International Continence Society Educational Course

ICS Sao Paulo, Brazil
July 28 – 29, 2006

PROGRAMME

ICS PARTNERS : Pfizer Medtronic

SAO PAULO, BRAZIL JULY 28 – 29, 2006

PROGRAMME

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ICS HISTORY AND COMMITTEES

Visit our website: www.icsoffice.org

The International Continence Society was founded in 1971 by Eric Glen under the name of the "Continent Club" and held its first annual meeting the same year in Exeter where 60 participants attended. In 2005, we have over 2,000 members from 70 different countries with over 3,000 delegates attending ICS 2004 in Paris.

The ICS aims to provide education and advancement of sciences concerned with urinary tract and pelvic dysfunction including urology, neurourology, gynaecology and urodynamics. The Society also promotes research into the causes, remedies and relief of incontinence and provides access to the results of that research via website, email, post, telephone, paper publication, newsletters and presentations, annual congresses and courses.

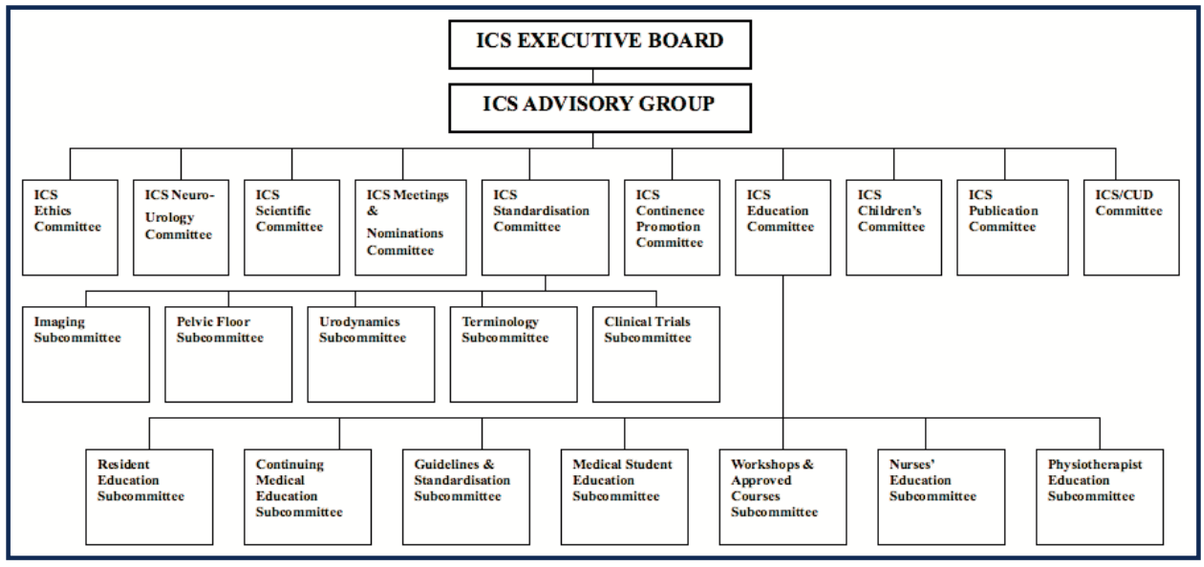
Our Annual Meeting is hosted by a different member each year, selected by members ballot four years in advance.

- 2006 Christchurch, New Zealand Chair, ***Ted Arnold***
- 2007 Rotterdam, The Netherlands Chair, ***Ruud Bosch***
- 2008 Cairo, Egypt Chair, ***Sherif Mourad***
- 2009 San Francisco, USA Chair, ***Anthony Stone***

Our membership subscription remains at £50 per annum and includes:

- Six bi-monthly copies of the Journal Neurourology and Urodynamics
- 40% reduction in registration to our Annual Meeting
- The ICS members' book and certificate
- Bi-annual ICS newsletters
- Access to other members worldwide
- Information and education via our website, office, courses and meetings.

