Aims of course/workshop
The aims and objectives are: giving a broad review of the diagnostic tools and measures to help identify Intrinsic Sphincteric Deficiency and to evaluate the degree of sphincteric weakness. The audience will be able to understand better how to decide upon the suitable mode of treatment for such cases according to the etiology and whether there is a concomitant lesion or not.

Learning Objectives
1. To provide a range of knowledge about refractory overactive bladder syndrome.
2. Discussion about difficult cases of lower urinary tract reconstruction including vesicovaginal fistula.
3. Controversial of female urology and pelvic organ prolapse will be discussed.
Pathophysiology of Intrinsic Sphincteric Deficiency

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Definition

- ICS (2002): "Urodynamic stress incontinence is noted during filling cystometry and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction... Any delineation into categories such as... intrinsic sphincteric deficiency may be simplistic and arbitrary, and requires further research."
- ICS-IUGA (2010): "..."
- ICS 2011 (Bristol): "Terminology should permit improved definition of the sphincteric mechanism, allow individual patient characterization and serve as useful waypoints in treatment decisions."

Causes of ISD

- Previous Pelvic Surgery (75%)
  - Anti-incontinence surgery
  - Urethral diverticulectomy
  - Radical Hysterectomy
  - Urethroscopy
  - Resection or incision of vesical neck
- Nosocomial (13%)
- Pelvic Irradiation
- Neurologic Conditions
  - Myeloplasia
  - Anterior spinal artery syndrome
  - LumboSacral neurologic conditions
  - Shy-Drager syndrome
  - end-stage Diabetes
- Aging & Hypoestrogenic States

Components of Urethral “Health”

- Intact fascial and muscular support
- Good blood supply
- Good nervous system supply

So...

- Any disruption of these features may result in decrease in functional capacity of the urethra
The Verdict?

- Anything that damages lateral urethra or supporting tissue
- Anything that restricts or interrupts blood flow caudally
- Anything that stretches the nerves repeatedly

Components of Urethral “Health”

- Intact fascial and muscular support
  - Previous or Radical surgery
  - Birth Trauma
  - Collective stretch, pressure & trauma aging
- Good blood supply
  - Previous surgery
  - Birth Trauma
  - Radiation*
- Good nervous system supply
  - Previous surgery
  - Birth trauma leading to neuropathy
  - Neuropathy due to NS disease, progressive (e.g. DM, aging)

Radiation Cystitis / Vasculitis

Endarteritis obliterans - With fibrous internal thickening of arterial wall due to radiation

Contorted internal elastic membrane artery due to radiation

Animal Model of ISD

- In search of animal model to manipulate in ISD research, a group at the University of Pittsburgh attempted to use a common bladder surrogate for urodynamics, the Sprague-Dawley rat.
- Cauterization of tissues lateral to the mid-urethra decreased LPP without affecting bladder function.
- This electrocauterization model produced low LPPs that, after 2 weeks, were maintained for up to 16 weeks. Histology suggests that damage to striated muscle and nerves might have contributed to the change in LPP in this model for ISD.

References

References

Adjustable Continence Therapy (ACT)

Ervin KOCJANCIC MD

Intrinsic Sphincter Deficiency represents a challenge in the treatment of Urodynamic Stress Urinary Incontinence (SUI). Diagnosis of Intrinsic Sphincter Deficiency (ISD) should address urethral elements, including pudendal innervation; striated sphincter mass and function; urethral smooth muscle, mucosa and submucosal cushions. Treatment should be focused on increasing urethral resistance. In patients with severe ISD creating an adequate intrinsic urethral resistance might be more beneficial than the correction of urethral hypermobility, which in itself may not result in stress urinary incontinence. Even if corrective surgery provides initial improvement; when factors affecting continence change, eg weight fluctuation and estrogen changes, there may be a need for secondary or even tertiary surgical intervention over time. Indeed, if no benefit was first achieved, a further alternative surgical option should ideally be considered. Given these parameters, we decided to assess the safety and efficacy of an implantable device, the Adjustable Continence Therapy (ACT®) which could be titrated over time as required in a group of women with recurrent stress urinary incontinence.

The ACT device:
The Adjustable Continence Therapy was developed by Uromedica, Inc. (Plymouth, MN). The device consists of two silicone elastomer balloons on each side of the proximal urethra with each connected via a conduit to a titanium port buried superficially in the fatty tissue of the labia majora. Placement of the balloons at either side of the bladder neck is achieved using two specially designed reusable blunt and sharp trocars and a U shaped cannula. There are 4 different device lengths; 6, 7, 8 and 9cm, which equates to the distance from bladder neck to skin with an additional 3-4cm for burial of the port.
Each balloon has a recommended maximum volume of 8cc. At any time post operatively, each balloon can be volumetrically increased or decreased by percutaneous injection through the port using a 23G Huber non coring needle in order to achieve optimum continence.

