before cystometry and between this bacteriuria and urgency (without DO) on cystometry. These results do not however support a policy of universal screening for bacteriuria before urodynamic investigation. Asymptomatic bacteriuria did not influence the urodynamic outcome except in patients with urgency (without DO); and the authors recommended that screening and treatment be considered individually in older women who are being investigated for storage symptoms. About 20% of this group of patients developed UTI (mostly asymptomatic) after the urodynamic investigation. The concept of 'symptomatic' is difficult in the frail elderly – for instance the development of delirium is a symptom of many conditions including UTI –but is not generally included in the outcome measures. This information should be included in the counselling before urodynamic investigation and should be incorporated into the patient information leaflet as part of good clinical practice. Unfortunately, there are few adequately powered studies (and none that we are aware of in this patient group) of the efficacy of antibacterial prophylaxis.

Secondly, given the multifactorial nature of incontinence in the elderly, [161] and the fact that there may be easily reversible causes or contributory factors, screening for these then conservative therapies are indicated initially.[522] Urodynamic examination is reserved for patients in whom conservative management has failed or has proved inadequate, who desire further attempts to correct or manage the incontinence, and who therefore need a detailed and objective diagnosis.

The place of urodynamics in the frail elderly with incontinence is therefore quite limited even in principle and, given that the number of studies seeking to establish its clinical utility is even smaller than in

younger adults, there is very little objective evidence for or against clinical urodynamics in this population group.

On the other hand, because of the changes in function that occur with age not only in the LUT, but in the neural system that controls it (or fails to control it), and also in other organ systems that may have an impact on urological problems, research urodynamics is essential to establish what these changes are, how they are related to other aging-associated changes, and how they may be reversed, so that there is a chance of developing new, more suitable therapies. Therefore, in academic centres at least, many geriatric patients should be examined so as to generate a steady stream of high-quality clinical urodynamic research, addressing mechanisms of disease and deterioration in all the main geriatric patient groups (including 'normal aging'), and in the less common patient groups as well.

2. WHAT IS USUALLY EVALUATED

Among the frail elderly, incontinence is the paramount troublesome symptom in both men and women, with a steeply rising incidence after age 80.[523] The type of incontinence appears to be predominantly urge.[123, 514] SUI is relatively uncommon in men of any age (except post radical prostatectomy) and it seems to become gradually less common in women after the age of about 50, [523] for reasons that are incompletely understood.

a) Urgency incontinence

Urgency incontinence is usually the result of DO. (It is believed that occasionally it may be due to involuntary relaxation of the urethral sphincter mechanism, without a measurable detrusor contraction.[5]) Thus one possible reason to perform urodynamics might be to identify DO. The relevant test would be filling cystometry. There are reasons to question whether this is the best approach:

1. In straightforward urgency incontinence in the elderly, DO is highly probable, and it is not necessary to perform urodynamics to prove this before trying pharmacological or behavioral therapy. This is one of the reasons for the limited clinical role of urodynamics referred to above.
2. Because DO is only one contributor to urgency incontinence,[161, 524] not all individuals with DO are incontinent. In fact, DO is believed to be quite common in healthy older people who are apparently free of bladder symptoms of any kind. Thus it is important to look not just for DO, but for actual leakage caused by detrusor contraction - DOI.
3. Because only the more difficult or intractable cases are investigated with urodynamics, it is important to look for other coexisting LUT dysfunction, beyond simple DO.
4. As a group the elderly find hospital intervention more difficult to tolerate, and therefore urodynamics and even measurements of flow rates or PVRs on a single occasion are less reproducible

Among the elderly, the most common type of DO is the 'terminal' pattern in which a single involuntary detrusor contraction occurs at the end of filling and leads directly to leakage (incontinence).[525][72] Quite frequently there is reduced bladder sensation also, so that the subject does not feel any sensation of bladder filling or the need to void until the contraction is about to take place,[526] and thus has very little warning of impending leakage. These characteristics are believed to have a neurological (cerebral) origin.[525, 526]

In elderly people, UUI frequently coexists with incomplete bladder emptying. Among men who have not had prostate surgery, urethral obstruction is a possible contributor to incomplete emptying. If there is no obstruction, and particularly in women in whom obstruction is rare, incomplete emptying is a sign of impaired bladder contractility.

The urodynamic abnormality underlying UUI with incomplete emptying (assuming no obstruction) has been named 'DHIC' (detrusor hyperactivity with impaired contractile function).[527] Its significance is that the standard pharmacological treatment of UUI – with antimuscarinics – may worsen bladder emptying and possibly cause urinary tract infection or even make the incontinence worse.

Thus the principal urodynamic tests that are done are:

1. Free uroflowmetry:

a. may be useful as a screening test for obstruction or diminished detrusor contractility

   - A slow, prolonged or intermittent flow curve may indicate either urethral obstruction or diminished detrusor contractility; pressure-flow studies are required to distinguish between them

2.Measurement of PVR urine:

a. to check whether anticholinergic (antimuscarinic) therapy is contraindicated because of a large residual

b. to help identify DHIC

Observation of consistently elevated PVR thus has therapeutic consequences and so, among urodynamic investigations, measurement of PVR urine is important. Clinical experience suggests that faecal loading of the bowel is a common cause of poor bladder emptying in this group, but there are no studies to confirm this. Even if screening to rule out constipation has been carried out initially, this should be reconsidered in the presence of a large residual volume.

If a large amount of residual urine is found in the absence of faecal loading then incontinence associated with chronic overdistension or infection may be suspected, and intermittent catheterisation may be indicated. The measurement is included in the Resident Assessment Protocol (mandated for nursing homes by the US Congress) along with the stress test.[528]. Even if screening to rule out constipation has been carried out initially, this should be reconsidered in the presence of a large residual volume.

If the PVR is small, significant infravesical obstruction or detrusor underactivity or acontractility is less likely, and a small dose of anticholinergic medication may be tried.

3. Filling cystometry:

a. to demonstrate or rule out DO or – more importantly – DOI

b. to identify the pattern of DO – terminal or phasic

c. to identify reduced or normal bladder sensation

Cystometry is sometimes said to be an essential part of the diagnostic evaluation, both in defining underlying pathophysiology and directing treatment.[155] However, none of these aims (a.-c. above) have particular therapeutic importance except in difficult cases where initial therapy has failed and it is uncertain what the underlying problem is.

A small number of frailer older women are considered for operative intervention of SUI but as their risks are higher so should they have cystometry first, especially as pure SUI is so unusual in the frail elderly?

4. Pressure-flow studies of voiding:

a. to identify or rule out prostatic obstruction (in men)

b. to identify or rule out impaired contractility (reduced detrusor contraction strength)

5. Simple cystometry:

It is sometimes recommended that urodynamics in the elderly should be done by “simple cystometry” if cystometry is indicated and no equipment or referral is available.[529] The procedure needs only an open syringe attached to a single-lumen catheter, steri1e water or saline and a tape measure. Fluid is infused by gravity at a pressure head of l5-20 cm H_2O. Bladder capacity, sensation of filling and presence of a detrusor contraction or overactivity can be semiquantified. Pressure is measured by observing the height of the column of water. These simple measures can be carried out at the bedside and may be useful for disabled patients.[530-535] Simple cystometry, as compared with multichannel cystometry has a specificity of 75-79% and a sensitivity of 75-88% for the observation of DO.[530, 531] The accuracy can be improved by combining it with even simpler tests [531, 532] such as a stress test to exclude SUI.[536]

However the clinical significance of these findings is limited. DO is found in up to 50% of symptom-free elderly (and so it is not pathognomonic), while DOI is the most likely finding in incontinent frail elderly in any case.[123, 514, 527] Thus the test is performed only to rule out DO in a small subset of patients.

Furthermore, most of the studies recommending simple cystometry were conducted before the widespread availability of simple bedside bladder scans and before the high prevalence of detrusor hyperactivity with impaired contractility (DHIC) was recognised.[514] This dysfunction is the most common abnormality observed in the frail elderly population with incontinence.[514, 527] A total of 185 patients who had persistent LUTS after TURP were enrolled in one study, and the results revealed that a normal videourodynamic tracing was found in 9%, pure DO in 10%, low detrusor contractility in 19%, DHIC in 14%, poor relaxation of the urethral sphincter in 19%, and bladder outlet obstruction in 28%.[267] DHIC is easily misdiagnosed as a stable detrusor on simple cystometry,[536] because single-channel cystometry is less sensitive for detecting low-pressure detrusor contractions than multichannel recording. If a detrusor contraction coincides with a cough, the leakage may be regarded as the sign of a positive stress test.

By design, simple cystometry can at best recognise only DO, or DOI if actual leakage is recorded. There is no possibility of studying voiding dynamics. Furthermore, the checks on measurement quality that are part of conventional urodynamics are not available. Hence, because recognition of DO by itself has little therapeutic importance, and urodynamics in the elderly is reserved for difficult or intractable cases, it is more reasonable in such cases to conduct a full urodynamic examination of both filling and voiding phases, in which quality control can be maintained to eliminate artifacts, and the more relevant aspects of LUT behavior can be assessed, such as obstruction and reduced detrusor contractility.

b) Stress urinary incontinence

Among older men, SUI is almost entirely confined to post radical prostatectomy patients (see section D.II, Patient evaluation: Men). Among elderly women, pure SUI seems to be rare. Urodynamic testing usually follows the methods used in younger women. Frequently, it is difficult to perform an adequate examination because the patient is not able to produce a strong enough cough or Valsalva manoeuvre to cause leakage during testing, and cannot easily be examined in the upright position, which is the most likely posture to produce incontinence. On the other hand, it may be just such factors that make SUI uncommon in this population in the first place.

A weak urethral sphincter (intrinsic sphincter deficiency,

ISD) is a contributory factor to SUI. There is some evidence that a weak sphincter or inadequate sphincter control may contribute to the severity of UUI as well.[155, 161] Methods of assessing the sphincter include measurement of VLPP (difficult for the reasons stated above) and urethral pressure measurements. Unfortunately, urethral pressures diminish with age, whether or not there is SUI, and are not diagnostic.

3. EVIDENCE FOR REPRODUCIBILITY AND RELIABILITY OF URODYNAMIC TESTS IN THE GERIATRIC OR FRAIL ELDERLY POPULATION

There is little published evidence about reproducibility and reliability in this patient population. Two groups have recently examined specific aspects of geriatric urodynamics which have some bearing on this topic. There is a little earlier evidence on the reproducibility of some parameters.

a) Filling cystometry

One group [537] sought urodynamic changes associated with behavioral and drug treatment of UUI in 105 ambulatory, nondemented, community-dwelling women, of mean age 67 years (range 55-91). Although oxybutynin and behavioral treatment were both effective, and although oxybutynin increased cystometric bladder volume at strong desire to void and bladder capacity, the authors were unable to demonstrate that the improvement in incontinence was related to the urodynamic changes observed – that is, that the changes mediated the improvement. One possible explanation for this negative result is that the urodynamic parameters measured show considerable variability, as in other patient groups (see sections C.I and C.II).

b) Post-void residual urine

Residual urine is believed to depend on the presence of bladder outlet obstruction (in men) as well as on detrusor underactivity (i.e. impaired contractility).[538] Thus, in a man, the presence of substantial residual urine (> 100 ml) in the absence of severe bladder outlet obstruction suggests that the increased residual urine is mainly due to a reduction in detrusor contractility, with bladder outlet obstruction making only a minor contribution. There may be an age-dependent decrease in contractility in both sexes.

Residual urine varies in a given individual for no known cause: recorded values wax and wane over time [192]. Significant daily variations have been observed in elderly patients of both sexes, with larger residuals (up to 40% greater) being measured in the early morning. Similar changes have been described in patients with bladder outlet obstruction or detrusor underactivity [67, 539]. No clear predictor of deterioration of residual urine volume or of complete urinary retention has been identified. Although the presence of faecal loading may be a significant factor, there is an absence of supporting evidence from formal studies.

c) Pressure-flow studies

Another group [221] compared consistency, reproducibility, and responsiveness of various methods of estimating detrusor contraction strength from pressure-flow studies. They retrospectively analysed urodynamic data on 84 females 53 years old or older, with UUI, who received either a titrated dose of antimuscarinic medication or placebo in a controlled trial. Data were gathered before and at the end of treatment. Three different variations of the stop test were compared. In a stop test, flow is prevented and the isovolumetric detrusor pressure attained is taken to be a measure of detrusor contraction strength. Flow may be stopped by a voluntary contraction of the urethral sphincter midway through voiding (voluntary stop test: often impossible in stress incontinent women); by blockage of the outlet by a balloon midway through voiding (mechanical stop test); or by attempted voiding against an outlet that is already blocked by a balloon (continuous occlusion).

The voluntary stop test yielded isovolumetric detrusor pressure values inconsistent with the other 2 tests (a mean and SD of 31 $\pm$ 16 cm H_2O as opposed to 47 $\pm$ 26 and 49 $\pm$ 24 cm H_2O). The mechanical and continuous occlusion tests gave very similar results that were highly correlated with one another ($r = 0.87$). Measurements pre- and post-treatment in the 20 women who received a placebo showed that the continuous occlusion test had the highest reproducibility ($r = 0.9$, $p < 0.01$), followed by the mechanical ($r = 0.7$, $p = 0.01$) and voluntary ($r = 0.7$, $p < 0.01$) stop tests. Treatment with oxybutynin decreased isovolumetric detrusor pressure by up to 6 cm H_2O, but the decrease was statistically significant only for the continuous occlusion test.

The authors concluded that to assess detrusor contraction strength in elderly females with UUI either a mechanical stop test or a continuous occlusion test is acceptable but the continuous occlusion test has better reliability and more sensitively detects slight drug-induced changes. Again this study is on relatively young women, this time just '53 years and older', once again demonstrating the lack of data in the elderly, let alone the frail elderly!

This work demonstrates that some urodynamic measurements in a geriatric population are quite reproducible, reliable, and responsive to the effects of treatment. This means that they may be useful for research, but are not necessarily clinically relevant. For example, there is no evidence that a weak detrusor contraction strength predicts poorer response to treatment with anticholinergic medication or surgery.

4. EVIDENCE THAT PERFORMING URODYNAMIC TESTING IMPROVES CLINICAL OUTCOMES IN THE GERIATRIC POPULATION

Few relevant studies have been published in this population. One publication [540] assessed the results of tension-free vaginal tape (TVT) for the treatment of SUI in 76 consecutive women more than 70 years old (median age 76 years). 31% (24/76) of the patients had OAB symptoms and 4 (3%) had proven DO controlled by anticholinergic therapy. All patients had preoperative multichannel urodynamic evaluation. At a mean follow up of 25 months, 67% of the patients were cured. Preoperative urgency symptoms were cured in 46% of the group. Among the failures, 14 (18%) had UUI, while "de novo" urgency without incontinence was noted in 21%.

Thus, this paper provides no clear evidence that preoperative urodynamics was able to predict the outcome of a popular SUI procedure in older women. It does show that post-operative difficulties may be due to urgency and UUI, which however could not be predicted from the tests performed preoperatively.

To summarise, there is no clear evidence that urodynamic testing improves clinical outcomes in the geriatric population

5. THE PRACTICAL INDICATIONS FOR URODYNAMIC STUDIES AND WHICH TESTS ARE NEEDED

a) Post-void residual urine

Based on the above, there is general agreement that PVR urine measurement is indicated before treatment of incontinence either with anticholinergic medication or by SUI surgery. A consistently large residual urine certainly is a reason for caution and careful monitoring of bladder emptying, and may be a relative contraindication to such treatment.

b) Uroflowmetry

Uroflowmetry is a simple and noninvasive test. A normal uroflow without much residual urine probably rules out significant urethral obstruction or impaired contractility, but this finding is unusual in the elderly. Conversely, a poor uroflow is common in the elderly irrespective of sex, and although it cannot distinguish between obstruction and poor contractility, in either case there is a relative contraindication to anticholinergic therapy. Consequently, uroflowmetry (with residual urine measurement) may be a useful screening tool prior to instituting therapy.

c) Pressure-flow studies

A frequently asked referral question, in an older man who is incontinent, has an enlarged prostate, and is cognitively impaired or has a disease such as Parkinson's disease or multiple system atrophy, is whether the incontinence is due to prostatic obstruction or to cerebral changes. If the former condition is present, then prostate surgery might be considered. As outlined above, prostatic obstruction is not usually the "cause" of UUI, which is typically multifactorial. However, there is weak evidence to suggest that, if the obstruction is urodynamically severe, then surgery may improve the incontinence.[541] If obstruction is equivocal or absent, then there is little point in performing surgery in an attempt to eliminate it. After screening with uroflowmetry and residual urine measurement, pressure-flow studies may be indicated in older men in whom obstruction cannot be ruled out and surgery is at least contemplated. See also discussion of Parkinson's disease below.

6. THE URODYNAMIC PARAMETERS IMPORTANT IN VARIOUS GERIATRIC CONDITIONS

Recent papers have examined the urodynamics of Parkinson's disease and related diseases. It is important to know the characteristic urodynamic features of these diseases, because a frequently asked clinical question is whether lower urinary tract dysfunction observed in an elderly male patient is due to such a disease or to BPE/BPO. Similar questions may sometimes arise in women.

a) Parkinson's Disease

One group [158] found that men with presumed obstruction-related lower urinary-tract symptoms were less likely to have UUI (DOI) on urodynamics than men or women with Parkinson's disease. DO due to Parkinson's disease occurred at smaller bladder volumes than that in obstruction-related DO, although this finding was more pronounced in women than in men. The duration and severity of Parkinson's disease were not related to the nature or severity of urodynamic abnormalities.