Today, the society employs four fulltime staff at its head office in Bristol, UK and has an Executive Board comprising four voluntary directors. There is also an Advisory Group and many committees dedicated to various tasks ensuring the Society's charitable objectives are maintained (see chart below).



ICS Education Committee

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Prof. Carlos Levi D'Ancona
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Dr. Michael Halaska
Mr. Hashim Hashim
Dr. John P.F.A. Heesakkers
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Dr. Menahem Neuman
Prof. Flavio Trigo Rocha
Dr. Peter K. Sand
Dr. Ajay Singla
Mrs. Marijke C. Ph.Slieker ten Hove
Mrs. Amanda Wells
Prof. Jean-Jacques Wyndaele

GREETINGS

It is a great pleasure to organise the International Continence Society Educational Course, the first in South America. The ICS is committed to providing high-quality education for all healthcare and allied professionals with an interest in continence worldwide.

For 35 years the ICS has held an internationally recognised multi-disciplinary annual meeting of the highest scientific quality and in recent years there have been both local workshops and pre-meeting courses. Now the ICS Education Committee, chaired by Linda Cardozo, have created the stand alone ICS educational course outside of the annual meeting with the aims of discussion and exchanging experiences with colleagues of different countries.

This ICS subsidised course is intended to appeal to younger doctors, nurses, physiotherapists and scientists who may find it difficult and too expensive to attend the annual ICS meeting but are keen to understand the important aspects of the ICS.

We've designed this course to hold discussion between local and foreign experts in urinary incontinence, urodynamics, physiotherapy and other topics. Discussions of clinical cases will stimulate learning and help decision making in difficult patients. Many other topics will be covered during the course of the meeting and we would welcome your feedback so that we can provide even better educational courses in the future.

Besides the event don't miss Sao Paulo, a luxurious, sophisticated and refined city. This cosmopolitan city - the countries wealthiest – exudes charm. There are glamorous restaurants run by renowned chefs, high standard hotels as well as exclusive products and services developed for discerning and special customers. Great shows, performances of national and international artists and musicians, along with concerts in distinguished halls such as Sala Sao Paulo, provide unique experiences for those who want to enjoy all the sophistication Sao Paulo has to offer.

We hope that the Education Course fulfils your expectations and you enjoy the city of Sao Paulo.

Carlos Arturo Levi D'Ancona
Course Coordinator

Professor Linda Cardozo
ICS Education Committee Chairperson

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Linda Cardozo


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Carlos Arturo Levi D'Ancona


Ubirajara Ferreira

MEET THE SPEAKERS

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Telma Guarisi

John Heesakker

Helmut Madersbacher

Andrea Marques

Cristiano Gomes Mendes

Mirca Ocanhas

Valdemar Ortiz

Aparecida Pacetta

Paulo Palma

Gisele Regina de Azevedo

Cassio Riccetto

MEET THE SPEAKERS

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Carlos Luis Rocha

Nelson Rodriques Netto Jr.

Irineu Rubinstein

Marcia Salvador Geo

Werner Schaefer

Marcus Tcherniakoviski

Luis Seabra Rios

Philip Van Kerrebroeck

Salvador Vilar Correia Lima

Mandy Wells

Avicia Burchill, ICS Education Coordinator

GENERAL INFORMATION

Course Venue

WTC Hotel (Formerly Hotel Gran Melia)
Av. das Nações Unidas 12.559
São Paulo – SP
Brazil
Tel.: +55 11 31465900
Fax: +55 11 32623368

Language

Lectures and presentations will be given in English and Portuguese with simultaneous translation.

Clothing

Casual for all occasions.

Registration and Hospitality Desk

The Registration and Information Desk will operate at the following times:

Friday, July 28, 2006	08:00 – 18:00
Saturday, July 29, 2006	07:30 – 17:00

Refreshments

Coffee - will be served in the exhibition area.