**Surgical Procedure:**
The procedure can be performed using general, regional or local anaesthesia, based on patients’ needs and physician discretion. The patient is placed in standard lithotomy position and the bladder is filled with 100 ml of dilute contrast through a 16Fr Foley catheter. The balloon of the catheter is filled with 10cc of pure contrast to enable fluoroscopic visualisation of the bladder neck. Bilateral 1cm small incisions are made in the Labial Sulcus at the level of vaginal introitus below the urethral meatus. Using fluoroscopic guidance and digital vaginal palpation, a sharp trocar loaded in a U shaped cannula is directed through the incision, perforating the pelvic diaphragm towards the bladder neck parallel to the proximal urethra anterior to the vagina. A blunt trocar may be employed to reduce the risk of urethral or bladder perforation. Once the tip of the trocar is at the bladder neck, the trocar is withdrawn and incremental markers along its shaft used to measure the required length of device to be implanted. The trocar is removed completely leaving the U shaped cannula in place. The ACT device is then inserted into the U shaped cannula using a pre loaded guide wire as a pusher. Once the correct position is confirmed on the image intensification screen, the balloon is filled with 1-1.5cc of isotonic contrast solution to stabilise its position, and the process is repeated on the contralateral side. The guide wire and U shaped cannula are removed after a fluoroscopic check. The ports are buried in the labia majora in a superior ventral position and the incision closed in two layers. A 16Fr urethral catheter remains in situ overnight as a precautionary measure. At our institution, we soak the devices in an
antibiotic solution before insertion and prescribe preoperative antibiotics consisting of 160mg Gentamycin and a post operative course of oral Ciprofloxacin 500mg once a day for 5 days as a prophylactic measure. First balloon adjustments may be conducted at 4-6 weeks to allow for creation of a pseudo capsule to occur around the balloon. Subsequent increments should be spaced with a minimum of 4-week intervals and continued until optimum continence has been achieved. A maximum of 1ml of isotonic solution should be inflated per balloon at each visit to avoid splitting of the pseudo capsule and increasing the risk of possible balloon erosion and migration.

From May 2001 until May 2006, 57 patients (mean age 62.59 years, (range 18-86 years) were enrolled, implanted with the Adjustable Continence Therapy device and evaluated post operatively with a minimum of 12 months follow up. A number of patients were treated prior to this date but not included in this evaluation due to the use of an earlier generation device, and the learning curve required for such an innovative procedure. Mean follow up was 72 months (range 12-84) with a median follow up of 58 months. All patients had undergone at least one previous pelvic surgery. Twenty seven patients had undergone one or more anti incontinence surgical procedures including Burch colposuspension; injectable bulking agents (Collagen, Macroplastique, Zuidex), Pubo Vaginal slings or tensionless tapes (TVT, TOT). No statistically significant differences were found between the different groups of each previous intervention. Six patients had also previously undergone prolapse repair. Nineteen (33.3%) patients had coexistent grade I prolapse which did not require concomitant surgical intervention. Mean duration of incontinence since failure of previous surgical treatment was 1.74 years (range 1-5 years). Twenty nine patients (50.9%) were obese (a BMI of ≥ 35) at time of surgery. Operative time was 20.3 mins (range 10-30 mins) with a blood loss of <50mls in all cases. Fourteen (24.6)% patients underwent implantation utilising local anaesthesia comprising
of 10mls per side 4% Bupivacaine and 1% lidocaine; 37 (64.9)% required spinal anaesthesia whilst 5 (8.8%) underwent general anaesthesia. Screening time for verification of balloon positioning using image intensification was 2.03 mins (range 1-3.6 mins) devices. Intra operatively, bladder perforations occurred in 2 patients, visualised by leakage of contrast from the bladder through the cannula and on fluoroscopic image. On each occasion, the trocar and cannula were removed, repositioned via a more lateral access and balloons inserted. In these 2 patients, the urethral catheter was retained for 48 hours. No further post operative sequale resulted. All other patients were able to void following catheter removal within 24 hours with no post void residual detectable on ultrasound. No postoperative analgesia was required and all patients were discharged within 24 hours of surgery.

There was a statistically significant improvement in Quality of Life based on I-QoL from 27.2 at baseline at each of the post operative evaluation points (p=<0.001). Pad count significantly decreased from 5.6 at baseline to 1.24 at 12 months which was maintained over time (Table 1). Patient self perception reported on Visual Analogue Score improved by 50% within 3 months and continued to improve over time as further adjustments improved continence

Postoperative adjustments were performed if incontinence persisted or recurred, or until optimum continence had been achieved. Eighteen patients (31.6%) did not require any postoperative adjustments. The remainder (68.4%) required singular or multiple adjustments range (1 -11) during the course of 6 years demonstrating the ability to titrate the ACT balloons long term.

Postoperative Urodynamics performed at 12 months was available on 30 patients and showed a statistically significant increase in VLPP from a mean value at base line of 48.18 cm H₂O +/- 24.38 to 86.0 cm H₂O +/-21.44. (p<0.01). However, there were no
statistically significant changes observed in the Maximum Urethral Closure Pressure following surgery (47.39 cm H2O +/- 24.35 at baseline compared to 51.06 +/- 19.31 post operatively).

Complications.
Labial haematomas were observed in 3 pre menopausal patients within 24 hours of implantation. The haematomas spontaneously reabsorbed without intervention and presumably resulted from inadvertent damage by the trocar to the vestibular bulb⁶. On questioning, none of these patients reported any deterioration in sexual function post operatively.