Another group [305] found that the majority of patients with Parkinson's disease (72%) or multiple system atrophy (100%) had symptoms of urinary tract dysfunction. Neurogenic DO was more common in Parkinson's disease (81% vs 56% in multiple system atrophy). Detrusor-external sphincter dyssynergia was seen only in multiple system atrophy (in 47%). Urethral obstruction (AG number or BOOI > 40) was more common in Parkinson's disease than in multiple system atrophy. A weak detrusor (impaired contractility) was less common in Parkinson's disease (66% of women and 40% of men) than in multiple system atrophy (71% of women and 63% of men). PVR urine volume > 100 ml was not observed in patients with Parkinson's disease but was present in 47% of patients with multiple system atrophy.

Thus urinary tract dysfunction was prominent in both diseases but patients with Parkinson's disease had

less severe dysfunction: primarily DO starting at small volumes and urethral obstruction. (Unfortunately these findings may make it difficult to distinguish from dysfunction associated with BPO). However, a PVR urine volume > 100 mL detrusor-striated sphincter dyssynergia, or an open bladder neck at the start of bladder filling are suggestive of multiple system atrophy. It has to be pointed out that multi system atrophy is diagnosed using other clinical criteria, and that residuals over 100 mL in frail older people are common

Recommendations (grade C)

- As urinary incontinence in frail elderly people may be the result of a number of contributory factors, many of which are reversible by simple measures, such patients should be first evaluated by a clinician skilled in the care of older people before any invasive investigations or more potentially harmful medications are given.
- Post-void residual urine measurement by a noninvasive method is recommended before institution of pharmacological or surgical treatment of incontinence. It should be repeated to monitor the effect of such treatment
- Uroflowmetry may be used to screen for voiding abnormalities prior to such treatment
- Filling cystometry alone has limited value in this patient population. “Simple cystometry” is not recommended unless a urethral or suprapubic catheter is already present for management but still must be interpreted with care
- Comprehensive urodynamics including, at a minimum, filling cystometry and pressure-flow study of voiding, is recommended in difficult and intractable cases that have not responded to behavioural or pharmacological therapy, and in whom further therapy is desired; and in complicated cases or cases with complicated comorbidity, where treatment is desired but the nature and aetiology of the urinary tract problems are unclear
- If stress urinary incontinence is suspected, extra tests of urethral function and/or pelvic floor mobility may be useful, although stress urinary incontinence is not only less common than in younger patients but may be difficult to prove or rule out in this population
- The committee recommends that comprehensive urodynamic testing be performed in specialised centres with a special interest in incontinence, by trained and certified staff who routinely perform urodynamic testing of any patients referred with suspected lower urinary tract dysfunction
- To maintain adequate urodynamic expertise in this difficult-to-examine patient population, and to provide a background of ‘regular’ patients against whom specific patients can be judged, it is essential that such centres examine substantial numbers of frail elderly patients

Topics for research

- Study of biological mechanisms of continence and incontinence in the frail elderly, especially those related to supraspinal control or lack thereof.
- Development and testing of treatments specific to the frail elderly.
- Establishment of the reproducibility and reliability of urodynamic measurements in the frail elderly.
- Investigation of the effect of faecal loading of the bowel on detrusor contraction, overactivity and residual volumes post micturition.
- The relationship between faecal incontinence and faecal loading in the absence of impaction.

E. SUMMARY OF RECOMMENDATIONS FOR CLINICAL PRACTICE RELATING TO URODYNAMICS

		NEUROGENIC BLADDER	FEMALE	MALE	CHILDREN	FRAIL ELDERLY
UROFLOW	Vol					
	MFR					
	PVR					
CMG	Sensation					
	MCC					
	DO					
	Compliance					
PF	nomograms					
	detrusor contractility					
Video X-ray/sono	bl neck					
	ext sph					
	whole LUT					
Urethral Function Tests	UPP					
	Stress UPP					
	DLPP					
	ALPP					
EMG	surf					
	needle					

Grades of recommendation	
Grade A	
Grade B	
Grade C	
Grade D	
Investigational	

F. ANORECTAL PHYSIOLOGY STUDIES

I. WHAT ARE ANORECTAL PHYSIOLOGY STUDIES?

Anorectal physiology studies (ARPS) incorporate a variety of measurements in the lower gastrointestinal (GI) tract which are intended to:

1. Aid diagnosis of anal incontinence
2. Quantify the effects of therapeutic intervention for anal incontinence
3. Aid prognosis of intervention to treat anal incontinence
4. Aid identification of continent individuals who are at risk of developing anal incontinence if they undergo surgery of the anorectum.

In many ways the lower GI tract is analogous to the LUT with the rectum (a reservoir for the storage and expulsion of faeces) being the analogue of the bladder and the anal canal (which acts as a valve to contain faeces within the rectum during storage and which acts as a tube to convey faeces away from the body during defaecation) being the analogue of the urethra.

Unlike the LUT which has to retain a substance of a fairly consistent viscosity to maintain continence (urine), the lower GI tract is not as simple in that the substance it is trying to retain for continence can have a wide range of textures (from “watery” to “hard”). Therefore, sphincters which might be adequate to maintain continence in the presence of hard stool may be totally inadequate when challenged with loose stool. This may well be a significant, confounding factor in measuring lower GI tract function but this has not been investigated with any great rigor.

There are simple ways of quantifying stool consistency [542, 543] which appear to be reproducible. [544] However, more objective measures also exist. [545]

The anal sphincters act as valves to contain faeces within the rectum until defaecation is convenient.

II. BASIC ANATOMY AND PHYSIOLOGY

1. INTERNAL ANAL SPHINCTER

The internal anal sphincter is a continuation of the smooth muscle lining of the rectum and it is under autonomic control. A study in 1979 reported a 75% contribution of the internal anal sphincter to the closure of the anal canal at rest [546] but other workers demonstrated that it is responsible for around 85% of the resting tone in the anal canal. [547, 548] However, there is some evidence that the contribution may be only between 50%-60%. [549] What is known is that the external anal sphincter does contribute to resting pressure in the anal canal [550]; probably to varying degrees in individuals.

It has long been thought that poor internal sphincter function makes an individual more likely to suffer from passive anal leakage throughout the day and night. However Deutekom et al have shown that there is also an association of passive faecal incontinence with poor external sphincter function. [551]

2. EXTERNAL ANAL SPHINCTER

The external sphincter is voluntary, striated muscle. It is this muscle that an individual activates to maintain continence when a defaecation desire is experienced but it is inappropriate to do so. Poor external sphincter function makes an individual more likely to experience urgency when a defaecation desire is experienced and often incontinence can occur on the way to the toilet.

3. PUBORECTALIS

There have been considerations in the past that puborectalis has a role in anal control. This part of the pelvic floor slings around back of the lower GI tract and creates the anorectal angle. During times of increased abdominal pressure it has been postulated that this angle creates either [552] or both [553] a "flap" valve or "flutter" valve effect to minimise the additional pressures challenging the sphincters. However, there is scant evidence to support the existence of either of these mechanisms. Bartolo in 1986 carried out work which showed that the presence of a "flap" valve mechanism was unlikely [554] and Bannister also confirmed this finding in the following year [555]

III. ANAL INCONTINENCE AND ANORECTAL PHYSIOLOGY STUDIES

Anal incontinence can result directly from poor sphincter function, altered rectal sensation, altered rectal compliance or recto-vaginal fistulae. Problems associated with the upper GI tract, which result in intestinal hurry and diarrhoea, can also directly lead to incontinence. Indirectly, anal incontinence can result from "overflow" due to poor evacuation. Incomplete defaecation may result from an anatomical problem such as rectocele but it can be a functional problem relating to poor rectal sensation, high rectal compliance, failure of the internal sphincter to relax during defaecation or the external sphincter actively contracting rather than relaxing during defaecation.

Anorectal physiology studies involve the measurement of sphincter function, rectal compliance and sensation and will be discussed in two parts. The first tests considered are those which measure parameters of lower GI tract function that can directly cause anal incontinence; these are termed tests relating to "primary incontinence". After that, tests which measure parameters of lower GI tract function that can indirectly cause anal incontinence will be considered; these are termed tests relating to "secondary incontinence"

IV. TESTS RELATING TO PRIMARY INCONTINENCE

1. ANAL MANOMETRY

The most common way of assessing sphincter function is by anal manometry. Pressures are measured in the anal canal at rest, during voluntary contraction of the muscles and sometimes during Valsalva or cough. A variety of devices are used to carry out manometry including air-filled [556] [557] and water-filled balloons, water-perfused catheters, catheter-mounted pressure transducers (also known as microtips and solid state catheters). [558] In 1983, Schouten and Vroonhoven described a simple system of anorectal manometry. [559] Even a simple tube system can give measurements of pressure in the anal canal. [560]

Devices for anal manometry can be single or multi-channelled with sensors arranged radially and/or longitudinally along the length of the catheter. In many instances, the device measuring pressure in the anal canal also has a balloon at its tip which can be placed in the rectum, inflated and the effect on the anal sphincters assessed.

The performance of many of the different systems have been compared [561, 562] and different measurements can be obtained with the different devices. Size and stiffness of catheter, rate of perfusion of water-perfused systems, orientation of sensors within the anal canal can all affect the measurement of pressure. [563] Some comparison between air-charged balloons, solid state systems and water-perfused catheters have shown minimal differences in pressure measurements. [564]

A study in 1998 showed that a water-perfused catheter

and a rectosphincteric balloon gave equivalent values of pressure (in 10 patients). [565]

A 'historical' state-of-the-art perspective of anal manometry was carried out in 1993 by Meunier and Gallavardin. [566] They discussed the methods of recording anorectal pressures with perfused catheters, sleeve catheters, water- or air-filled balloon catheters and microtransducers. They then discussed routine anorectal manometry and the parameters resulting from this investigation. The manometric findings in constipation in adults and children, in incontinence and in the descending perineum syndrome were presented and the usefulness of anorectal manometry in surgical and various conditions was discussed.

a) Units of pressure in anal manometry

There is no universal standard for units of pressure in anal manometry. These can be cm H_2O, mm Hg or kPa. Although it would be convenient to have a standard unit of measurement, conversion from one unit to another is trivial and it could be argued that a standard is not absolutely necessary. However, when authors quote values without units of measurement in even the abstract of their work [567], there is a strong argument for having a standard because without a standard, recognised unit, parameters quoted without units are meaningless.

In this chapter, pressure values will be cited in the units originally published by the authors.

b) Position for manometry

Traditionally, manometry is performed in the left lateral position. However, there are significant differences in the pressures of patients when placed in the erect position [568] and, because these measurements correlate better with symptom severity, the authors postulate that manometry may be more physiological than in any other position, particularly because most patients have their symptoms when ambulating.

Nevertheless, currently most manometry continues to be performed with the patient lying in the left-lateral position

2. RESTING PRESSURE

Pressures are recorded along the length of the anal canal with the patient at rest. As mentioned previously, the resting pressure within the anal canal arises from both internal and external anal sphincter activity; with the former thought to contribute the majority of the tone (between 50%-85% of the total). Therefore, measurement of the maximum resting pressure in the anal canal is thought to be indicative of internal sphincter function. It can be measured relative to atmospheric pressure or relative to rectal pressure (as is also encountered when measuring maximum pressure in the urethra) and, amongst others, it can be termed as 'maximal resting pressure', 'basal anal pressure', 'maximum resting anal pressure'. The term 'rectoanal pressure gradient' is also used but it is most frequently used to describe the pressure difference between the rectum and anal canal on defaecatory manoeuvres.

a) Reproducibility of resting pressure

In 1989, Rogers et al studied 16 subjects (mean (s.d.) age 50.7 (12.8) years, three men) on two separate occasions by two experienced investigators in random order. No significant differences were found between the results obtained by the two investigators in the measurements of anal canal length, and canal resting pressure and squeeze pressure. [569]

In a study of 10 healthy individuals in 1998, measurement of resting pressure was shown to be reproducible on occasions four hours apart and four days apart. [570] A small study of 6 women suggested that resting pressure was not affected by the menstrual cycle. [571] Goke et al demonstrated in 12 healthy volunteers that the day to day intraindividual variability of resting pressure was 13.5 % (which was considered to be relatively low). [572]

In1991, Ekhardt and Elmer looked at the reproducibility of sphincter pressure and length on three different days in 10 male and 10 female healthy subjects with the use of a pneumohydraulic capillary perfusion system. There was complete agreement between both observers in the analysis of anal resting pressure. The pressure profiles from different days correlated significantly ($p < 0.01$) with each other regardless of whether the studies were performed in the prepared or unprepared bowel. [573]

In 2004, Bharucha et al assessed the intra-individual day-to-day reproducibility of resting pressures in 19 healthy subjects and judged that they were highly reproducible on the basis of a value of $r \geq 0.7$. [574]

In 1997, Ryhammer et al showed in 58 healthy females that the mean difference for maximum anal resting pressure was 2.2 (95% confidence interval: -3.5 - 7.8) cm H_2O. They concluded that there was no systematic variation in the repeated measurements however, the nonsystematic variation was generally large. [575]

b) Normal values of resting pressure

Although there are some publications containing normal values for anal manometry, these are only specific for the type of manometer being used and how the manometric parameters were recorded. Therefore they cannot be universally applied.

Often they just include a small number of subjects (e.g. a recent determination of the normal ranges for manometry and balloon expulsion and rectal sensation determined in Thai men and women comprised 17 men and 13 women). [576] The mean resting pressure in this group of healthy Thai adults was 55.4 mm Hg

(1SD, 15.3 mm Hg). The measurements of resting pressure were similar in both men and women.

In 1987 McHugh and Diamant, using a multilumen continuously perfused catheter and a mechanized rapid pull-through technique, studied anal pressures in 143 incontinent patients and a control population of 157 healthy subjects. [577] In 10 male volunteers, pressures were determined using catheters that varied from 3 mm to 18 mm in diameter. In the control population, the resting anal pressure was significantly lower in females 40 years of age and over as compared to males. In women, parity did not correlate with resting anal pressure but aging was associated with a consistent reduction in resting anal pressure. In males, there was a similar but less impressive age-related reduction for resting anal pressure. A linear increase in resting anal pressures was recorded as catheter diameter increased from 3 to 12 mm. Normative data for the resting anal pressures are shown in **table 10**.

In 1992, Cali measured resting pressures in normal volunteers; 20 males, 21 nulliparous females and 18 multiparous females. The resting pressures were similar between males and nulliparous females; the nulliparous females had higher resting pressures than the multiparous females. [578]

In 2007, Chaliha et al reported that 95% of resting pressures in 286 healthy women in the third trimester of their first pregnancy were between 29-90 mm Hg. 12 weeks after delivery 161 of these women returned for re-evaluation and 95% of these resting pressures were between 27–98 mm Hg (with similar values between those who had bowel problems and those who did not). [579].

In 1998, Wong et al produced normal values of resting pressure from 11 normal subjects. [550] In 1994 Sultan et al reported the normal values of resting pressure for 93 nulliparous women and 21 healthy men. [580]

In 1994 Benninga et al carried out some studies of resting pressure in 13 healthy children. [581]

In 1991, Felt-Bersma et al produced normal values of resting pressure for 40 men and 40 women aged 20-87 with a perfused catheter system. The mean maximum basal pressure for the men was 68 mm Hg (1SD 21 mm Hg) and for the women was 63 mm Hg (1SD 19 mm Hg). There was no significant difference between the two however, the maximum basal pressure decreased significantly with age. [582]

In 1986 Gibbons et al studied resting pressure in 14 normal males and 11 normal females using probes of between 0.4 and 3 cm in diameter. The larger the probe, the higher the pressure.[583]

Normal values of resting pressure were tabulated in a 1999 review of anorectal testing techniques. [584] These are reproduced in **Table 10** along with a set of more recent data.

c) Sensitivity and specificity of resting pressure

The previous consultation noted that although resting pressure was lower in faecally incontinent patients, there was poor sensitivity to distinguish between continent and incontinent individuals [577, 591].

In 1987, McHugh and Diamant showed that although resting anal pressure was lower in 143 incontinent patients compared to a control population of 157 healthy subjects, 39% of incontinent females and

Table 10. Normal values of maximum resting pressures in the anal canal

Technique	Women	Age (years)	n	Men	Age (years)	n	Year	Ref
Station pull-through	58 (±3)		22	66 (±6)		15	1979	[585]
	50 (±13)		18	63 (±12)		18	1985	[586]
	54 (±5)		12	-	-	-	1991	[587]
	49 (±3)		12	49 (±3)		7	1995	[588]
	59 (20-99)	Antenatal	286				2007	[579]
Slow pull-through	46 (40-58)		35	60 (51-98)		23	1989	[589]
Rapid pull-through	100 (±22)		10	-	-	-	1984	[590]
	106 (±18)		10	-	-	-	1984	[590]
	102 (±19)	20-39	35	100 (±21)	20-39	27	1987	[577]
	76 (±24)	40-69	40	97 (±20)	40-69	31	1987	[577]
	53 (±22)	≥ 70	17	72 (±23)	≥ 70	3	1987	[577]

The values are expressed as means in units of mm Hg with either the SEM or the range in parantheses.