Lunch - will be served on the 4th floor. Please present your lunch tickets from your personal registration envelope to gain admittance.

Webcast

There will be a webcast of presentations at the main course which is accessible at **http://www.icsoffice.org/icscoursesaopaulo2006**

Welcome Cocktail

Friday, July 28, 2006 at 18:00 at the Hotel Gran Melia.

CME Accreditation

EU-ACME - This Educational Course is accredited within the EU-ACME programme by the European Board of Urology Accreditation Committee with 12 credits.

Associação Brasileira de Medicina - Comitê Nacional de Creditação – This Educational Course is accredited with 8 points by the Associação Brasileira de Medicina.

These credits are stated on your certificate of attendance. In order to receive your certificate of attendance please complete your evaluation form and hand in at the reception desk.

Free Registration ICS 2006

By attending this course you will automatically be entered into a free raffle to win a registration for the ICS 2006 Annual Meeting which is being held this year in Christchurch, New Zealand. Unfortunately we are unable to assist with the flights and accommodation but we are sure you'll agree that this kind donation from ICS New Zealand Committee will be greatly received by the recipient. The winner will be announced after lunch on the first day of the course.

ICS

SAO PAULO 06

PROGRAMME

PROGRAMME

FRIDAY, JULY 28, 2006

12:00 Buffet Lunch

13:00 Welcome
Nelson Rodrigues Netto Jr.

13:05 Presentation - Brazilian Urological Society
Sidney Glina

13:10 Introduction – aims and objectives of course
Linda Cardozo

13:15 ICS Mission & Education Committee
Walter Artibani

13:30 ICS standardisation & terminology
Philip Van Kerrebroeck

14:00-15:00 **How to predict outcome after BPE therapy**
Coordinator: ***Nelson Rodrigues Netto Jr.***

- 14:00 Clinical treatment
  Valdemar Ortiz
- 14:10 Acute urinary retention
  Walter Artibani
- 14:20 Detrusor overactivity and outlet obstruction
  Carlos Arturo Levi D'Ancona
- 14:30 Detrusor underactivity
  John Heesakkers
- 14:40 Discussion of clinical cases

15:00 Coffee Break

15:30 New prospects in urodynamics
Werner Schaefer

16:00-17:30 **My drug is the best for overactive bladder syndrome**
Coordinator: ***Walter Artibani***

16:00 Tolterodine (Pfizer)
Luis Carlos Almeida Rocha

16:10 Oxybutinin (Janssen - Cilag / Apsen)
Carlos Arturo Levi D'Ancona

16:20 Darifenacin (Novartis)
Joao Luis Amaro

16 :30 Trospium (Indevus)
Aparecida Pacetta

16 :40 Propiverine (Apogepha)
Helmut Madesbacher

16 :50 Oxybutinin patch (UCB Pharma)
Linda Cardozo

17:00 'Placebo'
Pedro Araño

17:10 Discussion of clinical cases

17:30 What can nurses do to help in the management of incontinent patients?
Mandy Wells

18:00 Close & Welcome Reception

SATURDAY, JULY 29, 2006

08:30-09:30 **Do we still need intestinal segments to treat vesical dysfunction?**
Coordinator: ***Irineu Rubinstein***

08:30 Risk using intestinal segments
John Heesakkers

08:40 How to avoid complications
Nelson Rodrigues Netto Jr.