Postoperative complications necessitating device removal included migration seen in 8/57 patients (14.1%) and urethral erosion in 2/57 (3.5%) patients. Additionally, 5 balloons were explanted due to device failure. Of these, 1 balloon containing 5.5cc deflated after one month. The other two balloons failed at 3 years, one containing 6cc and the other with 2cc. In total, 15/114 balloons (13.2%) were removed in 12 patients with only 3 patients requiring bilateral removal. Removal was performed in the outpatient office utilising topical anaesthesia only. A small incision was made over the port, the port grasped with forceps, the balloon deflated and the device was easily retrieved using a simple grasping technique. Five replacement balloons were implanted in 5 patients 6 weeks after removal. Two out of 5 patients became dry (no pads), 2 were significantly improved (< 1 pad a day) and 1 was unchanged.

Two (3.5%) patients had portal erosions occurring within a few days of implantation resulting from placement of the port directly inferior to the incision. The ports were cleaned with antibiotic flush, repositioned and the incision was resutured without any further problem. Had there been any question of infection associated with the erosion, the balloons would have been explanted and new balloons reimplanted at a later date.
The reported positive outcomes of tensionless tapes for the treatment of female stress urinary incontinence\textsuperscript{14} has given rise to a larger number of patients undergoing this procedure performed by an increasing number of surgeons across a number of specialities. Recent literature reviews suggest a dichotomy between patient satisfaction and dry rates with one study comparing a number of different commercially available slings indicating that dry rates range between 36.1\% and 45.2\%. This would suggest that there is a proportion of women who may require further intervention for treatment of their persistent incontinence, and for whom an alternative treatment option should be offered. Bulking agents provide relatively non invasive methods of treatment of stress urinary incontinence. Short term data suggests a cure rate of 59\% and additional improvement rate of 16\% at 12 months. Longer term results suggest a greater decline in success rates than retropubic suspension and sling procedures. Although the exact mechanism of placement of periurethral injectables has not been defined, an obstructive effect has been described which supports the entire wall, thereby increasing urethral resistance, albeit in the short tems. In our experience ACT results have not declined over time. Figure 2 demonstrates the different effects created. There may be a number of reasons why the ACT appears to be of benefit. Primarily, because continence is not a static state in women whose anatomy may alter due to weight fluctuation, estrogen changes, aging and unassociated surgery, the opportunity to post operatively regulate the urethral resistance is very beneficial to patient and physician. Secondly, 47.4\% of the patients in this group had failed previous anti incontinence surgery thus reducing the likelihood of success of further surgery; and thirdly the ability to perform a titratable procedure which can easily be reversed without sequelae if necessary is very attractive and contrasts to the removal of other prosthetic devices implanted for the treatment of SUI.
Conclusion:
Dealing with failed incontinence surgery and recurrent stress urinary incontinence has enormous social implications for the patient and represents a big surgical challenge for the physician.
Whilst our findings were encouraging particularly in terms of patients subjective outcomes, our study was limited in terms of the numbers of patients treated over the time period; the modification in procedural technique and the lack of more objective data. There is a need to conduct further study to establish the actual mechanism of action of the ACT in previous surgical failures, and to more closely monitor objective outcomes in the light of procedural and post operative management. We will continue to follow up our patients and await the results of other international studies to confirm whether these promising results can be replicated.

List of Figures:
Figure 1- Prior anti pelvic/ incontinence surgery

List of Tables:
Table 1- Results showing Quality of Life, Pad Count and Patient Global Impression Index.
Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Baseline (n=57)</th>
<th>12 Month (n=52)</th>
<th>24 Month (n=52)</th>
<th>36 Month (n=51)</th>
<th>48 Month (n=41)</th>
<th>60 Month (n=34)</th>
<th>72 Month (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IQoL</td>
<td>27.2 (SD 15)</td>
<td>65.9 (SD 17)</td>
<td>70.4 (SD 16)</td>
<td>70.4 (SD 16)</td>
<td>76.1 (SD 17)</td>
<td>78.4 (SD 17)</td>
<td>78.6 (SD 18)</td>
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<tr>
<td>Pad Usage</td>
<td>5.6 (SD 2.28)</td>
<td>1.61 (SD 2.10)</td>
<td>1.24 (SD 1.45)</td>
<td>1.14 (SD 1.84)</td>
<td>1 (SD 1.72)</td>
<td>0.65 (SD 1.10)</td>
<td>0.41 (SD 0.78)</td>
</tr>
<tr>
<td>PGI</td>
<td>2.33 (SD 1.04)</td>
<td>1.98 (SD 0.92)</td>
<td>1.78 (SD 0.86)</td>
<td>1.88 (SD 1.29)</td>
<td>1.76 (SD 1.0)</td>
<td>1.62 (SD 0.94)</td>
<td></td>
</tr>
</tbody>
</table>

Suggested reading:

7. Trigo-Rocha F, Gomes CM, Pompeo ACL, Lucon AM, Arap S. Prospective study evaluating efficacy and safety of adjustable continence therapy (proAct) for post radical prostatectomy urinary incontinence. J Urol 2006; 67: 965-969
minimally invasive Adjustable Continence Balloon device ProACT: Results of a Preliminary, Multicenter Pilot study. Urology 2007; 71(2):256-260
Bulking Agents in Intrinsic Sphincteric Deficiency

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Professor of Urology, Ain Shams University, Cairo
President of Pan Arab Continence Society

Urinary incontinence following radical prostatectomy has a reported incidence of 5 to 12% [1]. Post-prostatectomy incontinence and other forms of male urinary incontinence have a significantly negative impact on Quality of Life. Urethral incompetence usually requires interventional therapy. Treatment of ISD in men after radical prostatectomy is a technically challenging procedure.