44% of incontinent males fell within the 'normal' range. [577]

In 1995, Penninckx et al compared 'conventional' anal manometry in 27 control subjects (M:8, F:19; mean age: 47 yr) and in 40 incontinent patients (M:5, F:35; mean age: 49 yr). Discriminatory values of > 40 mmHg for maximum basal pressure could identify continent patients with 96%, and incontinent patients with 88% accuracy. [592]

In 1999, Osterberg et al compared maximum resting pressure in 156 patients with faecal incontinence (mean age 63 yr; 139 women, 17 men) and 25 healthy controls (mean age 54 yr; 20 women, five men) using a perfused catheter with a station pull-through technique. Although maximum resting pressure was higher in the continent group, there was not sufficient sensitivity and specificity to consider it as a diagnostic test. [593]

There has been no further evidence to dispute this although it has been suggested, in a reasonably sized study of 80 continent patients and 47 patients with idiopathic faecal incontinence that resting pressure gradient may be a more sensitive and specific discriminator than resting pressure itself. [594] However a study, 3 years earlier, in 22 individuals with normal faecal control and 36 patients with faecal incontinence suggests that resting pressure gradient is no better a discriminator than maximum resting pressure. [595]

Interestingly, Lejeune et al found that basal anal pressure had as good a sensitivity (77.2% and specificity (82%) as cardiac criteria in assessing diabetic autonomic neuropathy [596]

d) Resting pressure's sensitivity to change

In 1986, Holmstrom et al showed that in 11 patients who had a Ripstein operation for procidentia, the mean maximum anal resting pressure increased from 39 to 55 mm Hg ($p = 0.01$). [597]

In 1991, Sainio et al studied 28 patients who underwent transabdominal repair of rectal prolapse. In the 22 patients who were incontinent prior to the procedure, they demonstrated an increase in resting anal pressure in those who achieved continence after the procedure. [598]

In 1993, Kushwaha et al showed that resting anal pressure decreased 6 months after radiotherapy of the prostate and bladder [599]

Also in 1993, Church et al showed measurable changes in resting pressure following ileal pouch-anal anastomoses in 134 patients and coloanal anastomoses in 16 patients. [600]

In 2003, Norton et al showed in a randomised study to assess the effect of biofeedback, that resting pressure improved in 171 patients with faecal incontinence; irregardless of what conservative therapy they received. These improvements were largely maintained 1 year after finishing treatment. [601]

In 2004, Torrabadella et al showed that Sildenafil reduced the resting pressure of patients with chronic anal fissure. [602]

Also in 2004, Yeoh et al showed that in 38 patients who had radiation therapy for localized carcinoma of the prostate showed progressive reductions of basal anal pressures up to 2 years following the treatment and this was associated with an increase in bowel frequency, urgency and faecal incontinence. [603]

Again in 2004, Martinez-Puente Mdel et al evaluated biofeedback for treating faecal incontinence in 53 patients. Maximum anal resting pressures significantly increased after therapy. [604]

In 2005, Ram et al found that there were changes in basal resting pressure up to a year after lateral sphincterotomy for anal fissure. 50 patients with anal fissure were included in this study and underwent sphincterotomy; 12 healthy patients served as controls. All patients were examined 1 month before surgery and 1, 3, 6, and 12 months following surgery. The control group had 3 manometric evaluations 6 months apart. They showed that the mean basal resting pressure before surgery was 138 ± 28 mm Hg. One month after surgery, the pressure dropped to 86 ±15 mm Hg ($p < 0.0001$) and gradually rose to a plateau at 12 months (110 ± 18 mm Hg, $p < 0.0001$). At 12 months, the manometric pressure was significantly lower than the baseline ($p < 0.0001$). However, manometric measurements in the fissure group were still significantly higher than in the control group (110 ± 18 versus 73 ± 4.8 mm Hg, $p < 0.0001$). All patients were free of symptoms at the 12-month follow-up. They concluded that lateral internal sphincterotomy caused a significant decline in the resting anal pressure. During the first year following surgery, the tone of the internal anal sphincter gradually increased, indicating recovery, but still remained significantly lower than before surgery. However, postoperative resting pressures were higher than those in the control group, and no patient suffered any permanent problems with incontinence, so this decrease may not be clinically significant. [605]

In 2005, Alper et al extended the above report to include resting pressures in 38 patients with third-degree or fourth-degree symptomatic haemorrhoids who underwent haemorrhoidectomy in addition to the 50 patients with anal fissure who underwent sphincterotomy, and 12 healthy patients who served as controls. Before surgery, the resting pressure in the fissure group was significantly higher than in the haemorrhoid group, which was significantly higher than in the control group (138 ± 28.4 mm Hg vs. 108.4 ± 23 mm Hg vs. 73 ± 5.9 mm Hg, $p< 0.0001$). Twelve

months after surgery, anal resting pressure was significantly lower than the baseline measurements in both the fissure (110 ± 18.2 vs. 138 ± 28.4, p< 0.0001) and haemorrhoid groups (103.6 ± 21.5 vs. 108 ± 23, p< 0.0001), but both remained higher than the control group (103.6 ± 21.5 mm g vs. 73 ± 5.9 mm g, p< 0.0001). [606]

In 2006, Lovegrove et al conducted a meta-analysis of stapled versus hand-sewn ileal pouch anal anastomosis (IPAA) following restorative procto-colectomy published between 1988 and 2003. This comprised 4183 patients (2699 hand-sewn and 1484 stapled IPAA). Anorectal physiological measurements demonstrated a significant reduction in the resting pressure in the hand-sewn IPAA group by 13.4 mm Hg, with the stapled IPAA group having improved nocturnal continence, which was reflected in a higher anal pressure. [607]

In 2007, Toyonaga et al showed that maximum resting pressure significantly decreased following fistulotomy for intersphincteric fistula-in-ano in a prospective study of 148 patients. [608]

In 2008, Brisinda et al treated 80 patients with botulinum toxin for recurrent anal fissure following lateral internal sphincterotomy. Anorectal manometry at 1 month demonstrated a significant reduction in resting pressure. [609]

e) Does resting anal pressure predict outcome of intervention?

In 1993, Church et al, showed that pre-operative resting pressure was not predictive of continence following IPAA in 134 patients and coloanal anastomoses in 16. [600]

In a retrospective study in 1999, Hool et al found that preoperative resting pressure did not predict faecal continence following sphincter repair in 51 patients.

In 2000, Stadelmaier et al determined the clinical and physiologic parameters enabling the prognosis of continence after protective ileostomy closure secondary to rectal resection for rectal cancer. 65 patients who had undergone rectal resection (of whom 24 had had radiochemotherapy) were evaluated by clinical examination, anorectal manometry and orthograde contrast enema before ileostomy closure (baseline). Continence was evaluated by clinical findings 91 ± 52 weeks after stoma closure with the help of standardised questionnaires and classified according to the Wexner continence score. Correlations were found to be significant between the continence score and the level of anastomosis ($r = -0.58$, $p < 0.001$), median baseline resting pressure ($r = -0.52$, $p < 0.001$), and baseline rectal compliance ($r = -0.43$, $p < 0.001$). Additionally, radiochemotherapy impairs continence ($p = 0.0001$). Correlations were not significant between continence and baseline functional sphincter length, squeeze pressure, threshold for perception, urge and maximal tolerable volume, and continence for semiliquid contrast medium. Based on these findings, the continence score can be calculated before closure of a diverting ileostomy by applying multivariate analysis with the help of the following formula: Continence score = 18.23 - 0.94 x level of anastomosis - 0.18 x resting pressure + 3.72 x radiochemotherapy. [610]

In 2001, Mylonakis carried out a prospective study in 100 patients who had different types of surgery for various types of anal fistulae. The type of fistula and the preoperative anal pressures determined the operative procedure that was used. Six patients had some soiling postoperatively and 3 patients had impaired control of flatus. On the basis of this, the authors concluded that preoperative anal manometry is important in deciding the operative procedure for fistula surgery [611]

Also in 2001, Herman studied 33 patients with small, mobile rectal tumors (adenoma and carcinoma) undergoing transanal endoscopic microsurgery. They underwent anorectal motility studies (using pull-through anorectal manometry and rectal barostat) and endoanal ultrasound prior to surgery and 3 weeks and 6 months after TEM; controls were 20 healthy volunteers. The main risk factors of anorectal dysfunctions following TEM included: postoperative internal anal sphincter defects, low preoperative resting anal pressure, disturbed rectoanal coordination, extent (>50% of wall circumference) and the depth (full thickness) of tumor excision. They concluded that preoperative anorectal motility studies and anal ultrasound allow the identification of patients with the risk of postoperative anorectal dysfunctions. [612]

In 2002, Halverson et al prospectively measured perioperative resting pressures in 1439 patients undergoing ileal pouch-anal anastomosis. Posto-perative functional status was assessed at various time intervals from 6 months to 8 years after the procedure. They found that perioperative resting anal sphincter pressures greater than 40 mm Hg were associated with significantly better function and quality of life after the procedure. However, a low perioperative resting pressure (< 40 mm Hg) did not preclude a successful outcome. [613]

In 2004, Pescatori found that preoperative resting pressure did not predict continence following fistulectomy in 38 males. [614]

Prather, in a review in 2004 concluded that few physiological parameters have been consistently identified as important in predicting response to either biofeedback or surgery. He states that the process of isolating these factors has been hampered by heterogeneity in the definition of fecal incontinence, lack of consensus on what constitutes a successful

outcome, lack of follow-up data, variations in the way 'standard' treatments are implemented, and lack of properly powered randomized controlled trials. Factors that have not been found to be important in predicting outcome following biofeedback retraining include pudendal nerve damage and pretreatment anal canal pressures. The presence of some degree of anorectal sensation is the only preoperative assessment that has been found to be predictive of response to surgical therapy. [615]

In 2005, Gearhart et al studied 20 women, 29 to 84 years of age (mean age 50 years), with severe fecal incontinence and large (>or=50%) sphincter defects on ultrasound. All underwent an overlapping sphincter repair following anal manometry (mean resting pressure, mean squeeze pressure, anal canal length, compliance) and pudendal nerve terminal motor latency (PNTML) testing but none of these parameters was able to predict outcome following sphincteroplasty. [616]

In 2006, Glasgow et al showed that mean resting pressure measured preoperatively in 45 patients undergoing perineal proctectomy for rectal prolapse was not predictive of continence postoperatively. [617]

In 2007, Toyonaga et al showed that maximum resting pressure was not predictive of developing postoperative incontinence following fistulotomy for intersphincteric fistula-in-ano in a prospective study of 148 patients. [608]

In 2007, Pascual et al found that resting anal pressure was unable to predict success of pharmacological treatment of anal fissure in 124 patients. [618]

f) Comparison of measurement of resting pressure with digital examination

In 1989, Hallan et al compared digital examination and manometric evaluation in 66 patients and controls. There was good correlation between digital basal score and maximum basal pressure. The sensitivities and specificities of each assessment were similar in separating incontinent from continent individuals and they concluded that digital estimation was equally as good as assessment of anal sphincter function as anal canal manometry. [619]

In 1993, Siproudhis et al evaluated 50 patients (38 females and 12 males; mean age, 44.7 +/- 15 years) who complained of defaecatory difficulties to determine the accuracy of the clinical examination in diagnosing and quantifying pelvirectal abnormalities. Each parameter was then compared with the features of anorectal manometry and evacuation proctography performed by two independent observers. When compared with anal manometry, digital assessment was able to quantify resting and squeeze pressures and length of the anal canal with excellent correlation and good global agreement as well as predicting a short or hypotonic anal canal. [620]

In 1994, Herbst and Teleky showed that digital rectal examination preceding measurement of maximum resting pressure in 64 incontinent individuals and 14 controls caused unpredictable results, especially in patients with lower maximum resting pressures, and concluded that this practice should strictly be avoided. [621]

In 1998, Buch et al compared digital and manometric assessment of anal sphincter function in 191 patients who were divided into three groups: control, obstructive defaecation and faecal incontinence. A significant correlation was established between the digital and manometric tone assessments, both at rest and at squeeze. Digital assessment was found to be more sensitive but less specific than manometry in differentiating between faecal continence and incontinence. They concluded that digital examination is not an adequate substitute for anorectal manometry, but is a reasonable option where manometry is unavailable [622]

In 2005, Jones et al studied 40 consecutive patients (21 male) with chronic anal fissure. Twenty-two had normal maximum resting pressure on anal manometry and a further 3 had low pressures on anal manometry. On digital assessment, only five patients were evaluated as having no anal hypertonia. Digital assessment of anal tone correctly identified 14 of 15 patients with high manometric maximum resting pressure (STV, 93%), yet detected only 4 of 25 patients with normal or low pressures (SPT, 16%). The PPV of clinical assessment of anal tone was 40% and the NPV, 80%. Therefore, digital examination poorly correlated with manometric findings. [623]

In 2007, Dobben et al prospectively compared digital rectal examination with anal manometry and endoanal ultrasonography in 312 patients with faecal incontinence; 90% were females. Regarding resting pressure, they found that absent, decreased and normal resting pressures at rectal examination correlated to some extent with mean (±SD) resting pressures of 41.3 (±20), 43.8 (±20) and 61.6 (±23) mm Hg ($p<0.001$) respectively. They concluded that digital rectal examination can give accurate information about internal anal sphincter function. [624]

Conclusions (evidence level 3)

- Measurement of resting pressure in the anal canal is a parameter produced by devices of different type and size. There is no standardisation regarding how the measurement is made nor is there any universal agreement as to what unit of pressure should be used.
- In many hands the measurement is reproducible and sensitive to change following intervention.
- However, it is not of sufficient sensitivity and specificity to distinguish individuals with normal anal continence from those with anal incontinence.

- There is little evidence that it is has any prognostic power regarding the outcome of intervention.
- It gives a more sensitive indication of anal tone than digital examination

Recommendation (grade C)

- That this parameter continues to be used clinically in those situations where an objective measure of resting tone will help in the management of a patient with faecal incontinence.
- That consideration is given to some degree of standardisation in the measurement of this parameter.

3. HIGH PRESSURE ZONE AND ANAL CANAL LENGTH

The lower GI tract analogue of the "functional urethral length" is the "functional anal canal length" or "length of the high pressure zone (HPZ)". Rink et al defined this as the length of the anal canal which exerts at least 50% of the maximum resting pressure. [625] However, there is not universal agreement regarding this definition.

In 2006, Liu et al measured the HPZ in 17 asymptomatic nulliparous women and found it to be 39 (±1) mm in length. [626]. In 1989, Pedersen et al measured the physiological variation in this parameter in 78 healthy volunteers and found the maximum variation to be 10 mm with a 95% confidence interval of 4 mm. [589] Although they found higher resting and squeeze pressures in males, there was no gender difference in the length of the high pressure zone.

Although some workers have measured this parameter, it has not generally proved to be of any more value than the resting pressure.

However, in 1999, Yamana et al did show that, amongst other parameters, a longer preoperative HPZ was associated with better defaecatory function six months after low anterior resection for rectal cancer in 32 patients. [627]

Also in 1999, Hool et al carried out a retrospective review of the manometeric data of 51 patients having a sphincter repair. Following data entry into a logistic regression model, postoperative anal canal length was highly significant in predicting postoperative continence. [628]

Again in 1999, Osterberg et al compared the length of the high pressure zone in 156 patients with faecal incontinence (mean age 63 yr; 139 women, 17 men) and 25 healthy controls (mean age 54 yr; 20 women, five men) using a perfused catheter with a station pull-through technique. Although the high pressure zone was longer in the continent group, there was not sufficient sensitivity and specificity to consider it as a diagnostic test. [593]

In1991, Ekhardt and Elmer looked at the reproducibility of sphincter pressure and length on three different days in 10 male and 10 female healthy subjects with the use of a pneumohydraulic capillary perfusion system. There was complete agreement between both observers in the analysis of sphincter length but anal sphincter length varied greatly on different days. [573]

In 2007, Toyonaga et al showed that the length of the high pressure zone significantly decreased following fistulotomy for intersphincteric fistula-in-ano in a prospective study of 148 patients but it was not predictive of developing postoperative incontinence. [608]

In 2008, Rink et al showed in 61 patients having restorative proctocolectomy for ulcerative colitis that the HPZ at rest using vector manometry (see later) only had a sensitivity of 63.6% and a sensitivity of 59.1% for predicting incontinence after the procedure. [625]

Conclusions (evidence level 3/4)

- Measurement of manometric sphincter length in the anal canal is an unstandardised measurement which has been considered by relatively few investigators.
- It is not of sufficient sensitivity and specificity to distinguish individuals with normal anal continence from those with anal incontinence.
- There is little evidence that it is has any prognostic power regarding the outcome of intervention.

Recommendation (grade C)

- That the manometric length of the anal sphincter is not a clinically useful parameter.