08:50 New tissues
Helmut Madersbacher

09:00 Does radiation therapy preclude the use of intestinal segments?
Ubirajara Ferreira

09:10 Discussion of clinical cases

09:30 What is new in Neurourology?
Helmut Madersbacher

10:00-10:40 **Neurourology update**
Coordinator: ***Philip Van Kerrebroeck***

10:10 Neurostimulation
Helmut Madersbacher

10:25 Neuromodulation
Homero Bruschini

10:40 Coffee Break

11:00-12:10 **Men who leak**
Coordinator: ***Carlos Arturo Levi D'Ancona***

11:00 The impact on the quality of life
Walter Artibani

11:10 Injectable procedures
John Heesakkers

11:20 Urethral constrictor
Salvador Villar Correia Lima

11:30 Slings
Luis Augusto Seabra Rios

11:40 Artificial sphincter
Flavio Trigo Rocha

11:50 Discussion of clinical cases

12:10 Buffet Lunch

13:00-13:40 **Debate – physiotherapy treatment in stress urinary incontinence**
Coordinator: ***Paulo Palma***

13:10 For
Bary Berghmans

13:25 Against
Marcos Tcherniakoviski

13:40 What Duloxetine can offer in the treatment of SUI
Linda Cardozo

SATURDAY, JULY 29, 2006 (Cont.)

14:00-15:10 **My tape is best for SUI**
Coordinator: ***Linda Cardozo***

	14:00	How and why tapes work ***Werner Schaefer***
	14:10	TVT / TOT (Gynecare) ***Telma Guarisi***
	14:20	Sparc / Monarc (AMS) ***Irineu Rubinstein***
	14:30	Neomedic (Remeex System) ***Pedro Araño***
	14:40	Safyre (Promedon) ***Cassio Luis Zanettini Riccetto***
	14:50	Discussion of clinical cases

15:10 Coffee Break

15:30-16:30 **Debate – Vaginal prolapse**
Coordinator: ***Linda Cardozo***

	15:50	To mesh ***Walter Artibani & Paulo Palma***
	16:10	Or not to mesh ***Telma Guarisi & Marcia Salvador Geo***

16:30 How to deal with mixed incontinence
Philip Van Kerrebroeck

17:00 Close

ICS

SAO PAULO 06

COURSE
MATERIAL

ICS STANDARDISATION AND TERMINOLOGY

Philip van Kerrebroeck

The standardisation of terminology of lower urinary tract function and dysfunction is based on the elements of presentation and evaluation of any individual presenting with a problem related to the lower urinary tract. The trias consists of: symptoms, signs and conditions.

The inventory of symptoms together with the signs will allow to define a condition. This can lead to effective therapy.

Symptoms can be related to voiding, defecation or sexual function and can be accompanied by specific neurological complaints. However global symptoms can also be relevant for the further analysis. Voiding symptoms will be divided into two major categories: symptoms related to storage and symptoms related to voiding. Based on the presence of several symptoms, two symptom complexes can be distinguished: the overactive bladder syndrome and a syndrome indicated as LUTS (Lower Urinary tract Symptoms).

Signs can be the result of clinical and urodynamic investigation. However additional investigations can be relevant in order to be able to adequately define a condition.

The following conditions are recognised:

Incontinence to be divided in stress incontinence, urgency incontinence (idiopathic or neurogenic) and mixed incontinence.

Enuresis and nocturia.

Retention and bladder outlet obstruction.

Based on the specific picture a treatment or a combination of treatment modalities can be identified. The therapeutic options are divided into conservative approaches and surgical procedures.

The treatment of an individual patient will be the consequence of evidence based elements as well as empirical decisions (expert opinion and individual experience). Nevertheless a global approach is essential taking into account not only physical but also emotional and psychological aspects.

Decisions must not only include the appreciation of short term effects but also long term consequences.

HOW TO PREDICT OUTCOME AFTER BPE THERAPY – CLINICAL TREATMENT

Valdemar Ortiz

The progression of Benign Prostatic Hyperplasia (BPH) can be defined as a deterioration of clinical variables such as lower urinary tract symptoms (LUTS) and helth-related quality of life, decreased peak flow rate, increased prostate size and PSA, or unfavourable outcomes as acute urinary retention (AUR) and BPH-related surgery.