Surgical augmentation of intraurethral pressure includes slings and implants, such as artificial sphincters or periurethral bulking agents. The latter involves injection of a bulking agent at the area of the bladder neck and proximal urethra to enhance urethral resistance to urine flow by approximating the urethral mucosa.

The artificial urinary sphincter is a known effective solution in managing ISD. However, it carries the risk of disturbed bladder compliance and function to a degree that may affect the upper urinary tract. Moreover, there is the possibility of urethral erosion, especially in patients with a history of difficult pelvic operation and/or significant blood loss.

Complications such as infections and mechanical problems, requiring revisions are additional disadvantages. The sling operation is proving to be technically difficult in males, especially after radical pelvic surgery. Extensive fibrosis associated with male incontinence after surgery or trauma, and pelvic irradiation after radical prostatectomy further complicates the procedure, therefore, it is rarely performed.

Alternatively, injection or placement of a bulking agent has the advantages of being easily performed as an outpatient procedure because of the use of local anesthesia and a low complication rate, which makes it suitable especially in the elderly incontinent population.

Stress Urinary Incontinence (SUI), which is the involuntary loss of urine during stressful activities, develops in 10 to 30% of women of all ages [2]. In women, two types of sphincter abnormality are diagnosed,
bladder neck hypermobility and Intrinsic Sphincter Deficiency (ISD). ISD may account for a higher failure rate of surgical procedures performed to treat Stress Urinary Incontinence (SUI) due to ISD.

Historically, slings have been the procedure of choice, however this procedure may increase and/or produce a significant incidence of urinary retention. Peri-urethral or trans-urethral bulking agents, which are less invasive, have been used to treat ISD for many years and avoid recurrent surgical procedures. Bulking agents are able to coapt the urethral mucosa and as a consequence produce higher resistance to increased abdominal pressure.

Injection of bulking agents into the urethral wall has been attempted with a variety of substances. The materials used to date have a wide range of success rates. The following are the so far studied agents:

**Resorbable**
- Animal Origin - Bovine Glutaraldehyde Cross Linked Collagen
- Human Origin - Fat
- Chondrocytes (cell cultured, Reprogenesis Inc.)

**Non-resorbable**
- Polytetrafluoroethylene (Teflon)
- Silicone microimplants (Macroplastique)
- Carbon particles (Durasphere)
- Dextranomer and stabilized Hyaluronic acid (Zuidex)
- Polyacrilamide Hydrogel (Aquamid)
- Ethylene Vinyl Alcohol in Dimethyl Sulfoxide (Tegress)
- Inflatable Silicon Balloons (ACT & ProACT)

Good results were reported with the use of polytetrafluoroethylene (PTFE) in the 1960s and 1970s [3]. PTFE (Teflon) paste consists of particles that vary in size from 1 to 100 µm, with 90% smaller than 40 µm, resulting in distant migration and granuloma formation [4]. The long-term results have been disappointing, Kiilholma and Mäkinen reported that only 18% of patients were continent 5 years after polytetrafluoroethylene injection [5].

Collagen (Contigen) is expensive and may cause allergic reactions in around 3% of patients. In most studies incontinence returned gradually with a median continence duration of 23 months [6]. Repeat injections are necessary to achieve sustained continence, which increases the cost.
The main disadvantages of using autologous fat relate to the variability of resorption as well as repeated injections. At 1-year follow-up only 28% of patients are cured with this therapy [7].

Numerous reports on PDMS for the treatment of female SUI have been published [8]. Encouraging results are reported in these studies, including 1 with over 5-year follow-up.

The Dextranomer is a type of sugar molecule that has been used for a number of years in the treatment of wounds. Hyaluronic acid is a naturally occurring substance produced by the body to firm tissues and lubricate joints. The hyaluronic acid used in ZUIDEX is synthetically produced. Neither of the ingredients in ZUIDEX gel is derived from animals, thus avoiding rejection risks that exist with animal-based products.

Aquamid is a Polyacrilamide hydrogel which is an atoxic, non-resorbable sterile watery gel. It is homogeneous, stable, not biodegradable, and has tissue-like viscosity and elasticity [9].

Tegress is Ethylene Vinyl Alcohol copolymer (EVOH) dissolved in Dimethyl Sulfoxide (DMSO) carrier. Upon injection, the DMSO carrier rapidly dissipates from the EVOH copolymer, forming a cohesive, spongy mass that serves to bulk surrounding tissue. Long term results are not available.

The ACT Device consists of two small implantable balloons. During a short procedure, the balloons are surgically placed under the skin next to the bladder. ACT Therapy has been used in more than 1,000 women in Europe, Canada and Australia. It is currently being studied in the United States in a Food and Drug Administration clinical study. Results of a previous study suggest that after a mean follow-up of 36 months, 62% of patients were dry and another 16% were much improved [10].