4. PRESSURE ON VOLUNTARY CONTRACTION

Measurement of the maximum pressure in the anal canal on voluntary contraction is taken to be a measure of external anal sphincter function. Careful observation of the patient during this manoeuvre is essential to ensure that the patient has understood what is required and is using the appropriate muscle group (which is seen as an upward and inward movement of the anal region). Many patients will inappropriately use their gluteal muscles during this manoeuvre; others will tend to "bear down" instead of "squeezing". Achieving the correct manoeuvre, whilst remaining fairly still, is essential for a valid measurement. Nevertheless, it is also important to appreciate that even when the patient carries out the correct manoeuvre, there can be movement of the catheter; resulting in an erroneous

pressure reading. In essence, whilst the measurement of resting pressure within the anal canal is a fairly robust measure, the accurate measurement of pressure during voluntary contraction is beset by practical difficulties.

Pressure during voluntary contraction can be measured relative to atmospheric pressure and relative to rectal pressure. It can also be measured relative to the resting pressure at the corresponding location along the anal canal. Different terms have been used to describe pressure on voluntary contraction such as 'maximal squeeze pressure', 'incremental squeeze pressure', 'maximal voluntary squeeze', 'maximum squeeze pressure and 'maximum voluntary contraction pressure'. It can be measured in units of cm H_2O, mm Hg or kPa. There is no universal standard for these measurements.

a) Reproducibility of squeeze pressure

In 1989, Rogers et al studied 16 subjects (mean (s.d.) age 50.7 (12.8) years, three men) on two separate occasions by two experienced investigators in random order. No significant differences were found between the results obtained by the two investigators in the measurements of squeeze pressure. [569]

In1991, Ekhardt and Elmer looked at the reproducibility of sphincter pressure and length on three different days in 10 male and 10 female healthy subjects with the use of a pneumohydraulic capillary perfusion system. There was complete agreement between both observers in the analysis of squeeze pressure. The squeeze pressures on different days correlated significantly ($p<0.01$) with each other regardless of whether the studies were performed in the prepared or unprepared bowel. [573]

In 1992, Goke et al demonstrated in 12 healthy volunteers that the intraindividual day-to-day variability of maximal squeeze pressure was 17.3% (which was considered to be relatively low). [572]

In a small study of 6 healthy women in 1994, Schnegg et al showed that pressure on contraction was not markedly affected by the menstrual cycle. [571]

In 1997, Ryhammer et al showed in 58 healthy females that the mean difference for maximum anal squeeze pressure was -1 (95% confidence interval: -6.5 - 4.5) cm H_2O. They concluded that there was no systematic variation in the repeated measurements however, the nonsystematic variation was generally large. [575]

In 1998, Freys et al showed that in 10 healthy volunteers, maximum squeeze pressure was not reproducible on occasions 4 hours apart and four days apart. [570]

In contrast, Bharucha assessed the intra-individual day-to-day reproducibility of squeeze anal pressures in 19 healthy subjects in 2004 and judged that they were highly reproducible on the basis of a value of $r \geq 0.7$. [574]

b) Normal values of pressure on voluntary contraction

Although there are some publications containing normal values for anal manometry, these are only specific for the type of manometer being used and how the manometric parameters were recorded. Therefore they cannot be universally applied.

Often they just include a small number of subjects (e.g. a recent determination of the normal ranges for manometry and balloon expulsion and rectal sensation determined in Thai men and women comprised 17 men and 13 women). [576] The mean squeeze pressure in this group of healthy Thai adults was 170.3 mm Hg (1SD, 81.7 mm Hg). However, the measurements of squeeze pressure were greater in men than in women.

In 1987 McHugh and Diamant, using a multilumen continuously perfused catheter and a mechanized rapid pull-through technique described the resting and squeeze pressures in 143 incontinent patients and a control population of 157 healthy subjects. [577] In the control population, maximum squeeze pressures were significantly lower in females compared to men at virtually all ages. In women, parity did not correlate with maximum squeeze pressure but aging showed a consistent reduction in maximum squeeze pressure. In men there was no change in maximum squeeze pressure with age. The normal values for maximum squeeze pressure are summarised in **table 11** and shows that maximum squeeze pressure decreases with age in females but not males. Parity does not affect the maximum squeeze pressure.

In 1992, Cali measured pressures in 20 males, 21 nulliparous females and 18 multiparous females. The squeeze pressures were greater in the males compared to both the female groups. [578]

In 2007, Chaliha et al reported that 95% of squeeze pressures in 286 healthy women in the third trimester of their first pregnancy were between 50-163 mm Hg. 12 weeks after delivery 161 of these women returned for re-evaluation and 95% of these resting pressures were between 43–156 mm Hg (with similar values between those who had bowel problems and those who did not). [579].

In 1994 Sultan et al reported the normal values of squeeze pressure for 93 nulliparous women and 21 healthy men. [580]

In 1994 Benninga et al carried out some studies of squeeze pressure in 13 healthy children. [581]

In 1991, Felt-Bersma et al produced normal values of squeeze pressure for 40 men and 40 women aged 20-87 with a perfused catheter system. The mean

maximum squeeze pressure for the men was 183 mm Hg (1SD 73 mm Hg) and for the women was 102 mm Hg (1SD 36 mm Hg). There was a significant difference between the sexes ($p<0.001$) and squeeze pressure decreased significantly with age ($p<0.001$) in both men and women. [582]

In 1986 Gibbons et al studied squeeze pressure in 14 normal males and 11 normal females using probes of between 0.4 and 3 cm in diameter. The larger the probe, the higher the squeeze pressure.[583]

Normal values of squeeze pressure were tabulated in a 1999 review of anorectal testing techniques. [584] These are reproduced in **Table 11** along with a set of more recent data.

c) Sensitivity and specificity of squeeze pressure

The previous consultation noted that although squeeze pressure was lower in faecally incontinent patients, there was poor sensitivity to distinguish between continent and incontinent individuals [577, 591].

In 1987, McHugh and Diamant showed that although maximum squeeze pressure was lower in 143 incontinent patients compared to a control population of 157 healthy subjects, 39% of females and 44% of males fell within the "normal" range. [577]

In a study of anal manometry on 350 patients, 178 of whom had fecal incontinence and 172 of whom were continent and 80 control subjects, Felt-Bersma et al showed in 1990 that incontinent patients had lower anal sphincter pressures during squeeze compared to continent individuals. Although differentiation between incontinent and continent patients was not possible with a single test because there was complete overlap, they found that maximum squeeze pressure had a better sensitivity and specificity for identifying faecal incontinence than resting pressure. [629]

In 1995, Penninckx et al compared "conventional" anal manometry in 27 control subjects (M:8, F:19; mean age: 47 yr) and in 40 incontinent patients (M:5, F:35; mean age: 49 yr). Discriminatory values of > 92 mmHg for squeeze pressure could identify continent patients with 96%, and incontinent patients with 88% accuracy. [592]

In 1999, Osterberg et al compared maximum squeeze pressure in 156 patients with faecal incontinence (mean age 63 yr; 139 women, 17 men) and 25 healthy controls (mean age 54 yr; 20 women, five men) using a perfused catheter with a station pull-through technique. Although maximum squeeze pressure was higher in the continent group, there was not sufficient sensitivity and specificity to consider it as a diagnostic test. [593]

d) Pressure on voluntary contraction's sensitivity to change

In 1991, Sainio et al studied 28 patients who underwent transabdominal repair of rectal prolapse. In the 22 patients who were incontinent prior to the procedure, they demonstrated an increase in voluntary contraction pressure in those who achieved continence after the procedure. [598]

In 1993, Kushwaha et al showed that incremental squeeze pressure decreased 6 months after radiotherapy of the prostate and bladder [599]

In 2003, Norton et al showed in a randomised study to assess the effect of biofeedback, that squeeze pressures improved in 171 patients with faecal incontinence; irregardless of what conservative therapy they received. These improvements were largely maintained 1 year after finishing treatment. [601]

Table 11. Normal values of maximum squeeze pressures in the anal canal

Technique	Women	Age (years)	n	Men	Age (years)	n	Year	Ref
Station pull-through	135 (±15)		22	218 (±18)		15	1979	[585]
	159 (±45)		18	238 (±38)		18	1985	[586]
	90 (±9)		12	-	-	-	1991	[587]
	106 (45-216)	Antenatal	286				2007	[579]
Slow pull-through	103 (78-190)		35	163 (76-234)		23	1989	[589]
Rapid pull-through	179 (±55)		10	-	-	-	1984	[590]
	159 (±35)		10	-	-	-	1984	[590]
	171 (±40)	20-39	35	240 (±65)	20-39	27	1987	[577]
	132 (±169)	40-69	40	203 (±45)	40-69	30	1987	[577]
	116 (±40)	≥ 70	17	219 (±32)	≥ 70	3	1987	[577]

The values are expressed as means in units of mm Hg with either the SEM or the range in parantheses.

Similarly in 2004, Again in 2004, Martinez-Puente Mdel et al evaluated biofeedback for treating faecal incontinence in 53 patients. Maximum anal squeeze pressure significantly increased after therapy. [604]

In 2004, Yeoh et al showed that in 38 patients who had radiation therapy for localized carcinoma of the prostate showed progressive reductions of anal squeeze pressures up to 2 years following the treatment and this was associated with an increase in bowel frequency, urgency and faecal incontinence. [603]

In 2006, Leung et al showed in 12 children who completed a programme of electrical stimulation and biofeedback exercise of pelvic floor muscle for children with faecal incontinence after surgery for anorectal malformation that there was a significant improvement in faecal soiling 1 year after treatment and a significant increase in anal sphincter squeeze pressure of 29.9 mmHg (p = 0.007). [630]

Also in 2006, Lovegrove et al conducted a meta-analysis of stapled versus hand-sewn IPAA) following restorative proctocolectomy published between 1988 and 2003. This comprised 4183 patients (2699 hand-sewn and 1484 stapled IPAA). Anorectal physiological measurements demonstrated a significant reduction in the squeeze pressure in the hand-sewn IPAA group by 14.4 mm Hg, with the stapled IPAA group having improved nocturnal continence, which was reflected in the higher anal pressure. [607]

In 2008 Singh et al conducted a prospective randomized controlled trial for treatment of postoperative pain in 32 patients undergoing haemorrhoidectomy. Patients were given an inter-sphincteric injection of either placebo or botulinum toxin (150 units). Maximal squeeze pressure was significantly lower in the botulinum toxin group at weeks six and twelve (mean 87.1 mmHg; 95% CI 66.9 - 107.1) compared to the placebo group (mean 185.8 mmHg; 95% CI 134.2 - 237.4) at week twelve (p=0.0014). [631]

Also in 2008, Brisinda et al treated 80 patients with botulinum toxin for recurrent anal fissure following lateral internal sphincterotomy. Anorectal manometry at 1 month demonstrated a significant reduction in maximum voluntary squeeze pressure. [609]

Again in 2008, Munasinghe et al carried out on audit of biofeedback in 50 patients with faecal incontinence. They showed significant increases in maximal squeeze pressure. [632]

e) Does voluntary squeeze pressure predict outcome of intervention?

As detailed in section 2e, Stadelmaier et al determined the clinical and physiological parameters enabling the prognosis of continence after protective ileostomy closure secondary to rectal resection for rectal cancer. There were no significant correlations between continence and baseline squeeze pressure. [610]

As detailed in section 2e, Prather, in a review in 2004 concluded that pretreatment pressures in the anal canal are not important in predicting response to either biofeedback or surgery. [615]

As detailed in section 2e, Gearhart et al found that mean squeeze pressure was unable to predict outcome following sphincteroplasty in 20 women with severe faecal incontinence. [616]

In 2006, Glasgow et al found in 45 patients that squeeze pressures >60 mm Hg preoperatively were a good indicator of post-operative continence following perineal proctectomy for rectal prolapse. However, abnormalities of pudendal nerve function and mean resting pressures were not predictive of postoperative incontinence. [617]

In 2008, Dobben et al attempted to develop an efficient diagnostic strategy for patients with faecal incontinence to identify subgroups that may benefit from pelvic floor physiotherapy. They studied 281 consecutive patients with faecal incontinence (mean age 59 years), 252 were female. All patients were then offered standardised pelvic floor physiotherapy. A high maximal squeeze pressure by anorectal manometry was associated with a positive treatment outcome but was not a strong predictor. [633]

In the same year, the authors from this study, together with many others, reported on 250 consecutive patients (228 women) who underwent medical history and a standardized series of tests, including physical examination, anal manometry, pudendal nerve latency testing, anal sensitivity testing, rectal capacity measurement, defaecography, endoanal sonography, and endoanal magnetic resonance imaging. Subsequently, patients were referred for pelvic-floor rehabilitation. In addition to the baseline Vaizey score, three elements from medical history were significantly associated with a poor result (presence of passive incontinence, thin stool consistency, primary repair of a rupture after vaginal delivery at childbed). The predictive value was significantly but marginally improved by adding the following test results: perineal and/or perianal scar tissue (physical examination), and maximal squeeze pressure. They concluded that anorectal physiology studies have a limited role in predicting success of pelvic-floor rehabilitation in patients with fecal incontinence. [634]

f) Comparison of measurement of pressure on voluntary contraction with digital examination

In 1989, Hallan et al compared digital examination and manometric evaluation in 66 patients and controls. There were good correlations between digital squeeze score and maximum squeeze pressure. The sensitivities and specificities of each assessment were similar in separating incontinent from continent individuals and they concluded that digital estimation was equally as good as assessment of anal sphincter function as anal canal manometry. [619]

In 1991, Kaushal and Goldner carried out a digital and manometric determination of maximal anal squeeze pressure in 27 patients. Subjective digital assessment showed that three patients had absent squeeze pressure (grade 0); two patients had markedly reduced (grade +1); six patients had reduced (grade +2); and the remaining 16 patients had normal maximal squeeze pressure (grade +3). Simultaneous objective anal sphincter pressure measurements, when compared with these subjective values, revealed a correlation coefficient of 0.97 ($p < 0.05$). They concluded that the clinician can reliably use the digital rectal examination to voluntary anal sphincter contraction strength. [635]

However, Eckardt and Kanzler in 1993 showed considerable differences between the two methods of assessing voluntary anal contraction. [636].

In the same year Siproudhis et al evaluated 50 patients (38 females and 12 males; mean age, 44.7 ± 15 years) who complained of defecatory difficulties to determine the accuracy of the clinical examination in diagnosing and quantifying pelvirectal abnormalities (as detailed in section 2f). They found that digital assessment was able to quantify squeeze pressures with excellent correlation and good global agreement. [620]

As detailed in section 2f, Buch et al compared digital and manometric assessment of anal sphincter function in 191 patients who were divided into three groups: control, obstructive defaecation and faecal incontinence. They concluded that digital examination is not an adequate substitute for anorectal manometry, but is a reasonable option where manometry is unavailable [622]

In 2007, Dobben et al prospectively compared digital rectal examination with anal manometry and endoanal ultrasonography in 312 patients with faecal incontinence; 90% were females. Regarding squeeze pressure, they found that absent, decreased and normal squeeze pressures at rectal examination correlated to some extent with mean (±SD) incremental squeeze pressures of 20.6 (±20), 38.4 (±31) and 62.4 (±34) mm Hg ($p<0.001$) respectively. They concluded that digital rectal examination can give accurate information about external anal sphincter function [624]

g) Endurance and fatigability

Apart from measuring pressure at the height of a maximal contraction, some workers have assessed the voluntary sphincter squeeze endurance with mixed results.

The *consensus* statement of 1999 defined 'sphincter endurance' as the length of time the patient can maintain a squeeze pressure above the resting pressure. [637]

In 1993, Chiarioni et al studied anorectal sensorimotor function in 16 patients with liquid stool incontinence and severe urgency (10 with diarrhoea) unresponsive to conventional medical treatment, and in 16 healthy volunteers. The only significant difference found between incontinent patients and controls was a reduction in squeeze duration. Fourteen patients were selected to receive biofeedback treatment. Treatment was associated with a substantial improvement in continence in 12 patients and with a significant decrease in urgency ($p < 0.05$). Bowel frequency was not significantly influenced. Most patients showed a persistent improvement in anal motor function. Functional parameters were not predictive of outcome of treatment. [638]

In 1996, Rao et al showed that biofeedback therapy improved duration of squeeze in 19 patients with faecal incontinence. [639]

In a retrospective study in 1998, Marcello et al examined the records of 26 healthy volunteers, 33 patients with anal seepage, 75 patients with gross incontinence and 49 patients with severe constipation. For these patients they had calculated both fatigue rate (which is the slope of a linear regression line fitted to the declining pressure when the patient is instructed to contract for 40 seconds) and also the fatigue rate index (which is the projected time in minutes, from this linear regression line, for pressure to reach resting pressure). They showed that fatigue rate index was much shorter in the faecally incontinent group compared to the patients with severe constipation. [640]

In 1998, Mitrani et al showed that squeeze duration on manometry was better in 7 men with idiopathic faecal incontinence compared to 24 women with faecal incontinence of a similar age. [641]

In 1999, Rao et al showed that squeeze duration on manometry was better in healthy men compared to healthy women. [642]

Telford et al in 2004 showed differences in fatigue rate index between 42 incontinent patients and 20 continent controls. Fatigue rate and maximum squeeze pressure were not different between the two groups. [643]

In the same year, Martinez-Puente Mdel et al showed that maximum duration of anal squeeze improved following biofeedback therapy in 53 patients with faecal incontinence and this was matched by an improvement in both incontinence scores as well as the patient's subjective satisfaction. [604]

Work by Saad suggested that duration of squeeze might be a better distinguisher between normal and abnormal rather than resting or squeeze pressures. [644] However, Bilali and Pfeifer in 2005 [645] have more recently suggested that such measurements are not clinically useful in distinguishing normal from abnormal. However, they compared 96 faecal incon-

tinent patients with 35 patients who had chronic constipation and this may not be a valid comparison because patients with difficult defaecation may have this problem because of poor muscle function.