The best way to getting information on the natural history of BPH is by longitudinal studies of community-dwelling men and from placebo arms of controlled studies conducted in men with symptomatic BPH.

The Olmsted County epidemiological study and the Veterans Affairs Cooperative study has shown a cummulative increase in prostate volume, severity of LUTS, AUR, need for BPH-related surgery and a decreased in the peak flow rate in untreated men.(1,2). Risk factors for disease progression include prostate volume, age, peak flow rate and PSA on initial presentation.(3,4)

Medical therapies for patients with symptomatic BPH include 5α-reductase inhibitors and α-blockers. The MTOPS, a prospective, randomized, double-blind, multicentre, placebo-controlled trial, was established to determine whether the combination of finasteride and doxazosin provides significant long-term benefits to BPH patients compared with either agent alone. BPH-related surgery and the risk of AUR were significantly reduced by finasteride and combined therapy by 69% and 64%, and by 79% and 67%, respectively. Combined therapy provided greater symptom relief than either type of monotherapy (5).

The financial and convenience considerations of combined therapy may affect its long-term use. However, a recent study showed that it may not be necessary to continue α-blocker beyond 6 months of treatment, with no compromise in clinical benefit to the majority of men following initial combination therapy with dutasteride (6). Serum PSA and prostate volume were significant predictors of AUR and the subsequent need for BPH-related surgery in the PLESS study. Spontaneous episodes of AUR occurred in no patient whose prostate volume was less than 40ml. Similarly, in the lowest basal PSA (< 1,2ng%), the incidence of spontaneous AUR was 1,4% (7).

Based on the evidence, an algorithm can be proposed by which patients are further substratified into those with mild to moderate symptoms with no bother, and those with moderate to severe bother. The former, can be further stratified by their prostate size and their PSA level. If the PSA is in the low risk range (<1,5ng%), or the prostate < 40ml, no treatment is needed. However, if the prostate is large (> 40ml) and the PSA is >1,5ng%, preventive therapy with a 5α-reductase inhibitor may be contemplated. Those patients with moderate to severe symptoms who were bothered by their symptoms can also be divided in to those at low risk of progression that are clearly best treated with an α-blocker and those with moderate to severe symptoms and bother who have a high risk of progression, with larger prostate (>40ml) and a PSA>1,5ng%, should be offered combined therapy with both an α-blocker and a 5α-reductase inhibitor (8).

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HOW TO PREDICT OUTCOME AFTER BPE THERAPY – ACUTE URINARY RETENTION

Walter Artibani

Lower urinary tract symptoms (LUTS) are a major health problem. That terminology, initially suggested by Abrams in 1994 (1), was recommended by the 5th International Consultation on Incontinence to replace imprecise terms such as "clinical BPH", "symptomatic BPH", and "prostatism" (2). The same consultation recommended the use of the terms benign prostatic hyperplasia (BPH) only in case of histological confirmation, and benign prostatic enlargement (BPE) when such pathological data were lacking.

According to the last ICS standardization of terminology, acute retention of urine is defined as "a painful, palpable or percussable bladder, when the patient is unable to pass any urine". (3).

There are a few population-based cohort studies and placebo-controlled studies to allow some understanding of predictors of natural history and disease progression. The Olmsted County study examined the outcomes of a randomly selected cohort of 2115 community-dwelling men aged 40–79 years. The relative risk of AUR increased with age, symptom severity and prostate volume (4), while Health Professional Follow-up Study showed that worsening of symptoms over a 2-year follow-up increased the risk of AUR by two to three times, regardless of baseline severity (5). Analysis on the placebo arm of PLESS demonstrated that prostate volume and PSA values were predictors of both spontaneous and induced episodes of acute urinary retention. (6). Similarly, secondary analysis on the placebo arm of the MTOPS demonstrated that prostate volume (< 30 Vs. >30 mL) and PSA (< 1.5 Vs. >1.5 ng/ mL) turned out to be predictive of acute urinary retention (7). Interestingly, Emberton et al. showed that patients in the placebo arm of MTOPS who did not develop AUR had a stable PVR throughout the study, while those who subsequently developed AUR had a steady increase in PVR (8).