The use of bulking agents is a good, safe and effective alternative for the treatment of intrinsic sphincter deficiency in male and female patients. Although having lower efficacy than other surgical procedures, represent an alternative minimally invasive approach and may be particularly suited to those who have recurrent urodynamic stress incontinence following previous surgery.
References


10- Kocjancic E, Carone R, Bodo G, et al. 36 Month Follow-up with Adjustable Continence Therapy (ACT) in Female Stress Incontinence Due to Intrinsic Sphincter Deficiency (ISD) [abstract]. Taken from: International Continence Society (Montreal). 2005;624.
Conservative Management and Functional Training

Maura Seleme PhD, PT

Intrinsic Sphincteric Deficiency, Diagnosis and Management
Wednesday 7th October 2015
14:00-17:00

Introduction
Maura Regina Seleme, PhD - PT
Pelvic Physiotherapist - Brazil, France and The Netherlands
Coordinator and teacher Specialization in Pelvic Floor Dysfunctions for physiotherapists at Faculty Inspirar – since 2011

- Specialized in Urogynecology, Dysfunction ano-rectal and Sexology – France
- DU in Urodynamics - University of Medicine Xavier Bichat in the School of Medicine – Sorbonne – France
- IUGA ambassador SIG Pelvic Floor Rehabilitation for Brazil - since 2009.
- Director abafi-BRASIL and abafi-HOLLAND www.abafi.com.br and www.abafi holland.com

Intrinsic sphincteric deficiency
- type III stress urinary incontinence (SUI) is generally defined as a condition that involves intrinsic sphincter deficiency (ISD). Although the clinical parameters for ISD are loosely defined as a Valsalva leak-point pressure <60 cmH\textsubscript{2}O or a maximal urethral closure pressure <20 cmH\textsubscript{2}O, consensus is lacking.

Treatment options for intrinsic sphincter deficiency.

Shah SM, Gaunay GS.

Intrinsic sphincteric deficiency and conservative management?

Proper diagnostic tools SUI
- type I SUI
dysfunction PF: PFMT + - no awareness PF: Knack - awareness PF: BF/ES +
+ function compromised RES/TL: PFMT/EX +
+ general obstructing factors:PFMT/EX/info +/-

- type II SUI
yes/no dysfunction PF: PFMT +/-

- type III SUI
no dysfunction PF:
PFMT -, only compensation!!

Luqinbuehl 2014
intrinsic closure mechanism

- continence
  - intrinsic urethral closing mechanism:
    - tunica mucosa
    - tunica spongiosa
    - tunica muscularis

- supporting extrinsic mechanism
  - function pelvic floor

Guidelines on Stress Urinary Incontinence - Royal Dutch Society for Physiotherapy (KNGF) – 2011

structures of urethral support

- properties female urinary sphincter
  - coaptation (intrinsic sphincter)
  - compression (m. levatores ani)
  - support (fasciae & ligaments)


stress continence control system

- urethral support system pelvic floor
  - levator ani muscles & endopelvic fascia

40% – strong & fast PFM contraction clamp urethra, increasing urethral pressure to prevent UI during abrupt increase intra-abdominal pressure DeLancey 1988a

- against pubic symphysis, creating mechanical pressure rise DeLancey 1988b

- stiffness

aims PFMT → SUI

- ↑ PFM strength and/or timing PFM contraction ICI 2013
- Conditions: require repetitive active exercise Hall et al 1999

- ↑ PFM endurance Dumoulin et al 2011

- improve extrinsic cm Ashton-Miller et al 2001

- positive effect on ucm Rud et al 1980


assessment: history taking

associated pathology - diabetes, obesity, lower back pain, SDT - sexually transmitted disease, depression, neurological disease, medications

urogynecology - age of sexual initiation, infection, menopause

anorectal - constipation, hemorrhoids, anal incontinence

surgery? - hysterectomy, prolapses

obstetric history - episiotomy, vaginal delivery, baby weight

urinary behavior

Frequency:
day:_______ night:_______

( ) dysuria  ( ) abdominal strength
( ) difficulty to control urine
( ) urgency  ( ) pain
( ) burning feeling
Start Date:____________________

Incontinence ( ) daytime
( ) nighttime

With some effort ( ) urgently ( )

which kind of urinary incontinence?

What is wrong with you?? What do you expect from me?

visual analog scale
local, personal and social

pelvic floor dysfunction should be classified according to “ICS Standartisation”

By palpation of the pelvic floor muscles, the contraction and relaxation are qualified:
- Voluntary contraction can be absent, weak, normal or strong, and voluntary relaxation can be absent, partial or complete.
- Involuntary contraction and relaxation is absent or present.
- Based on these signs, pelvic floor muscles can be classified as follows:
  - non-contracting pelvic floor
  - non-relaxing pelvic floor
  - non-contracting, non-relaxing pelvic floor.

pelvic floor hyperactivity

physical examination shown by movies produced by abafi-HOLLAND 2014
diagnostic process in physical therapy

<table>
<thead>
<tr>
<th>CONCLUSION condition PF</th>
<th>Overactive</th>
<th>Normal</th>
<th>Coordination disorder</th>
<th>underactive</th>
<th>non functional</th>
</tr>
</thead>
</table>

KNGF Guidelines

Guidelines on Stress Urinary Incontinence - Royal Dutch Society for Physical Therapy (KNGF) - 2011

working mechanisms PT

- Conscious contraction before & during abdominal pressure & continuation contractions as behavior modification to prevent descent PF - the KNACK
  - Miller 1998

- Fast feed forward loop!!!!!! Pre-contraction!!!!
- Functional training!!!!

key-word timing

- Building up "stiffness" & structural support PF !!!
- Dose-responses, dosage exercises i.e., frequency, intensity, duration, kind of exercise, motivation, adherence, protocol
  - Ashton-Miller 2001; Bø 2004

key-word strength

the 4 Fs

- F = find
  - Feel the pelvic floor
- F = feel
  - Feel the pelvic floor
- F = force
  - Force the pelvic floor
- F = follow through
  - Follow trough, keep exercising

find information!