In 1997, Patankar et al showed that EMG-based biofeedback in 55 patients with chronic constipation and or faecal incontinence, sphincter endurance and net strength, as measured by noninvasive electromyography, significantly improved. [646]

Conclusions (evidence level 3)

- Measurement of pressure in the anal canal on voluntary contraction is a parameter produced by devices of different type and size. There is no standardisation regarding how the measurement is made nor is there any universal agreement as to what unit of pressure should be used.
- There is no conclusive evidence to show that the measurement is reproducible.
- In many hands the measurement is sensitive to change following intervention.
- However, most workers agree that it does not have sufficient sensitivity and specificity to distinguish individuals with normal anal continence from those with anal incontinence.
- There is little evidence that it is has any prognostic power regarding the outcome of intervention.
- It gives a more sensitive indication of anal pressure on voluntary contraction than digital examination
- There have been a few studies which have investigated the endurance or fatigability of the external anal sphincter on voluntary contraction. There is no consensus as to its ability to distinguish individuals with normal anal continence from those with anal incontinence. There is some evidence that it is sensitive to change following intervention.

Recommendation (grade C)

- That measuring pressure changes on voluntary contraction of the external anal sphincter continues to be used clinically in those situations where such an objective measure will help in the management of a patient with faecal incontinence.
- That consideration is given to some degree of standardisation in the measurement of this parameter.

- That further investigation is made of the clinical value of measuring the endurance of the external anal sphincter and, if appropriate, the optimum way of measuring it.

5. VECTOR MANOMETRY

Pressures, both at rest and on contraction, can be measured radially within the anal canal and symmetry indices calculated to quantify the degree of asymmetry of pressures around the anal canal. Vector volumes can also be calculated from these pressures along the anal canal. These measurements do not have a sound scientific basis to them because they are not measuring true sphincter pressures (because pressure is a scalar quantity which cannot be different across the diameter of the anal canal). Rather, they are detecting directionally dependent forces which are artefactual and vary considerably with the stiffness and position of the catheter.

In 1992, Ho and Goh compared conventional anal manometry with computerised three-dimensional vector volume analysis in 25 people with normal faecal control and 22 patients with idiopathic faecal incontinence. The conventional parameters of mean resting and maximum voluntary contraction pressures did not differ significantly between normal and incontinent subjects. The computer calculated vector volumes and pressure symmetries (both at rest and during contraction) were not significantly different between the two groups. They concluded that the vector volume calculations gave little additional objective information to the conventional indices to discriminate milder degrees of idiopathic faecal incontinence. [647]

In 1993, Williams et al studied the effect of lateral sphincterotomy on internal anal sphincter function in patients with chronic anal fissure. They showed that lateral sphincterotomy produces a decrease in anal canal resting pressure and produces a significant increase in manometric asymmetry of the resting anal canal by creating a detectable segmental defect. [648]

In 1994, Yang and Wexner assessed anal pressure vectography (APV) in 50 consecutive patients with faecal incontinence and compared it with anal manometry, anal sphincter electromyography, and anal ultrasonography. Fifty consecutive patients with faecal incontinence were evaluated. APV showed significantly higher mean maximal resting and mean maximal squeeze pressures than conventional manometry. Thirty eight patients had isolated decreased EMG activity in a single quadrant. However, only five of the 38 patients (13.2%) had the same defect localised by APV. Twenty seven patients had anal sphincter defects on ultrasound examination but only 3 of the 27 patients (11.1%) had the same defects localised by APV. The authors concluded that APV has no apparent advantages, so its use cannot be supported because it had poor correlation with other anorectal physiological tests, including anal manometry, anal sphincter EMG, and anal ultrasonography. [649]

In 1997, Sentovich et al evaluated how well anorectal manometry and transanal ultrasonography diagnose anal sphincter injury. Computerised manometry analysis (mean maximum resting and squeeze pressures, sphincter length, and vector symmetry) and transanal ultrasonography were performed in 20 asymptomatic nulliparous women and 20 asymptomatic parous women, and the results were compared with those obtained in 31 incontinent women who subsequently underwent sphincteroplasty and, thus, had operatively verified anal sphincter injury. Decreased anal sphincter length and vector symmetry were found in only 42% of women with known anal sphincter injury. [650]

In 1999, Zbar et al compared conventional water-perfused and vector volume anal manometry in female patients with neurogenic fecal incontinence and chronic anal fissure and in healthy female volunteers. There was a statistically significant relationship between parameters measured by conventional manometry and those variables derived from vector volume manometry at rest and squeeze. [651]

In 2000, Fynes et al tried to determine the role of anal vector manometry in the assessment of postpartum anal sphincter injury and to establish the most suitable method of anal vector volume analysis for identifying significant external anal sphincter (EAS) injury in an at-risk parous population. They recruited 101 consecutive women with a history of instrumental or traumatic vaginal delivery and performed anal ultrasonography and anal vector manometry. Seventeen women had significant EAS disruption identified by anal ultrasonography. Anal vector symmetry index (VSI), determined by analysis of mean maximum squeeze pressure, yielded 100% sensitivity for significant EAS disruption, with a positive predictive value of 61%. They concluded that anal vector manometry complements endoanal ultrasonography and that VSI, determined by means of the squeeze pressure profile, correlates best with significant EAS disruption identified at anal ultrasonography. [652] However, it is difficult to see how vector manometry complements ultrasonography on the basis of this study; the figures suggest that 11 patients who had a defect on ultrasound would have been judged not to have a defect on VSI.

In 2002, Nazir et al used transanal ultrasonography and vector volume manometry to determine whether a correlation exists between anal incontinence, occult sphincter injuries, anal manometry values, and delivery variables in primiparous women after their first vaginal delivery. Nineteen of the 86 women studied experienced flatus incontinence postpartum. After 12 months, only one-third of the women were still incontinent. Fourteen women (19%) showed anal sphincter injuries on ultrasound but these were not associated with vector volume manometry values at 5 months. Vector volume manometry values were not associated with flatus incontinence at 5 months, but were reduced in women who had flatus incontinence at 12 months after labour. [653]

In 2002, Damon et al studied anal sphincter defects detected by ultrasonography, in a population of fecal incontinent parous females without previous anoperineal surgery. From 100 consecutive incontinent patients, 61 females with at least one previous vaginal delivery and no past anoperineal surgery were studied. Anal vector manometry was performed to measure anal pressures at rest and during voluntary squeeze, and the anal asymmetry index. Twenty-three had a normal sphincter (38 percent), and 38 (62 percent) had a defect detected by ultrasonography: 20 isolated defects of the external sphincter and 18 combined defects of the internal and external sphincters. Combined defects were significantly larger. The radial size of the defects was positively correlated with the severity of clinical symptoms. Anal pressure asymmetry index was significantly increased in the group with combined defects compared with the two other groups. An index of 25 percent or greater had a very high (100 percent) negative predictive value for the presence of a defect larger than 90 degrees. They concluded that anal vector manometry may be a useful tool to confirm the relation between echographic anal sphincter lesions and fecal incontinence. [654]

In 2003, Damon et al assessed the impact of rectal prolapse on anal pressure asymmetry in patients with anal incontinence. 44 patients, (42 women, mean age: 64 (11) years), complaining of anal incontinence, underwent anal vector manometry, endo-anal ultrasonography (to assess sphincter defects) and pelvic viscerogram (for the diagnosis of rectal prolapse). Resting and squeeze anal pressures, and anal asymmetry index at rest and during voluntary squeeze were determined by vector manometry. Patients with rectal prolapse had a significantly higher anal sphincter asymmetry index at rest, whether patients with anal sphincter defects were included in the analysis or not. Among patients without rectal prolapse, a higher anal sphincter asymmetry index during squeezing was found in patients with anal sphincter defects. They concluded that in anal incontinent patients, anal asymmetry index may be increased in case of anal sphincter defect and/or rectal prolapse. In the absence of anal sphincter defect at ultrasonogaphy, an increased anal asymmetry index at rest may point to the presence of a rectal prolapse. [655]

In 2008, Rink et al studied in 61 patients at a median of 86 months after restorative proctocolectomy for ulcerative colitis using 3-dimensional vector manometry. The specificity and sensitivity of the vector volume at rest of the HPZ for the prediction of incontinence was 63.6% and 59.1%, respectively. The corresponding values were 67% and 68%, respectively, for radial asymmetry at rest. They

concluded that a strong anal sphincter at rest and a consistent radial distribution of the sphincter pressure are the most reliable indicators of continence after restorative proctocolectomy obtained by vector manometry but their clinical usefulness is limited. [625].

Conclusions (evidence level 3)

- Measurement of pressure in the anal canal by vector manometry is, at best, comparable to other methods of anal manometry.
- Measuring asymmetry by vector manometry is not as sensitive as endoanal ultrasound in detecting sphincter deficiencies.

Recommendation (grade C)

- Although vector manometry can be used to measure pressures in the anal canal for clinical purposes, it should not be used for diagnosing sphincter deficiencies where there is access to endoanal ultrasound.

6. RECTAL SENSITIVITY BY BALLOON DISTENSION

Some workers assess the response of the rectum to distension by a water-filled or air-filled balloon without manometry to assess the threshold volume for sensation (onset of sensation), sensation of desire to defaecate and maximum tolerated volume (urgency of defaecation). Whilst there are differences between different patient groups [656, 657] there is no validation or standardisation of the technique and no real literature on its sensitivity or specificity. Intuitively, values must depend on the size of the balloon, the rate of inflation and the substance with which it is inflated.

In 1978, Farthing and Lennard-Jones showed that the maximum volume of air tolerated within a rectal balloon was less in colitic patients than in normal subjects. Smaller volumes were tolerated by patients with a spontaneously bleeding mucosa than by those with less severe inflammation. Severe urgency of defaecation with incontinence was experienced by about half those with spontaneous mucosal haemorrhage but was infrequent among other colitics. [656]

In 1989, Ferguson et al compared the subjective response to rectal balloon sensation in 37 healthy subjects, 54 patients with idiopathic faecal incontinence, and 36 with complete rectal prolapse and incontinence. There was no significant difference for any parameter of rectal balloon sensation between patients with idiopathic faecal incontinence. Patients with complete rectal prolapse and incontinence differed only in onset of sensation. They concluded that the appreciation of rectal distension is maintained in idiopathic faecal incontinence. [658]

In 1990, Sun et al studied ramp distention of the rectum with water and air at randomised rates of 10, 20, 50, and 100 mL/min and during intermittent rapid distension with air in 12 normal male subjects. There were no significant differences between the results of ramp inflation with water or with air, and the repeated infusion of the same medium yielded reproducible results. However, they showed that the rectal sensory and anorectal motor responses to distension depend on the rate and pattern of distension. They concluded that results from different laboratories cannot be compared directly unless the pattern and rate of distension are the same. [659]

In 1991, Felt-Bersma et al showed, by rectal balloon distension in 80 mainly healthy volunteers (40 men and 40 women aged 20-87, mean 45 years) that the volume of rectal perception increased with age and should be taken into account when interpreting the measurement. [582]

In 1995, Hoffmann et al retrospectively evaluated anal manometric studies on 170 patients with varying degrees of faecal incontinence. They were divided into three groups based on presenting complaints: complete incontinence (incontinence of gas and liquid and solid stool), partial incontinence (incontinence of gas and liquid stool), and seepage and soiling (incontinence of small amounts of liquid and solid stool without immediate awareness). Amongst other parameters, the minimum rectal sensory volume, and minimum volume at which reflex relaxation first occurs, were compared with those of 35 control group subjects with normal faecal continence. The minimum rectal sensory volume was greater in all incontinent groups than in controls. Sensory volume of the seepage and soiling group was significantly greater than that of the complete incontinence and partial incontinence groups. The difference between sensory volume and the volume producing reflex relaxation was greatest in the seepage and soiling group and differed from that of the partial incontinence and control groups. They concluded that the findings suggest that the mechanism of incontinence is different in seepage and soiling patients and involves a 'dyssynergy' of rectal sensation and anal relaxation. [660]

In 1998, Rasmussen et al compared 'standard' anal manometry parameters with rectal compliance measurements in 36 patients with faecal incontinence and in 22 control subjects. Patients with faecal incontinence had lower rectal volumes than controls at constant defecation desire (median 138 mL and 181 mL, $p < 0.05$) and at maximal tolerable volume (median 185 mL and 217 mL, $p < 0.05$). They concluded that patients with faecal incontinence have a lower rectal volume tolerability than control subjects with normal anal function. [595]

In 2003, Chang et al in a randomised study treated 22 patients who had functional constipation with

impaired rectal sensation. Twelve were treated with electrical stimulation therapy and 10 with biofeedback therapy. Overall symptoms of patients significantly improved after each therapy in both groups but rectal sensory threshold volumes for desire and urge to defaecate and maximal tolerated volume improved significantly only in the electrical stimulation therapy group. [661]

However, this test may have some relevance to faecal seepage because Rao et al in 2004 confirmed some of the conclusions of Hoffman et al [660] showed there was a link between impaired threshold for first rectal sensation and faecal seepage in a prospective study of 25 patients with faecal seepage, where their results were compared with 26 faecal incontinence patients and 43 healthy controls. [662]

Also in 2004 Chang et al, following the earlier work of 2003, reported the case of a 25-year-old female patient who complained of intractable constipation for ten years. She had impaired rectal sensation and was treated by electric stimulation therapy for the purpose of improving impaired rectal sensory function. After 14 sessions of electric stimulation therapy, her constipated symptoms improved dramatically. Furthermore, the desire and urge threshold volumes were decreased. [663]

In 2004, Shafik et al investigated the hypothesis that sympathetic skin response can be used as a tool for objective assessment of rectal sensation. The response was recorded in 24 healthy male volunteers using a surface electrode applied to the skin of the palmar surface of the subject's hand and a reference electrode to the dorsum of the same hand. The EMG activity of the pelvic floor muscles was registered by a surface electrode fixed to the perineal skin and a rectal balloon was filled in increments of 10 mLof saline. Skin and pelvic floor responses occurred with every rectal sensation and corresponded with the volunteers' subjective perception. The authors concluded that that they had identified a novel approach whereby skin response from the hand could act as a surrogate for measuring rectal sensation by balloon distension. However they acknowledged that further studies were required to investigate the role of this reflex in defaecation and sympathetic disorders. [664]

In 2005, Milone and DiBaise showed in 10 healthy volunteers that sildenafil increases rectal volumes to first sensation, desire to defecate and maximal tolerable volume. [665]

In 2007, De Ocampo et al examined sensory and motor responses of the anorectum during rectal distenson in 23 healthy subjects by placing a six-sensor probe in the anorectum and utilising graded rectal balloon distensions. Studies were repeated in six subjects. In 4 subjects (17 percent) the sensorimotor (anal contractile) response first occurred synchronously with a sensation of fullness (Group 1) and in 19 (83 percent) with a desire to defecate (Group 2). Mean balloon volume for inducing the sensorimotor response in Groups 1 and 2 were 80 ± 14 mL and 96 ± 26 mL and were not significantly different. Repeat studies showed good reproducibility (intraclass correlation coefficient = 0.9; $p < 0.05$). They concluded that a desire to defecate is associated with a unique, consistent, and reproducible anal contractile response: the sensorimotor response. This response could play an integral role in regulating anorectal sensation and function. [666]

Conclusions (evidence level 3)

- Measurement of rectal sensitivity to balloon distension is age and technique dependent.
- It is sensitive to change following intervention
- Faecally incontinent patients may have some degree of rectal hypersensitivity.
- There is a link between impaired first rectal sensation and faecal seepage.

Recommendation (grade C)

- The committee recommends that rectal sensitivity to balloon distension continues to be used in the assessment of the anorectum for clinical purposes.
- However, further investigation is required to explore the full potential of measuring this parameter in the patient with anal incontinence by standardising the technique.

7. ANAL AND RECTAL MUCOSAL SENSITIVITY TESTING BY ELECTRICAL STIMULATION

In 1986, Roe et al described a new technique for quantifying anal sensation utilising mucosal electrosensitivity and described the findings in 97 patients. Normal subjects (n = 20) have a sensory threshold varying from 2 to 7.3 mA; being most acute in the region of the anal valves. Sensory awareness also extends into the upper anal canal. Patients with faecal incontinence (n = 17) have a sensory deficit whilst patients with haemorrhoids have less sensitive mucosa displaced into the upper anal canal. Patients with acute fissure-in-ano (n = 10) have lower thresholds of sensation at the site of the fissure and slow transit constipation patients (n = 22) have normal anal sensation. They concluded that the technique is reproducible and should prove useful in the investigation of anorectal disorders. [667]

In 1988, Rogers et al utilised the same technique to compare, amongst other parameters, mucosal electrosensitivity in 11 patients with idiopathic faecal incontinence and nine normal controls. [668] Electrical

stimulation was by a constant current generator delivering square wave pulses of 0.1 ms and delivered at a rate of 5 pulses per second. Two platinum electrodes mounted on a probe delivered these pulses to the mucosa and the current was increased in steps of 0.1 mA until the patient experienced a tingling sensation. They showed that there was a sensory deficit in the anal canal in patients with faecal incontinence compared with controls. For example, the median threshold current was 10.1 mA in the mid anal canal of those with faecal incontinence compared to 3.7 mA for those with normal faecal control.