Data from the placebo arm of the ALFAUR study allow to assess the natural history of patients after acute urinary retention (9-10). The risk of failure of a trial without catheter is about 50%, with patient age, retention volume and Alfuzosin therapy being independent predictors of success in multivariate analysis (9-10). However, prolonged Alfuzosin therapy did not reduce the risk of surgical therapy within 6 months from the first episode of retention (10).

Further data were provided by the ALF-ONE study, a clinical practice study which enrolled 3514 patients, including patients with history of acute urinary retention, to be treated by Alfuzosin 10 mg once daily (11). The study pointed out that history of acute urinary retention, as well as increases in symptom and bother scores were independent predictors of further episodes of acute urinary retention and/or need for surgery.

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HOW TO PREDICT OUTCOME AFTER BPE THERAPY – DETRUSOR OVERACTIVITY AND OUTLET OBSTRUCTION

Carlos Arturo Levi D'Ancona

The clinical presentation of overactive bladder (OAB) is often similar to bladder outlet obstruction (BOO). The prevalence of OAB increases significantly at older age, similar to the natural history of BOO. The rates of OAB increase with advanced grade of obstruction, but had no impact on symptoms of BOO. To distinguish between BOO and OAB, cystometry and pressure flow study are necessary. In 162 patients with LUTS and suspected BOO the urodynamic evaluation demonstrated OAB in 45% of the cases and 55% had stable bladder. In this study, patients with BOO and OAB were older, had a higher PSA, voided smaller volumes, and were more obstructed. Prostate volume (measured by transurethral ultrasound), Qmax, IPSS, and PVR did not predict whether the patients had a combined BOO + OAB or not. Another study also observed that patients with BOO and OAB were older and had a higher IPSS.

After 3 months of treatment with doxazosin, 35% of the patients with BOO and OAB reported a symptomatic improvement. In those patients with no respond with alfa blocker, 73% improved after adding tolterodine. Acute urinary retention developed in 3.3% treated with the alfa blocker and anticholinergic drugs. Combination treatment with an alpha-blocker plus an anticholinergic improves quality of life in patients with bladder outlet obstruction and concomitant detrusor hyperactivity.

Detrusor overactivity (DO) in men with evidence of outflow obstruction due to benign prostatic hypertrophy typically resolves in about two thirds of patients after TURP. Twelve males (mean age 80 years) with symptoms of OAB and BOO, were studied by 24-hour monitoring of incontinence and videourodynamic examination, before and after TURP. Preoperatively, all patients showed detrusor hyperactivity, which resolved postoperatively in only one patient, a significantly smaller proportion than that consistently reported in younger patients. In the geriatric population, detrusor hyperactivity and urge incontinence may be the result of age-associated changes and not secondary to obstruction.

Detrusor overactivity can be classified in three patterns: 1- continual sporadic bladder contractions; 2 – a single episode of bladder contraction occurred at volume of < 160 mL with saline leaking around the urethral catheter; 3 – a single episode of contraction at bladder volume > 160 mL. Cystometric patterns can predict the post-operative course. Twenty patients with BOO and DO underwent TURP and cystometry was carried out between 3 and 6 months after operation. Most pattern 1 patients had persisting DO, whereas DO disappeared after surgery in pattern 3 patients, and pattern 2 patients had an intermediate outcome.

For patients with the combination of severe BOO and severe OAB, no straightforward and safe treatment exists due to the risk of urge incontinence after TURP. To simulate the status after TURP and register the risk for urge incontinence a biodegradable polyglycolic stent can be used. After this stent was inserted in the prostatic urethra, 68% of the patients noticed no or only minor leakage and they had been subjected to TURP with good results. A biodegradable PGA stent seems to be a new tool to test the risk for post-TURP incontinence in patients with combined BOO and severe OAB.