- Information anatomy & PFM
- Talking about perineum !!!!!

find and feel perineum

how to contract the pelvic floor

Imagine that you are tightening your anus as you squeeze the ball in your hand
**how to contract the pelvic floor**

- contraction
- relaxation
- respiration
- perception

**use evidence-based program!!!!!**

PFM training – SUI level 1, grade A ICI 2012


- 8-12 MAXIMAL contractions– inward & upward
- 6-8s contraction & relaxation
- 4 fast contractions– 8s of relaxation
- 3 sustained contractions 20s

**invasive techniques**

to show before the examination and first treatment an anatomical board with the muscles and intern organs localization

Talking about perineum !!!!!!

**manual therapy**

myofacial Training Effects:
- relaxation
- enhanced flexibility
- increase of blood circulation
- pain reduction
- sensory perception
- scar tissue manipulation
- reduction of fibrotic adhesions
- reduction of hypertonicity

**vaginal cones**

Theory: the cone weight intend to motivate the training so that the women contract firmly with progressive weight.

Use Period (15-20 min) adequate

It can cause ↓ blood supplement ↓ O2 consumption, fatigue & muscle sore

Synergist contractions instead of MAPs contractions

Refined protocol if used as BF

Arvon et al 2001,
Plevnik 1985,
Hay-Smith et al 2001,
ICI 2005


lack of consistency ES protocols

insufficient evidence ES > no or placebo treatment

conclusive evidence is lacking, but PFMT > ES

insufficient evidence to determine if ES >

no extra benefit in adding ES to PFMT

need for more basic research working mechanism ES

need to determine best ES and outcome measures

ICI 2012

UI & dysfunction PF: without awareness

objective biofeedback

restoration awareness PF

* if awareness restored → only PFMT

Berghmans et al 1998

kind of patient population who might benefit from BF

weak pfm

unaware of pfm

needs motivation in the exercises

women unable to contract their pelvic floor muscles voluntarily.

patients with structural sphincter defects that can’t undergone surgery.


types of BF

EMG-BF

Manometric BF

US BF

awareness automatization

signal acquisition
detection-amplification-translation

US BF

the ultrasound image is also able to provide direct feedback to the patient on patterns of muscle activation and assist them in the correct activation of these muscles.


ultrasound imaging allows physiotherapists to measure properties of muscle (cross-sectional area, thickness, length and displacement) in a reliable, repeatable manner

biofeedback through EMG

Biofeedback through EMG is nowadays as stable as the pressure registration.

It allows the use of small probes, applying biofeedback and electrotherapy at the same time (ideal on dyspareunias).

It doesn’t allow variables of muscle stretching and can be modified according to hormonal impregnation and vaginal opening size.

Selene, 2005

Manometric BF

- Less accurate than EMG
- Needs a pressure variation to be registered
- No influence from hormonal changes
- Easy to accommodate to the vaginal introitus

Binder, 2002

Sessió

Receive the action potential of the motor unit muscle fiber depolarization - contraction - repolarization – rest

FIGURE 3

FIGURE 4

FIGURE 2
Advantages to include BF in the treatment:

- no side effects
- not invasive
- active participation of the patient
- motivation in the training exercises
- the learning process offered by the biofeedback
- do not limit future options

Conclusions:

- In literature protocols of biofeedback showed a wide variation in:
  - Descriptions on patient education
  - Contraction parameters
  - Numbers of training sessions
  - Numbers of repetitions
  - Duration of training
  - Use of accessory muscles
  - Patient positioning, etc.

Recommendations:

- improve experimental design
- include long term follow-up data
- to use an adequate sample size that allows for meaningful analysis
- better methodological quality
- BF standardization

PFMT + biofeedback:

- wireless BF for functional training
- BF during sporting activities
- mimicking activities where normally UI

Wireless biofeedback

- Simple exercise asking for bending the knees causes a good PFM contraction...
just walking.....................

Walking with a bad posture, observe weak motor unit activity of the PFM.

Walking with correct posture (stretched out), significant motor unit activity of the PFM.

working the pelvic floor
nice advice

always walk in good posture

NO

YES

coughing causes PFM PRE-contraction

brusque unexpected movement causes PFM PRE-contraction

new technology in functional training

the Statics and Dynamics Abdomino-Pelvic

© Salerno, Berghmans, Uchoa 2014
direction of pressure transmitter in the pelvic floor

thoracic diaphragm

Thank you very much!
Maura Seleme

www.abafi.com.br
www.abafi holland.com
Slings for Female Intrinsic Sphincteric Deficiency

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Conventional Incontinence Procedures

- Needle suspensions
- Anterior colporrhaphy
- Burch or MMK Colposuspension
- TO Mesh Slings
- RP Mesh Slings
- Fascial sling
- Bulking Agents

Why do these surgeries not last?