In 1989, Rogers et al studied 16 subjects (mean (s.d.) age 50.7 (12.8) years, three men) on two separate occasions using two experienced investigators in random order. Amongst other tests, they carried out electrophysiological assessments of anorectal motor and sensory function. No significant differences were found between the results obtained by the two investigators in the measurements of the thresholds of mucosal electrosensitivity. They concluded that the standard tests of anorectal sensorimotor function are repeatable by different investigators. [569]

In 1990, Kamm and Lennard-Jones compared rectal sensation assessed by balloon distension and rectal mucosal electrosensitivity using a bipolar ring electrode. The methods were compared in 13 healthy control women and 26 women with severe idiopathic constipation. Balloon distension in the rectum revealed an elevated sensory threshold (16.9 ± 4.4 vs. 30.4 ± 3.1 mL air, controls vs. patients, $p = 0.018$) and the volume required to elicit a call to stool (61.1 ± 9.1 vs. 97.5 ± 6.4, $p = 0.003$) in subjects with severe constipation. The maximum tolerated volume was similar in the two groups. Rectal mucosal electrosensitivity testing demonstrated an elevated sensory threshold in the constipated subjects (16.3 ±3.0 vs. 27.4 ± 2.1 mA, $p = 0.005$). They concluded that electrical testing avoided the variables inherent in balloon distention and was well tolerated, accurately quantifiable, and reproducible. The raised threshold to electrosensory mucosal testing suggests the presence of a rectal sensory neuropathy in patients with severe idiopathic constipation. [669]

In 1995, Gee et al studied the relationship between perineal descent and anal mucosal sensitivity. There were significant correlations between perineal position at rest and at squeeze, with electrosensitivity. They concluded that perineal descent traumatizes the pudendal nerves, damaging the large diameter sensory axons. They thought that this may be a precursor of motor axon damage or may correlate with the global pelvic sensory loss found in patients with perineal descent and faecal incontinence. [670]

In 1995, Ho and Goh compared the accuracy and sensitivity of annular and unilateral electrodes in assessing patients with haemorrhoids, perineal descent, incontinence, constipation, or after low anterior resection (107 subjects). They found that in normal controls (n = 19), annular thresholds ranged from 0.5 to 2.7 mA and unilateral thresholds from 0.6 to 2.6 mA. In prolapsed hemorrhoids, unilateral was more sensitive than annular electrode in detecting deficits at the upper ($p < 0.0001$), mid ($p < 0.005$), and lower ($p < 0.0005$) anus. Patients with perineal descent had a sensory deficit in the upper anal canal, detected more consistently by unilateral electrode ($p > 0.05$). No significant abnormalities were found in neuropathic incontinence, after anterior resection and in patients with chronic constipation. Repeated measurements of the unilateral electrosensory technique were found to be consistent ($r = 0.8878$; $p < 0.001$). They concluded that by being more sensitive than the annular technique, the unilateral electrode method may become, with refinement, a useful test for quantifying anal sensation. [671]

In 1996, Meagher et al assessed the validity of tests of rectal mucosal electrosensitivity by studying 68 patients in three groups (group 1: 50 patients undergoing assessment in the anorectal physiology unit, group 2: 10 patients with coloanal or ileoanal anastomosis, group 3: 8 patients with a stoma). In addition the electrosensitivity was measured in groups 1 and 2 by placing the electrode, mounted on a catheter with a central wire, against the anterior, posterior, right and left rectal or neorectal walls. To assess the influence on this test of loss of mucosal contact due to faeces, a further 8 cases with a normal rectum had electrosensitivity evaluated with and without a layer of water soaked gauze around the electrode to stimulate faeces and prevent the electrode from making contact with the rectal mucosa. There was marked variance in the sensitivity of the different regions of rectal wall tested. In group 1 patients the mean sensitivities were: central 36.6 mA, anterior 27.4 mA, posterior 37.9 mA, right 22.3 mA and left 25.6 mA. This circumferential variation suggests that the pelvic floor rather than rectal mucosa was being stimulated. All patients in group 2 had recordable sensitivities, and the mean sensitivity threshold was significantly higher than group 1 patients in the central ($p = 0.03$), right ($p = 0.03$) and left ($p = 0.007$) positions. In group 3 the sensitivity was greater within the stoma at the level of the abdominal wall muscle than intra-abdominally or subcutaneously, again suggesting an extra-colonic origin of the sensation. The sensitivity threshold was significantly greater with the electrode wrapped in gauze ($p < 0.01$), and loss of mucosal contact was not detected by the EMG machine. They concluded that it is uncertain what is being measured during rectal mucosal electrosensitivity testing. It does not appear to measure mucosal sensitivity, and is probably influenced by the presence of faeces. [672]

In 1997, Felt-Bersma et al undertook a study to determine the anal sensitivity in controls and in different

patient groups and to establish which factors determine anal sensitivity. Anal sensitivity was assessed in 387 patients with different anorectal diseases and in 36 controls by means of a catheter with two electrodes placed in the anal canal. A constant current (square wave stimuli 100 microsec, pulses per second) was increased stepwise from 1 to 20 mA until the threshold sensation was reached. Controls had a threshold sensation of 3.4 ± 1.7 mA and this was significantly increased in patients with faecal incontinence, soiling, hemorrhoids, mucosal prolapse, constipation, anal scars, anal surgery, and sphincter defects; patients with faecal incontinence had the highest mucosal electrosensitivity (MES) of 6.7 ± 4.3 mA. They concluded that anal sensitivity is diminished in all patients with anorectal diseases except for anal fissures and proctitis but it has limited clinical value and should be used in conjunction with other tests in a research setting. [673]

In 1998, Poen et al investigated the long-term clinical and anorectal functional results 5 years after primary repair of a third-degree obstetrical perineal rupture. In 40 of the 117 women who responded to a postal questionnaire and attended for investigation, anal mucosal electrosensitivity was increased at 4.7(1.7) mA compared to the values in normal controls of 2.5(0.8) mA. However, the risk of incontinence was only related to the presence of a combined sphincter defect or subsequent vaginal delivery. [674]

In 1999, Yamana et al studied 32 patients who underwent low anterior resection for rectal cancer. Anorectal physiological studies were performed preoperatively and six months postoperatively. In univariate regression analyses, a longer preoperative high pressure zone and a more sensitive anal mucosa were associated with better postoperative defecatory function. Using multiple regression analysis, in which age, gender, the level of anastomosis, and preoperative physiologic parameters were examined as independent variables, a longer preoperative high pressure zone, a larger preoperative maximum tolerable volume, and lower sensory threshold of the anal canal were associated with better postoperative defecatory function. Postoperative function score was found to be predictable using the following formula: 1.47 + 0.496 x high pressure zone (cm) + 0.007 x maximum tolerable volume (ml) - 0.247 x sensory threshold (mA) of the anal canal.

Hence, they concluded that early postoperative defecatory function after low anterior resection is predictable from preoperative high pressure zone, maximum tolerable volume, and anal mucosal electrosensitivity. [627]

In 2005, Broens and Penninckx assessed the effect of age and sex on the rectal filling sensation and anal electrosensitivity and explored the relation between anal electrosensitivity and the parameters of the rectal filling sensation. Tests were carried out in 19 control subjects; 10 were younger than 60 years and 9 were older than that. Altogether, there were 11 men and 8 women. They showed that anal electrosensitivity did not differ between the two age groups but women had a significantly lower electrosensitivity 4 and 5 cm from the anal verge than men.

The rectal filling sensation did not differ between sexes. However, in the older age group, the rectal volumes required to induce filling sensations were smaller than those observed in the younger age. Anal electrosensitivity at different anal levels did not correlate with the rectal volume or pressure parameters of successive rectal filling sensations. They concluded that rectal sensation did not correlate with anal electrosensitivity, probably because the receptors are not stimulated by the type of anal stimulation used or because different receptors are involved. Hence, the rectal filling sensation test cannot be replaced by the simpler anal electro-sensitivity test. [675]

In 2007, Tomita and Igarashi examined the significance of the anal canal sensitivity contribution to soiling in 40 patients a mean of 103.6 months following ileostomy closure after ileal J pouch-anal anastomosis for ulcerative colitis. They studied 26 patients without soiling, 14 patients with soiling and compared them with a group of 28 healthy controls. They showed that there was significantly lower sensitivity in the proximal and middle anal canal in ileal J pouch-anal anastomosis patients with soiling. [676]

Conclusions (evidence level 3)

- Measurement of anal mucosal sensitivity testing by electrical stimulation is reproducible by different operators. There is no clear indication whether the measurement is affected by gender or age.
- Measurement of rectal mucosal sensitivity testing by electrical stimulation has been found to be reproducible by some workers but others have not found this and have demonstrated to some extent that the presence of faeces in the rectum affects the result.
- There are differences in the sensitivities between some patient groups and controls.
- Anal mucosal sensitivity is one of the factors that may help predict early postoperative defecatory function after low anterior resection.

Recommendation (grade C)

- Anal and rectal mucosal sensitivity testing by electrical stimulation has limited proven clinical value and it use should be currently restricted to research.

8. THERMAL TESTING

In 1987, Miller et al investigated the role of temperature sensation in idiopathic faecal incontinence by studying the minimum detectable temperature change in the lower, middle and upper zones of the anal canal and rectum in 33 normal subjects, and 20 patients with idiopathic faecal incontinence. A water perfused thermode was used to vary anorectal temperature from 37 C down to 32.5 C and up to 41.5 C. The anal canal in the control group was highly sensitive to temperature change, the lower rectum was significantly less sensitive. At each level in the anal canal and lower rectum the incontinent group were significantly less sensitive than the controls. The mid-rectum had no appreciable sensation in either group. The authors concluded that this sensory deficit may be an important factor in idiopathic faecal incontinence. [677]

In 1988, Miller et al used this technique to determine the thermal sensitivity in the anal canal in 20 continent patients with haemorrhoids and to compare the results with 40 control subjects and 22 patients with idiopathic faecal incontinence. Anal manometry was performed and sensation to mucosal electrostimulation and temperature change in the lower, middle, and upper zones of the anal canal assessed. Thermal sensation was impaired in the hemorrhoid group as compared with controls, but not to the same degree as in idiopathic faecal incontinence. There was some correlation between the two tests of sensation and the reproducibility of thermal sensory thresholds was reasonable (correlation coefficient of 0.82). They concluded that patients with hemorrhoids have a mild anal sensory deficit, but continence in this group is likely to be augmented by other factors. [678]

In 1996, Solana et al compared anorectal sensitivity to electrical and thermal stimuli in 21 healthy controls (11 females and 10 males; mean age 51.8 ±11 years, range 33-67) and 19 patients (18 females and 1 male; mean age 48 ±15 years, range 20-71) with obstructed defaecation. In the controls the electrical sensitivity threshold was minimal in the mid anal canal, where sensory receptor presence is greater. Sensitivity was significantly higher in the upper and lower anal canal regions and much higher in the rectum. A similar sensory profile was recorded in the patients with obstructed defaecation, though with significantly higher thresholds at all points with respect to the controls. The thermal stimulus thresholds in the lower and middle anal canal were significantly smaller than in the upper canal region and rectum, and the thresholds were again higher among the patients with obstructed defaecation than among the controls. In all cases the thresholds for heat were lower than for cold stimuli. They concluded that patients with obstructed defaecation had sensory deterioration at all points studied in the anal canal and rectum. Sensory pudendal neuropathy was found to be associated with the pudendal motor neuropathy. [679]

In 2001, Altomare et al studied the long term effects of stapled haemorrhoidectomy; particularly with regard to some concern about the risk of injury to the internal anal sphincter. Internal anal sphincter function and morphology, and anal canal sensitivity were studied prospectively in 20 patients (11 women) with stage III haemorrhoids. All underwent preoperative anorectal manometry, rectoanal inhibitory reflex testing and three-dimensional transanal ultrasonography. A test of anal sensation was administered to evaluate ability to discriminate between air and warm water. All the investigations were repeated 6 months after the operation. The maximal resting pressure, the maximal squeeze pressure, the rectoanal inhibitory reflex and the width of the internal anal sphincter did not change after operation. However, the ability of the anal mucosa to discriminate air from warm water improved in five patients. The authors concluded that stapled haemorrhoidectomy can improve anal sensation in patients with preoperative sensory impairment. [680]

Also in 2001, Salvioli et al quantified anal perception of temperature and light touch in 22 unselected patients with faecal incontinence (21 F, 33-75 yr). Control values were obtained from two groups of 11 (seven F, 32-53 yr), and 32 (18 F, 19-44 yr) volunteers. Most of the patients had low sphincteric pressures and ultrasonic abnormalities. Temperature perception was impaired in incontinent patients, to a greater extent in the proximal anal canal and in patients with passive, as opposed to urgency, incontinence. Intraluminal pressures for sensations of rectal distension were lower in incontinent patients ($p = 0.02$). Artificial stools elicited sensations of rectal filling at lower volumes than did a barostat bag, and in patients with urgency, as opposed to passive, incontinence. Therefore, they found that although temperature sensation is impaired, the perception of rectal distension is not always reduced in faecal incontinence. Artificial stool tended to induce sensations at lower volumes than did balloon inflation. They concluded that altered sensory mechanisms may contribute to the pathophysiology of faecal incontinence. [681]

In 2003, Chan et al used a thermal probe in the rectum to assess rectal sensation as an alternative to either balloon distension or electrical testing. This was carried out in 31 healthy subjects and compared with other anorectal physiological measurements. The median rectal heat threshold was similar in males (median, 47 C; range, 44-50 C) compared with females (median, 45 C; range, 43-50 C). There was a high degree of repeatability with rectal heat and balloon distension thresholds, but not electrostimulation thresholds. A strong correlation was found between rectal heat thresholds and defecatory desire and maximum tolerable volumes measured with balloon distension. The authors concluded that heat stimulation is a simple technique that has a high degree of repeatability and may be an objective assessment of sensory function in the rectum. [682]

Conclusions (evidence level 3/4)

- Different patient groups have different responses to thermal testing of the anal canal and rectum.
- The reproducibility of the measurement is unknown regarding thermal testing of the anal canal but appears to be reproducible in the rectum (in the one study that looked at this)
- Intervention may alter the response of the anal canal to thermal testing.

Recommendation (grade C/D)

- Thermal testing of the anal canal and rectum has no proven clinical value and it use should be restricted to research.

9. SALINE RETENTION TESTS

The saline continence/retention test assesses the ability of the lower GI tract to retain fluid in the rectum. It is used as an outcome measure following treatment [683-686] but there is a paucity of data regarding what is normal.

The saline continence test measures the ability to retain 1500 ml of saline infused in the rectum, via a tube at a rapid rate of 60 ml/min whilst the patient is seated on a commode. The time and volume of first leak as well as the total volume leaked can be measured. [585]

In 1982, Leigh and Turnberg evaluated 76 patients with diarrhoea due to a variety of causes. Using a saline retention test, they found that all but 7 of 42 continent subjects could retain more than 500 ml before leaking, whereas 19 of 22 frequently incontinent subjects leaked after infusion of less than 500 ml. They proposed that the saline-infusion test was a simple method of measuring this disturbance of anorectal function. [687]

In 1988, Allen et al compared the ability to retain rectally infused saline in three groups of subjects: 14 patients complaining of faecal incontinence, 14 age- and sex-matched continent patients, and 14 sex-matched younger normal controls. An additional group of unmatched normals and incontinent patients demonstrated significant differences in their ability to retain rectally infused saline. The patients leaked sooner and retained less; however, the performance of the normals was considerably reduced from that reported in previous studies. [688]

In 1989, Penninckx et al described a balloon-retaining test which consists of progressive filling of a compliant intrarectal balloon in a patient in the sitting position. The pressure inside the balloon is monitored and the patient is asked to retain the balloon as long as possible and to report first, constant, and maximal tolerable sensation levels. They claimed that this test is a more realistic approach to the evaluation of faecal continence than the rectal saline infusion test and proposed that it permits objective evaluation of the effect of different treatments in incontinent patients. [689]

Also in 1989, Yoshioka et al performed posterior abdominal rectopexy in 12 patients with a full-thickness rectal prolapse of whom 9 had faecal incontinence. The prolapse was successfully controlled in all cases and six of nine patients were rendered continent. They found that delayed leakage during the saline infusion test preoperatively helped predict the return of continence. [690]

In 1990, Felt-Bersma et al carried out the saline-infusion test in 350 patients, 178 of whom had faecal incontinence and 172 of whom were continent. Compared with continent patients, incontinent patients leaked earlier and more with the saline infusion test. However, differentiation between incontinent and continent patients was not possible because there was considerable overlap. [629]

In 1995, Penninkcx et al carried out the rectal saline infusion test and the balloon-retaining test in 27 control subjects (M:8, F:19; mean age: 47 yr) and in 40 incontinent patients (M:5, F:35; mean age: 49 yr). The uncontrollable evacuation of a balloon, progressively filled with water at 60 ml/min, before the maximum tolerable sensation level was reached, was related to the degree of clinical incontinence. The balloon-retaining test proved to be superior to the rectal saline infusion test for the determination of the severity of incontinence. The saline infusion test, however, was found to be more adequate to identify minor defects of continence. [592]

Conclusions (evidence level 3/4)

- Different patient groups have different abilities to retain saline or a fluid-filled balloon in the rectum.
- Although continent individuals have better retention than incontinent patients there is considerable overlap between the two groups
- The reproducibility of the measurement is unknown
- It may help predict the return to continence of some patient groups post-operatively

Recommendation (grade C/D)

- Saline retention and balloon retention tests have limited clinical value and it use should be restricted to research.