HOW TO PREDICT OUTCOME AFTER BPE THERAPY – DETRUSOR UNDERACTIVITY

John Heesakkers

Detrusor underactivity or bladder hypocontractility leads to voiding impairment. Because of the decreased detrusor contractility the bladder is not capable of complete emptying. The causes for this are situation after inflammation with fibrosis of the detrusor; increasing stiffness of the bladder which causes decreased contractility as well and loss of contractile elements because of aging.

Most of the time detrusor underactivity becomes apparent in males that start suffering from LUTS. Because of prostate growth the resistance of the bladder outlet increases. With a hypocontractile bladder complete emptying of the bladder is not feasible and is accompanied by a weak voiding stream and sometimes residual urine after voiding. Patients that have detrusor underactivity also use straining as a method to empty the bladder.

The diagnosis of detrusor underactivity is made by a pressure flow study since this is the only way of distinguishing bladder outflow obstruction and detrusor underactivity. In males the diagnosis is quite straight forward. If a low uroflow is accompanied with a detrusor pressure of adequate magnitude and duration bladder outflow obstruction is present. However of a low uroflow and a low detrusor pressure is indicative of detrusor underactivity. Since extensive research has been done in males suffering from prostatic enlargement suggestive of bladder outflow obstruction, it is known what normal contractility in male bladders is related to increased bladder outlet obstruction. The cut off points are expressed in nomograms like that form the ICS, URA, Schaefer and CHESS classifications. These areas of normal obstructed and equivocal domains are based on the outcome after some desobstructing therapy. Patients with a obstructed bladder benefit from desobstruction whereas patients that are hampered by detrusor underactivity do not benefit that well from desobstruction.

In females things are not that clear. Women are able to void by decreasing the outlet resistance instead of by increasing the detrusor pressure. This has to do with potential and kinetic energy. The work that is executed by the bladder is put in potential and kinetic energy. If there is no flow (bladder outlet closed) the energy that is released by bladder contraction only leads to detrusor pressure increase: this is called potential energy. If all work is put in the kinetic urinary flow, the bladder is emptied without detrusor pressure increase. Because of the lack of a prostate and the short urethra there hardly is any bladder outflow resistance and a massive flow can be achieved without detrusor pressure increase.

Therefore it is wrong to deduct from a low flow and no increase in detrusor pressure that detrusor underactivity exists. On the other hand when a low flow is present as well as high detrusor pressure in women once can conclude that bladder outflow obstruction is present. This is mostly the case after placement of a tensionfree tape in a non-tensionfree fashion.

MY DRUG IS BEST FOR OAB – TOLTERODINE (PFIZER)

Luis Carlos Almeida Rocha

Drug used for the treatment of overactive bladder since 1997, and composed by a tertiary amine with anti-muscarinic activity. It is fastly absorbed by the small bowel and its activity begins 15 – 30 minutes after ingestion.

In our country is sold in two main presentations: one that has fast release, disposable in 1 and 2 mg (Detrusitol 1 mg / Detrusitol 2 mg); and another that has long action, disposable in 4 mg for once daily taking (Detrusitol LA 4 mg).

This drug was used several times in phases II, III and IV clinical trials, that confirmed its efectivity and safety. The International Continence Society gave it evidence level 1 and recommendation level A by the pure anti-muscarinic action and its efectivity for the treatment of overactive bladder.

Overactive bladder is a highly prevalent condition, affecting one by six adult people. Milson et al showed that 40% of the people that has this disease don't think there is a treatment for the disease or think that is part of the aging process, lasting for the incontinence the main cause because they seek a physician (Milson I et al. BJU Int. 2001; 87: 760-766).