If only attached to soft tissue (ie muscle or “fascia”), failure may be inevitable…

SO  Attach to bone!

OR  A ligament close to bone!

Suburethral Sling

- Strap of biological or synthetic material placed at the UVJ
- Stabilizes urethra
- Simulates “pubourethral ligament”
- Establishes continuity between the urethra and pubic bone

Traditional Suburethral Sling

- Giordano (1907) reported the first urethral sling
- McGuire and Lytton (1978) reported a 80% success rate for the “pubovaginal sling” noting an “intrinsic weakness” in the urethral sphincter in
- 75% of patients who failed multiple incontinence surgeries had
- 13% in women with no history of surgery
- Sand (1987) noted a 3-fold increase in Burch failure in a subgroup of patients with MUCP <20cm H2O
- Recommend more obstructive procedure

Contemporary Results Allografts

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>Processing Method</th>
<th>Improved (%)</th>
<th>Follow-up (mos.)</th>
<th>Cure (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliot</td>
<td>26</td>
<td>SD, – IR</td>
<td>92</td>
<td>15</td>
<td>77</td>
</tr>
<tr>
<td>Amundsen</td>
<td>104</td>
<td>FD, – IR</td>
<td>84</td>
<td>19</td>
<td>63</td>
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<tr>
<td>Wright</td>
<td>59</td>
<td>FD, – IR</td>
<td>98</td>
<td>12</td>
<td>NA</td>
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<tr>
<td>Hands</td>
<td>16</td>
<td>FD, – IR</td>
<td>86</td>
<td>12</td>
<td>79</td>
</tr>
<tr>
<td>Brown</td>
<td>121</td>
<td>FD, ? IR</td>
<td>83</td>
<td>12</td>
<td>74</td>
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<tr>
<td>Fitzgerald</td>
<td>35</td>
<td>FD, + IR</td>
<td>83</td>
<td>6</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>361/302</td>
<td></td>
<td>86.5%</td>
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</tbody>
</table>

Contemporary Results Autologous

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>Type of fascia</th>
<th>Success (%)</th>
<th>Follow-up (mos.)</th>
<th>Post-op retention (%)</th>
<th>De novo urgency (%)</th>
<th>Sling erosion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morgan</td>
<td>247</td>
<td>rectus</td>
<td>98</td>
<td>52</td>
<td>2.4</td>
<td>7.5</td>
<td>0</td>
</tr>
<tr>
<td>Chaine</td>
<td>251</td>
<td>rectus</td>
<td>92</td>
<td>36</td>
<td>2.0</td>
<td>3.0</td>
<td>0</td>
</tr>
<tr>
<td>Gower</td>
<td>32</td>
<td>fascia lata</td>
<td>67</td>
<td>14</td>
<td>3.0</td>
<td>9.0</td>
<td>0</td>
</tr>
<tr>
<td>Beck</td>
<td>170</td>
<td>fascia lata</td>
<td>92</td>
<td>NR</td>
<td>&lt;1.0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Haas</td>
<td>40</td>
<td>fascia lata</td>
<td>86</td>
<td>48</td>
<td>2.7</td>
<td>10.0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>rectus</td>
<td>88</td>
<td>52</td>
<td>2.7</td>
<td>10.0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>96.1%</td>
<td>2.3%</td>
<td>4.5%</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Burch vs. Sling?

- **SISTER Trial: Multi-center RCT Burch vs. Sling with autologous fascia (N = 655)**
  - 79% F/U at 2y, combo of subjective & objective criteria
  - Sling vs. Burch: overall success 47% vs. 38%** (any leak)
  - Sling vs. Burch: stress success 66% vs. 49%**
  - Sling patients had more UTI, void dysfunction, DOI
  - Systematic review / Meta-analysis of 13 RCTs Burch and traditional sling (N = 760)
  - No statistically significant differences b/w traditional slings and other types of sling
  - Due to low numbers, no direct comparison of women with low urethral resistance or intrinsic sphincteric deficiency

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MUS Introduction

- Number of SUI surgeries have increased dramatically since mid-1990s introduction of TVT
  - Reuters Marktscan Commercial Claims & Encounters 2000-09
  - (N = 32.9 Million women aged 18-64) 74 Million person-years
  - 182,110 SUI procedures (246:1/100K person-years)
  - Suburethral sling (198:3/100K person-years) 37.3% (2000); 89.1% (2009)
  - Burch (25.9/100K person-years) 40.6% (2000); 3.8% (2009)
  - Highly successful at treating SUI, can be introduced via a top-down or bottom-up RP approach, or an inside-out or outside-in TO approach (TOMUS, N=597)
  - RP 80.8% objective cure, 62.2% subjective
  - TO 77.7% objective cure, 55.8% subjective