10. RECTAL COMPLIANCE

Isometric and isobaric distension of the rectum to assess its compliance (the ratio of changes in volume to changes in pressure) are options available for

testing of the faecally incontinent (although more commonly used for those with constipation).

In isometric assessment, compliance of the rectum is assessed in a manner similar to cystometry whereby a rectal balloon is filled with water up to a specified volume and the pressure change inside the balloon from the start to the end point enable compliance to be calculated (after correcting for the compliance of the balloon).

In the isobaric assessment of compliance, a barostat (a device used to maintain constant pressure in a closed system) is connected to a thin, infinitely compliant bag which is inflated in the rectum in a variety of ways; often 'stepwise' and 'ramp' are used. The volumes at various pressures and levels of rectal sensation can be measured.

Measurement of rectal compliance has been used in both paediatric [691, 692] and adolescent [693] constipated subjects. It has also been used in adults with constipation. [694] It has also been used in the investigation of subjects with irritable bowel syndrome (IBS) [695], ulcerative colitis [696] and obstructed defaecation. [697]

There is little data to assess its sensitivity in detecting the faecal incontinent from healthy subjects.

In 1986, Varma and Smith showed that in 15 patients, the proctometrogram (a method of measuring rectal distensibility by continuous controlled fluid inflation with a balloon) was reproducible. [698]

In 1990, Rasmussen et al studied rectal compliance in 31 patients with faecal incontinence, 8 patients with constipation, and 16 control subjects. Patients with faecal incontinence experienced a constant defaecation desire at a lower rectal volume and also had a lower maximal tolerable volume and a lower rectal compliance than control subjects (median 126 vs 155 mL, 170 vs 220 mL, and 9 vs 15 mL/mm Hg, respectively; $p < 0.05$). Constipated patients had a higher constant defaecation desire volume and maximal tolerable volume than controls (median, 266 ml and 300 ml; $p < 0.05$). There were no differences in the parameters between patients with idiopathic faecal incontinence and patients with incontinence of traumatic origin, indicating that a poorly compliant rectum in patients with faecal incontinence may be secondary to anal incontinence due to the lack of normal reservoir function. [699]

In 1992, Sorensen et al measured the volume of air inflated in a latex balloon placed in the rectum and the corresponding pressures in 48 subjects (24 men and 24 women) at three points: (1) earliest defaecation desire; (2) constant defaecation desire; and (3) maximum tolerable volume. The rectal pressures in all three cases were higher in men than in women. Woman aged over 60 years had higher rectal compliance than men in the same age group, while no difference was found between men and women below the age of 60 years. Day-to-day variation of the measurements was tested in ten subjects. Reproducibility was good only for maximum tolerable volume. Reproducibility of rectal compliance decreased with increasing values for this parameter. They concluded that maximum tolerable volume is a reproducible parameter and suitable for clinical use in evaluation of patients with faecal incontinence or constipation. [700]

In 1997, Whitehead and Delvaux presented a standardisation of barostat procedures for testing muscle tone and sensory thresholds in the GI tract. [701]

In 1998, Hammer et al examined the reproducibility of repeated assessments of sensory perception, basal tone, and compliance and/or elastance of the rectum during distension. They studied 5 healthy volunteers and found that repeated distensions evoked reproducible responses of sensation and compliance and/or elastance on a single day, providing a conditioning distension preceded them. They also found that day-to-day variability was also sufficiently small to allow valid comparisons to be made on different days in healthy persons. [702]

In 1998, Rasmussen et al studied whether anorectal pressure gradients discriminated better than standard anal manometry between patients with faecal incontinence and subjects with normal anal function. Anorectal pressure gradients were measured during rectal compliance measurements in 36 patients with faecal incontinence and in 22 control subjects. With standard anal manometry, 75% of patients with faecal incontinence had maximal resting pressure within the normal range, and 39% had maximum squeeze pressure within the normal range. Anorectal pressure gradients did not discriminate better between faecal incontinence and normal anal function, since, depending on the parameters used, 61%-100% of the incontinent patients had anorectal pressure gradients within the normal range. They concluded that measurements of anorectal pressure gradients offer no advantage over standard anal manometry when comparing patients with faecal incontinence to controls. [595]

In 2000, Felt-Bersma et al measured the rectal compliance in 974 consecutive patients and compared them with 24 controls. Rectal compliance measurement was performed by filling a latex rectal balloon with water at a rate of 60 ml per minute. Volume and pressure at three sensitivity thresholds were recorded for analysis: first sensation, urge, and maximal toleration. At maximal toleration, the rectal compliance (volume/pressure) was calculated. They did not see any effect of age or gender in either controls or patients. They concluded that rectal compliance measurement

with a latex balloon is easily feasible and some patient groups showed an abnormal rectal visceral sensitivity and compliance. However, there was an overlap with controls. [703]

In 2001, Krogh et al noted that pressure-volume measurement during distention with a compliant balloon is the most commonly used method for computation of rectal compliance. However, they stated that intraindividual and interindividual variations are apparently large, restricting the usefulness of the method. Therefore, they compared the in vivo reproducibility of pressure-volume measurement during distention with a compliant balloon and pressure-volume measurement during rectal distention by a large, noncompliant bag, and rectal impedance planimetry. They also carried out an in vitro study of their reproducibility and validity. For the in vivo study, 10 healthy volunteers (6 men) aged 21-59 years were randomised to either rectal pressure-volume measurement with a compliant balloon or rectal impedance planimetry. After a one-hour rest, the other procedure was performed. After two weeks, both procedures were again performed in the same order. During rectal impedance planimetry the volume of the bag used (maximum volume 450 ml; secured at both ends to the probe) was continuously registered, measuring pressure-volume relations during rectal distention by a large, noncompliant bag. They found that in vivo reproducibility for pressure-volume measurement with a large, noncompliant bag and rectal impedance planimetry was significantly better than for pressure-volume measurement with a compliant balloon. No statistically significant difference was found between pressure-volume measurement with a large, noncompliant bag and rectal impedance planimetry. In vitro reproducibility was studied using polyvinyl chloride tubes with known cross-sectional areas. The reproducibility of pressure-volume measurement with a large, noncompliant bag and rectal impedance planimetry was good, but some elongation occurred, reducing the validity of pressure-volume measurement with a large, noncompliant bag. Coiling and elongation of the balloon within the lumen were major sources of error for pressure-volume measurement with a compliant balloon. They concluded that in vivo and in vitro reproducibility of methods used for measurement of rectal compliance can be improved by restricting the effects of elongation within the lumen either by using a large-volume, noncompliant bag or by rectal impedance planimetry. However, pressure-volume measurement will to some degree depend on the properties of the balloons or bags. [704]

In 2001, Herman et al showed, using a rectal barostat that transanal endoscopic microsurgery in 33 patients with small, mobile rectal tumors, rectal compliance significantly changed 3 weeks after surgery and remained low at 6 months. There was a control group of 20 healthy volunteers. [612]

In 2005, Cremonini et al demonstrated that isobaric testing is fairly reproducible in healthy volunteers. The 34 participants had rectal barostat assessments carried out three times, at 2 centres. The results from the 2 centres differed minimally and the authors concluded that pressure threshold for pain and sensory ratings at 36-48 mmHg of distension are reproducible. [705]

In 2005, Siproudhis et al showed that rectal compliance was altered in some patients with faecal incontinence. They investigated 148 patients (12 men, 136 female) with incontinence to liquid and/or solid stools. Pain during isovolumic rectal distension at a level of 100 mL or less was experienced in 21 subjects. They showed that, as defined by isobaric distensions, incontinent patients with this low maximal tolerable volume more frequently had a poorly compliant rectum when compared with those with a higher maximal tolerable volume. Unsurprisingly, incontinent patients with low maximal tolerable volume more frequently had a hypersensitive rectum when compared with those with normal or high maximal tolerable volume. However, only four of 21 incontinent subjects with low maximal tolerable volume had an isolated hypersensitive rectum. They concluded that both sensitivity and compliance are altered in patients with low maximal tolerable volume but a more extensive study of the role of sensory and compliance aspects of subjects with incontinence is warranted. [706]

In 2006, Fox et al validated a barostat measurement of rectal capacity. Slow staircase (0-40 mm Hg) and rapid phasic (12-40 mm Hg) barostatic distentions were performed on two separate days in 41 healthy, continent subjects, filling sensations were assessed by visual analog score. Correction for rectal capacity measured at 40 mm Hg reduced the “normal range” of compliance measurements. Compared with unadjusted volume measurements, normalised rectal volume (percentage filling relative to rectal capacity) improved the description of rectal sensation visual analogue score. They concluded that barostat measurements of rectal capacity at 40 mmHg are highly reproducible and not affected by distention protocol. Correction for rectal capacity provides an assessment of rectal wall stiffness independent of rectal geometry and improves the association of barostat volume measurements with rectal sensitivity and continence. [707]

In 2008, de Nardi et al studied 10 patients with third-degree and fourth-degree haemorrhoids who underwent stapled hemorrhoidopexy. One week before and six months after surgery, they underwent three different rectal distensions (pressure-controlled stepwise, volume-controlled stepwise, and ramp) controlled by an electronic barostat. They showed that rectal distensibility and volume thresholds for sensations decrease after stapled haemorrhoidopexy and persist for at least six months after surgery. [708]

The American Gastroenterological Association concluded in 1999 that measurement of rectal compliance, by whatever means, had no established clinical value. [584]. They stated that although the measurement appears to be reproducible in some patients and is sensitive to change in some patients, there is overlap of values between abnormal and controls and it has no role in the prediction of outcome. Therefore, its clinical value has still not been demonstrated. Papers published since 1999 do not appear to have substantially challenged this view.

A recent report from the German Societies of Neurogastroenterology (committee for proctology), Abdominal Surgery (coloproctology working group), and Coloproctology concluded that if compliance measurements have to be carried out, they are best done with a 'static' system measuring the pressure change on instilling 100 mL of fluid in the rectal balloon rather than using a barostat. [709]

Conclusions (evidence level 2)

- Measurement of rectal compliance is fairly reproducible to some extent; particularly at the maximum tolerable volume.
- There are differences in rectal compliance between some patient groups and controls. However there is a fair degree of overlap and there is no proven clinical benefit from carrying out this measurement
- There is some evidence that rectal compliance is altered by intervention.

Recommendation (grade B)

- Measurement of rectal compliance has limited clinical value and its use should be restricted to research.

11. NEUROPHYSIOLOGICAL TESTING

There are some electrophysiological tests employed in faecal incontinence. The techniques and their limitations are described in the chapter relating to imaging , neurophysiology and other tests and there has been a recent review paper [710]. However, it is worth briefly mentioning a few points here.

a) Pudendal nerve motor latency

Pudendal nerve terminal motor latency (PNTML) testing has been applied in lower GI tract dysfunction since its development in 1984 [711]. An intrarectal device electrically stimulates the pudendal nerve where it angulates around the ischial spine in the pelvis and the latency is the measurement of the time taken for the electrical impulses to travel down the nerve and cause the external anal sphincter to contract. The initial work by Kiff and Swash showed that patients with faecal incontinence had a slowing of electrical conduction along the pudendal nerves compared to those with normal faecal control.

Whilst initially it was used to investigate the aetiology of faecal incontinence, it has since been used prognostically to predict likely success from various operative procedures such as post anal repair, procedures for rectal prolapse and sphincteroplasty. However there are different opinions regarding its use in this way. For example, Gilliland et al demonstrated that it has good prognostic value in predicting success following sphincteroplasty [712] whilst Chen et al in the same year demonstrated it has no prognostic ability in this respect [713].

These differences in conclusions probably reflect the fact that this is an inherently insensitive test (see chapter on Imaging, Neurophysiology and other Tests) which is operator dependent and it is probably for limitations such as these that the American Gastroenterological Association in 1999 could not recommend its use in faecal incontinence [584]. Nevertheless some workers still regard it is a useful test and even spend time considering how best to teach the technique to trainees [714]. It continues to be widely used, particularly in a research setting [715, 716] when trying to understand the effects of therapeutic intervention.

Initial work showed some correlation between PNTML and external anal sphincter function as assessed by manometry. [717] However, several workers have more recently demonstrated that pudendal nerve terminal motor latency does not correlate with the function of the external anal sphincter [718-720], even when considering patients with intact sphincters on endoanal ultrasound.

Bilateral neuropathy has been shown to correlate with poor resting pressure in the anal canal but not with squeeze pressures [721]

Chemoradiation prior to restorative proctectomy for rectal cancer appears to have a significant risk of prolonging nerve latencies [722]

Fistula and haemorrhoid surgery do not appear to affect pudendal nerve latencies (although a mean of 2.4 ms in both groups tends to suggest that either these patients are already compromised or the technique of measurement is not ideal) [723]

Even recently its value in predicting success from sacral nerve stimulation has been assessed although it has not been found to have any predictive value [724]

Obtaining the same measurement by intravaginal stimulation appears to produce equivalent results to intrarectal stimulation [725]

Although most nerve latency assessments are carried out with a digital device, other workers have reported good results using an externally manipulated device which causes less discomfort to the patient. [726, 727]

Recently, the whole compound muscle action potential (CMAP) from the external anal sphincter (produced by stimulating the pudendal nerve) has been studied [728]. Initial results show some differences between nerve latency and the other parameters of the CMAP (the amplitude of the response, the duration of the response and the area under the curve). However, these differences may prove to be of no real clinical significance and the CMAP may have no real advantage over PNTML.

Pudendal nerve latency testing has also been used in studying perineal neuralgia although the measurements have not been of much use in detecting the problem, clinical evaluation has been shown to be superior [729]

- Normal values of PNTML

Normal values of PNTML have been published but vary widely. Pradal-Prat et al describe average values of 5.52 ± 1.9 ms on the right and 5.74 ± 1.6 ms on the left in male subjects and 6.16 ± 1.8 on the right and 6.42 ± 1.96 on the left in female subjects. [730]

Lefaucheur reported values of between 1.8 to 5.6 ms (mean ± SD 2.94 ± 0.8 ms) using a St Mark's electrode and a range of 2.2 to 5.4 ms (3.7 ± 0.9 ms) using an externally manipulated device [727]

Many workers use the threshold values of between 2.2 ms and 2.4 ms, reported by Ricciardi [721] with 2.2ms being reported by Hill et al [719]; derived from the previous work of Smith et al [731] and Allen et al [726]

Tetzschner reported normal values for mean PNTML of 1.91 ms (2 SD, 0.52 ms) in women and 1.74 ms (2 SD, 0.33 ms) in men [732]. Allen et al reported a mean value of 1.9 ms (1 SD, 0.2ms) in the immediate post-partum period and 8 weeks post-natally in over 50 women having their first child. [726]

Smith et al reported a mean value of 1.6 ms (1 SD, 0.2 ms) in 28 nulliparous women and 1.7 ms (1 SD, 0.2 ms) in 14 parous women with normal urinary control. Women with USI had a mean value of 1.9 ms (1 SD, 0.2 ms), 42 women with both USI and genito-urinary prolapse had a mean value of 1.9 ms (1 SD, 0.3 ms), whilst continent women with genito-urinary prolapse had a mean value of 2.1 (1SD, 0.3 ms). [731]

- Repeatability of PNTML

There is some evidence to suggest that PNTML has both good intraobserver and interobserver reproducibility [732]

Conclusions (evidence level 2/3)

- Pudendal nerve terminal motor latency is a fairly reproducible measurement but it is an inherently insensitive measure of neuropathy
- The substantially different published 'cut-off' values discriminating normal from abnormal demonstrate that the measurement is operator dependent and may often not be carried out in an optimal fashion
- There is no conclusive evidence that it is predictive of success following intervention.
- Patients with incontinence have may have longer latencies than continent individuals but there is considerable overlap between the groups.

Recommendation (grade B/C)

- Measurement of pudendal nerve motor latency has no proven clinical value.
- There may be merit in continuing to use it as a research tool provided that it is carried out in a well-controlled, optimal manner. Although it is an inherently insensitive measure of neuropathy, patients with genuinely markedly prolonged values of latency could have a different response to therapy compared to those who do not.

b) Needle electromyography

Needle EMG of the external anal sphincter has been used for many years to help understand the aetiology of faecal incontinence. Both single fibre [733] and concentric needle techniques [734] have been used and continue to be used in a research setting[735, 736]. In a clinical setting, concentric needle EMG has been used to map the integrity of the external anal sphincter but the advent of endoanal ultrasound, which is a more comfortable procedure, has largely made this application of EMG obsolete [737]. The current sole clinical application for concentric needle EMG is in the investigation of possible anismus (see later) where it is considered to be more sensitive than defaecography.

c) Strength-duration tests

The strength-duration test is an electrophysiological test of superficial muscle which predates EMG. It can determine muscle denervation directly by putting a surface electrode over the muscle, applying square waves of diminishing pulse width and determining at each pulse width the current required to elicit a twitch from the muscle. Normally innervated muscle and denervated muscle have different shaped curves when the current required to elicit a twitch is plotted against the pulse width. Denervated muscle is less excitable and requires more current to elicit a response.

This technique has recently been applied to the external anal sphincter and distinguishes people with normal faecal control from those with faecal incontinence,; especially when combined with manometry [738]. Work has confirmed that this technique is measuring properties of the sphincter [739] and the optimum position for stimulating the muscle has been

determined [740]. A small study of 13 women in 1994 suggests that this technique could be a more sensitive measure of neuropathy than PNTML [741] however, until larger studies have been carried out on this technique, the role of this test in faecal incontinence is uncertain.

d) Endoanal ultrasound

Perhaps one of the universal investigations relating to faecal incontinence, along with manometry, is that of endoanal ultrasound to image the sphincters. The usefulness of this is discussed in the chapter on Imaging, Neurophysiology and other Tests.

V. TESTS RELATING TO SECONDARY INCONTINENCE

1. RECTOANAL INHIBITORY REFLEX

In the normal, healthy individual, the internal sphincter relaxes in response to rectal distension. [547, 742] In some individuals, there can be a lack of the nervous connections between the upper GI tract and the internal sphincter (e.g. Hirschsprung's Disease) [743-745]. Usually this is congenital and occurs in infants but there are rare occasions when it can manifest itself in the adult. [746]

The relaxation of the internal sphincter in response to rectal distension can be simply be assessed by inflating a balloon in the rectum and measuring pressure in the anal canal – a decrease in pressure indicating the presence of the rectoanal inhibitory reflex (RAIR).

Technically, the reflex can be difficult to elicit if the anal canal has poor resting pressure.

Whilst biopsy is the gold standard investigation for Hirschsprung's Disease, there is evidence that looking for the RAIR is just as sensitive [747] and is an effective screening test before biopsy is considered to provide the definitive diagnosis. [657]

In 2007, Kawahara et al described a micromanometry sleeve technique for assessing the RAIR in newborn infants. They claim that the technique has very good sensitivity. [748]

A systematic review in 2006, compiled from the results of the testing of 933 infants, confirms that manometry and rectal suction biopsy are the most accurate tests in the diagnostic workup of Hirschsprung disease. [749]

Assessment of the RAIR has not been confined to infants. In 1998, Deen et al used it to assess 30 patients with diabetes and compare it with the data from 22 age- and sex-matched healthy controls. Twelve of the diabetics had impaired continence for gas (n = 12) and liquid faeces (n = 3). None of the controls had incontinence. They classified the RAIR into three categories: normal, present, abnormal (requiring more distension than normal to elicit a response). They found that the RAIR was present in eight, abnormal in five (one incontinent) and absent in 17 (11 incontinent) diabetics, while it was present in 18 and abnormal in four controls ($p = 0.031$). They concluded that the RAIR was impaired in significantly more patients with diabetes than controls and that it was either impaired or absent in all diabetic patients with incontinence. [750]

In 2007, Shafik et al [751] noted that the RAIR was elicited with a lower volume of rectal distension in a large proportion of women who suffer from the inadvertent passage of flatus during intercourse compared to women without this problem..

There is also evidence that the RAIR can be altered by therapy:

In 2002, Sunic-Omejc et al treated 49 children with chronic idiopathic constipation; 24 were allocated to conventional and 25 to biofeedback therapy. Amongst other factors, the volume to elicit the RAIR became significantly higher in the group who had had biofeedback therapy (and this group had a better symptomatic response to therapy compared to the group treated with conventional therapy). [752]

In 2003, Saigusa et al retrospectively reviewed the records of 100 patients who had ARPS before and after restorative proctocolectomy with ileal pouch-anal anastomosis for mucosal ulcerative colitis. The rectoanal inhibitory reflex was noted in 96 patients before surgery, but it was found in only 53 (53 percent) after ileostomy closure. Incontinence status data was available in only 62 of the 100 patients (32 RAIR-positive; 30 RAIR-negative). There were significant differences relative to the incidence of nocturnal soiling (12/30 (40%) 23/32 (72%), $p = 0.0012$) favouring the presence of the rectoanal inhibitory reflex. They concluded that preservation of the rectoanal inhibitory reflex correlated with a decrease in the incidence of nocturnal soiling after double-stapled ileoanal reservoir construction. [753]

In 2004, Sangkhathat et al showed that the RAIR was present in 94% of cases without constipation and 12.5% of cases with constipation following anoplasty in 24 infants aged less than 3 years. They concluded that RAIR plays an important role in emptying function and, as far as possible, this function should be preserved during reconstruction. [754]

Conclusion (evidence level 1/2)

- Assessment of the rectoanal inhibitory reflex in infants is a valuable tool in screening for Hirschsprung's Disease.

Conclusions (level 3)

- The rectoanal inhibitory reflex may be different in different patient groups and can be modified by intervention.

Recommendation (grade A/B)

- Assessment of the rectoanal inhibitory reflex by manometry is clinically valuable in screening for Hirschsprung's Disease.

Recommendation (grade C)

- Assessment of the rectoanal inhibitory reflex in any other patient group is of no proven clinical value.

2. ANISMUS

When a patient attempts to defaecate by initiating a Valsalva manoeuvre, puborectalis and the external sphincter should relax. In some patients, the muscles tighten up and this is termed anismus.

Its presence can be detected by EMG of the muscles using surface electrodes or needle electrodes. Evacuation proctography is also used to detect anismus but the results do not always correlate with EMG and evacuation proctography may be a less sensitive indicator of anismus. [755, 756]

Difficulty evacuating a rectal balloon (see next section) is also used as a marker for anismus but again, this does not always correlate with EMG. [755, 756]

A further option to detect anismus is by measuring pressure in the anal canal when the patient performs a Valsalva manoeuvre. [757] If a water-perfused system is used, this may stimulate abnormal muscle activity and overdiagnose anismus. [758] Movement of the pressure sensor during straining is another confounding factor in this assessment and it is not particularly sensitive.

In 2007, Murad-Regadas et al used a different imaging approach to determine anismus. They showed that on anal endosonography, changes in the ano-rectal angle on straining correlated with the presence or absence of anismus as determined by anal manometry [759]

Therefore, it can be seen that there several different methods to test for the presence or absence of a paradoxical contraction of puborectalis and the external anal sphincter on straining. However, measurements by the different techniques are not always in agreement and, whilst it is tempting to consider that needle EMG may be the most sensitive indicator of anismus, there is no real evidence to substantiate such a claim. Perhaps the presence of anismus, detected by one of the methods above, is best confirmed with a positive finding on one of the other tests. This sensible approach was suggested by Park et al in 1996. [760]

The other consideration relating to this topic is that it is difficult to know what the clinical significance of the finding of anismus is. Although there are individuals with defaecatory difficulty who have the finding of anismus, there appear to be many patients who have no difficulty with evacuation who also show evidence of anismus. [756, 761, 762]

Nevertheless, if anismus is treated by biofeedback or botulinum toxin, some patients will show relief of their symptoms and a measurable normalisation of muscle function on straining. [763, 764]

Conclusions (evidence level 3)

- Anismus, the paradoxical contraction of puborectalis and the external anal sphincter on straining, can be detected by various techniques. The techniques all have different sensitivities to detect this phenomenon but there is no evidence to demonstrate which is the best.
- Although anismus can be found in patients with difficult defaecation, it is present in many who do not have such problems. Therefore its clinical significance is uncertain.
- Treatment of anismus can result in normalisation of muscle function and defaecation difficulty in some patients

Recommendation (grade C)

- Techniques to detect anismus may have some validity and lead to the effective treatment of some patients with difficult defaecation.
- The clinical significance of anismus needs more verification and the optimum technique to detect it needs to be determined

3. RECTAL COOLING TEST

In 2007, Shafik et al carried out measurement of rectal pressure with saline at 30ºC and then at 4ºC. They found that the iced fluid increased rectal tone in healthy controls and constipated patients with anismus while it had no effect in the other patients with consipation. They postulated that the lack of increase of rectal tone may be secondary to rectal inertia. They concluded from this preliminary study that this test might be useful in subdividing constipated patients into those who have rectal inertia and those who have anismus. [765] There have been no further reports on this measurement.

4. BALLOON EXPULSION TESTS

The test determines the ease with which a balloon in the rectum can be expelled. It is alleged to help determine the cause and management of difficult defaecation [766] and study the effects of treatment [767, 768]. However the lack of standardisation coupled with the often unphysiological position a patient has to adopt for defaecation is a current limitation of tests of this sort.

5. AXIAL FORCES

In 2006, Bharucha et al studied the dynamics of defaecation. They measured axial rectoanal forces with an intrarectal sphere or a latex balloon fixed at 8, 6, or 4 cm from the anal verge and connected to axial force and displacement transducers. [769] Rectoanal forces and rectal pressures within the latex balloon were measured at rest and during squeeze, simulated evacuation, and a Valsalva manoeuvre). The measurements were carried out in 12 asymptomatic women and 12 women with symptoms of difficult defaecation. Anal resting and squeeze pressures were also assessed by manometry and were similar in control patients and symptomatic patients.

At rest, axial rectoanal forces were directed inward and increased as the device approached the anal verge. Control patients augmented this inward force when they squeezed and exerted an outward force during simulated expulsion and a Valsalva maneuver.

The force change during these manoeuvres was also affected by device location and was highest at 4 cm from the verge. In the patients with difficult defaecation, the force at rest and the change in force during all manoeuvres was lower than in control patients.

The rectal pressure during a Valsalva maneuver was also lower in those with difficult defaecation compared to control patients, suggestive of impaired propulsion. They concluded that the women with defecatory symptoms had weaker axial forces not only during expulsion but also during a Valsalva manoeuvre and when they contracted their pelvic floor muscles, suggestive of generalized pelvic floor weakness

This is an interesting development but the sample size is much too small to determine whether this test has any clinical or research potential. There have been no further publications relating to this measurement.

VI. PUBLISHED RECOMMENDATIONS/GUIDELINES REGARDING PRACTICE OF ANORECTAL PHYSIOLOGY STUDIES

To date, there has been no universal standardisation of the tests, the terminology or the units of pressure employed in anorectal physiology studies. In 2007, there were some recommendations regarding manometry (including sensory testing and compliance measurement) published in German [709]. 8 years prior to that, there were recommendations published by the American Gastroenterological Association [584] and even earlier in 1989, a British working party made some recommendations relating to these measures [770]. None have been universally adopted.

In 2002, Azpiroz et al stated that tests for which there is consensus regarding their clinical utility include 1) resting anal canal pressure, 2) anal canal squeeze pressure (peak pressure and duration), 3) the rectoanal inhibitory reflex elicited by balloon distension of the rectum, 4) anal canal pressure in response to a cough, 5) anal canal pressure in response to defaecatory manoeuvres, 6) simulated defecation by means of balloon or radiopaque contrast, 7) compliance of the rectum in response to balloon distension, and 8) sensory thresholds in response to balloon distension. However, they acknowledged that the clinical utility of all anorectal manometric tests is limited by the relative absence of 1) standardisation of test protocols and 2) normative data from a large number of healthy individuals. They also stated that the interpretation of these diagnostic tests is also complicated by the fact that patients are able to compensate for deficits in specific physiological mechanisms maintaining continence and defaecation by utilising other biological and behavioral mechanisms. [771]

In 2004, Kouraklis and Andromanakos discussed evaluating patients with anorectal incontinence. They discussed the investigations used to evaluate anorectal physiology including anorectal manometry, anal endosonography, nerve stimulation techniques, electromyography, defaecography, endoluminal magnetic resonance imaging, the saline continence test, and the balloon-retaining test. They concluded that, although all of these tests are important, the most useful for patients with incontinence are anal manometry, anal endosonography, and the pudendal nerve terminal motor latency test, because they can identify anatomical or physiological abnormalities for which there may be effective treatments. [772]

In 2004, Bharucha discussed outcome measures for faecal incontinence. Whilst acknowledging that there is no standardisation for anal manometry, he expressed the opinion that, providing careful attention was paid to techniques, that there was sufficient

reproducibility for anal pressures, rectal compliance and sensation to enable them to be used as outcome measures. He outlined problems with surface EMG and pudendal nerve terminal motor latency assessment which prevents them from being considered as an outcome measures. He thought that needle EMG was a more reliable measure than surface EMG but did not pass an opinion as to whether there was evidence for it being a good outcome measure; he expressed the view that it may help identify people who would respond to therapy such as sphincter repair or sacral nerve stimulation. [773]

In 2005, Prott et al acknowledged that there were conflicting recommendations from consensus groups with regard to the assessment of resting anal sphincter pressure. In 54 patients suffering with constipation or faecal incontinence, they evaluated and compared the performance of stationary, stationary pull-through and slow pull-through techniques for evaluating resting anal sphincter pressures. Although the measurements from each technique highly correlated with each other, they concluded that resting anal sphincter pressure varies according to the specific technique employed and made a plea that standardised anal sphincter testing should be established to enable inter-laboratory comparisons. [774]

In 2005, Ortolani et al stated that anorectal manometry is the basic investigation for the study of anorectal function. However, they stated that lack of a standard execution technique and of any common definition of the manometric parameters constitutes a major limitation. They proposed a standard technique for performing manometry which would enable manometry to be performed in less than 30 minutes and yield approximately 10 parameters which are easily identified and interpreted. [775] However, there does not appear to be any subsequent publications using this proposal.

In 2007, Deutekom et al studied a consecutive series of 162 patients with faecal incontinence. They found that the hypothesised associations between urgency and passive incontinence and functional and anatomical impairment of the anorectum were less clear-cut than previously assumed. They concluded that patients presenting with faecal incontinence should undergo physiological investigation. [551]

In 2007 a consensus conference on faecal incontinence formed part of the programme at the International Conference on Faecal Incontinence (Bari, Italy). [776] The expert participants discussed the place of endoanal ultrasound, PNTML assessment, anal manometry, EMG and rectal sensitivity testing by balloon distension in the assessment of a patient with faecal incontinence. Most thought that endoanal ultrasound was the most useful investigation in helping to determine treatment and some carry it out on every patient they see with faecal incontinence. There was also a strong opinion that assessment of rectal sensation was important. At best, the other tests were carried out on an individual basis, some carrying out PNTML assessment in order to counsel patients regarding the outcome of a sphincter repair. Interestingly, one expert carried out anal manometry and PNTML assessment not because he needed it but because “there’s no journal that will accept a paper from me when I haven’t done it!”

In 2008, Thekkinkattil et al again acknowledged that that there is no standardisation of investigations, and treatment outcomes are variable for patients with faecal incontinence. They also pointed out the lack of a pretreatment classification of incontinence. They proposed that patients could be divided into four groups: traumatic incontinence, neuropathic faecal incontinence, combined faecal incontinence and idiopathic faecal incontinence (according to manometric variables and demographics). Their hope is that such a classification system will enable comparison and interpretation of the outcomes of different studies and also help in the selection of patients for appropriate treatments. [777]

G. SUMMARY OF RECOMMENDATIONS FOR CLINICAL PRACTICE RELATING TO ANORECTAL PHYSIOLOGY STUDIES

		ADULT	CHILDREN
Anal manometry	resting pressure		
	squeeze pressure		
	rectal sensitivity (balloon distension)		
	RAIR		
Neurophysiology	PNTML		
	surface EMG		
	needle EMG		
Compliance	static		
	barostat		
Electrical sensitivity	anal		
	rectal		
Other Tests	saline retention		
	balloon expulsion		

Grades of recommendation	
Grade A	
Grade B	
Grade C	
Grade D	
Investigational	

There have been old [778] and more recent reviews of these tests[779]

1. The only test under the umbrella of anorectal physiology studies that appears to have proven clinical value is determining the presence or absence of the RAIR in newborn infants.
2. There have not been any major studies setting out normal ranges for the parameters measured in ARPS. Therefore, the sensitivity of the measures to distinguish normal from abnormal is largely unknown.
3. This situation is compounded by the great variety in techniques of testing, size and types of catheter for manometry, the lack of standardisation of other techniques of testing the lower GI tract, the lack of standardisation of terminology and even simple issues such as to whether particular tests require an empty or full rectum.
4. A minor point but there is no universal unit of pressure adopted for anal manometry which does not help comparisons of the results from different centres.
5. Many studies have shown changes in the measured parameters as a result of treatment but, without there often being a control arm, the significance and relevance is unknown.
6. There is some evidence to suggest that some of the tests under the umbrella of ARPS can help in determining patient management.

Recommendations

The committee recognises that anorectal physiology studies are helpful in objectifying the function of the anorectum and aiding the diagnosis of the cause of faecal incontinence. There is some evidence that some of the tests can help determine patient management.

However, the committee recommends that urgent consideration needs to be given to standardising the tests and terminology. This will then help to better determine the reproducibility, reliability and prognostic value of the tests. It should then also be possible to generate a universally useful set of normative data.

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German Societies of Neurogastroenterology (committee for proctology), Abdominal Surgery (coloproctology working group), and Coloproctology. [709]

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