**Traditional Sling vs. MUS?**

- Multicenter, RCT of Autologous fascia sling, TVT and Pelvic sling (N = 72, 79, 50):
  - Pelvic poor results at 1yo. 1yo (73%, 61% improved, 22% dry)
  - At 6mo.: improved: AFS 95%, TVT 92% (NS)
  - At 1y, improved: AFS 90%, TVT 93% (NS)
  - AFS 6y, dry: AFS 48%, TVT 55% (NS)
  - AFS took 20m longer, had higher CISC rates (9.9 vs. 1.5%)
- Systematic review / Meta-analysis of 39 RCTs comparing Burch, AFS sling and MUS
  - Patients undergoing AFS & MUS had similar cure rates*
  - AFS had more LUTS & Higher Re-operation Rate*
  - Retropubic MUS had slightly higher continence rates vs. Burch
  - Retropubic MUS had higher complication rate (bladder perf)

![Slings for Female ISD](Image 49x77 to 54x83)


**TVT vs. ISD?**

- Retrospective sample of a prospective, multicenter cohort, followed-up at 4 years (N=49):
  - 74% completely cured
  - 12% significantly improved
  - 14% not cured: majority >70 yo or MUCP <10cm H2O
- Some experts advise omitting the ¼ inch gap when placing the TVT in women with ISD:
  - Tape placed touching urethra (still without tension)
- Retrospective cohort of women with ISD treated with TVT (N=35):
  - Strict definition of ISD: MUCP < 20cm H2O & VLPP < 60cm H2O
  - High success rate of 91.4% at 1y
  - 2 of 3 failures had a “fixed urethra”

![Slings for Female ISD](Image 49x296 to 54x302)


**TOT vs. ISD?**

- Retrospective cohort of women undergoing TOT, divided into three treatment groups, F/U at 1 and 2y (N=35):
  - ISD with UH (G1): 96.1% and 87.5%
  - ISD w/o UH (G2): 88.7% and 86.7%
  - UH w/o ISD (G3): 96.6% and 96.4%
  - Lack of UH a “risk factor” for TOT failure
- One-year F/U of TOMUS, RCT of women w/ SUI randomized to TOT or TVT (N=557):
  - Examined a subgroup of women who “Failed” Obs. or Subj. (N=260)
  - Women in lowest Quartile of MUCP (< 45cm H2O) or VLPP (< 86cm H2O) had a 2-fold increase OR of failure (OR 1.88, 2.23)

![Slings for Female ISD](Image 49x515 to 54x521)


**Best MUS for ISD? TVT vs. TOT**

- Retrospective cohort of women comparing RP approach (TVT) to the TO approach (Monarc) (N=145):
  - Note: MUCP of < 20cm H2O exclusion for TOT group
  - Monarc was nearly 6 times more likely to fail at 3 months after surgery in women with borderline MUCP (42 cm H2O or less)
  - Success (Obs.) RP 97% vs. 91% TO, (Sub.) RP 80% vs. 84% TO
  - Low MUCP: (O) RP 97% vs. 84%** TO, (S) RP 87% vs. 77%***
- Prospective, RCT of women with USI and ISD, assigned to TVT or TOT, and F/U over three years (N=164):
  - Major outcome was recurrent symptomatic SUI requiring surgery
  - TVT 1.4% vs. TOT 20%, RR 7.73** (95% CI 2.1-113)
  - Overall success rates TVT 83.7% vs. TOT 72%***

![Slings for Female ISD](Image 66x79 to 262x238)


**Best Overall Sling?**

- Retrospective cohort of women with USI and ISD placed in one of 3 groups (N=256):
  - PVS (N=87), TVT (N=94) and TOT (N=72)
  - ISD Definition: < 20cm H2O MUCP or < 60cm H2O VLPP
  - 2 Year Cure Rates: 87.2%, 88.9%, 34.9%
  - 7 Year Cure Rates: 59.1%, 55.1%, N/M
- Inelastic RP MUS in women with ISD (N=247)
  - 87.4% subjective improvement, 7.2% retension, 7.7% reintervent
- Retrospective cohort of women with recurrent USI or ISD, treated with an adjustable sling (N=126):
  - 87% cured, 13% not
  - Of those, 7% declined intervention

**Typical Complications**

<table>
<thead>
<tr>
<th>Complications</th>
<th>PVS (n=87)</th>
<th>TVT (n=94)</th>
<th>TOT (n=72)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder injury</td>
<td>1 (1.2%)</td>
<td>0</td>
<td>0</td>
<td>0.6</td>
</tr>
<tr>
<td>De novo urgency</td>
<td>14 (16%)</td>
<td>14 (15%)</td>
<td>13 (18%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Voiding dysfunction (one month longer)</td>
<td>18 (19%)</td>
<td>17 (18%)</td>
<td>8 (11%)</td>
<td>0.75</td>
</tr>
<tr>
<td>V.D. Requiring surgery</td>
<td>0</td>
<td>3 (3.1%)</td>
<td>1 (1.4%)</td>
<td>0.26</td>
</tr>
<tr>
<td>Recurrent UTI</td>
<td>2 (2.3%)</td>
<td>6 (6.4%)</td>
<td>0</td>
<td>0.06</td>
</tr>
<tr>
<td>Mesh Erosion</td>
<td>-</td>
<td>1 (1.1%)</td>
<td>1 (1.4%)</td>
<td>1</td>
</tr>
</tbody>
</table>

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Questions?