Tolterodine versus placebo used for overactive bladder significantly increase (19,7 to 31,4 min) the time between urgency episodes (Urgency-Free Interval – UFI) (Cardozo L et al. J Urol. 2005; 173:1214-1218) and lowers the number of voids in 24 hours (Data, Pfizer Inc).

It diminishes in a significant proportion the urgency sensation in 24 hours (Khullar V et al. Neurourol Urodyn 2002;21:378-379), controlling the symptoms in young adults and elderly older over 65 years old (Zinner NR et al. J Am Geriatr Soc 2002;50:799-807).

After 12 weeks using tolterodine there is effective control of the urge-incontinence episodes in 24 hours, diminishing significantly urinary leak (Data of Pfizer Inc), and controlling urge-incontinence in patients with several degrees of incontinence (Landis JR et al. J Urol 2004;171:752-756).

Another possible indication is for men older than 40 years that has overactive bladder associated with bladder outlet obstruction. A recent trial using this anti-muscarinic agent with an alfa-adrenergic blocker showed significant improvement of symptoms when compared with using the alfa-adrenergic blocker alone. The association reduces in 50% the acute urinary retention episodes compared with placebo (Lee JL et al. BJU Int. 2004; 94:817-820 + Abrams P et al. Neurourol Urodyn. 2001;20:547-548).

When the adverse effects of tolterodine are compared with the same therapeutic activity drugs (as oxybutinine, trospium, darifenacina), it has the least number of events related with blurred vision, dry mouth, constipation (Chapple C et al. BJU Int. 2004;93:303-310, Haab F et al. Eur Urol 2004;45:420-429, Halaska M et al. World J Urol 2003;20:392-399).

Among contributing factors that make this drug the choice for overactive bladder treatment, when compared with oxybutinine, are the treatment abandon rates that are 3 times lower (Homma Y et al. BJU Int 2003;92:741-747) and , finally, the costs that are till 30% lower when compared with oxybutinin in its long action formulation and continuously used for long periods (Chapple CR et al. ICS. Seoul, Korea, September 2001).

MY DRUG IS BEST FOR OAB – OXYBUTYNIN (JANSSEN-CILAG)

Carlos Arturo Levi D'Ancona

Oxybutynin is an anticholinergic drug with a high affinity for muscarinic receptors in the bladder and the parotid gland. Oxybutynin binds to M3 muscarinic receptors on the detrusor muscle, preventing cholinergic activation, thus relaxing the muscle. Oxybutynin is indicated for the treatment of urinary incontinence, urgency and frequency in patients with idiopathic detrusor overactivity. The drug is also indicated for the treatment of adult and pediatric patients with symptoms of detrusor overactivity secondary to neurogenic disease.

The osmotic system (OROSÆ- based) oxybutynin extended-release (ER) provides sustained drug delivery, minimizing the fluctuation in plasmatic oxybutynin concentration. Oxybutynin ER is a non-disintegrating tablet formulation that reaches the colon in 3-5 hours after oral administration. Thus, oxybutynin is released throughout the gastrointestinal tract, mainly in the colon. The formation of the active metabolic N-desethyloxybutynin (NDO) with oxybutynin ER is slighter than that with oxybutynin immediate-release (IR).

The antimuscarinic properties of oxybutynin result in several urodynamic effects, such as increase in bladder capacity, decrease in detrusor pressure at maximum cystometric capacity and also reduce percentage of patients demonstrating uninhibited detrusor contraction.

Oxybutynin was significantly more effective than placebo in reducing the weekly urinary urge incontinence episodes in patients with overactive bladder (OAB). Oxybutynin significantly reduced the mean weekly number of urge incontinence episodes by 84 to 90%. Oxybutynin ER was as effective as IR in relieving symptoms of OAB. The Quality of Live was significantly improved with oxybutynin.

The adverse events of patients include dry mouth, constipation, somnolence, diarrhea, nausea, headache, dizziness, blurred vision and dry eyes. The decrease in saliva output and the consequent increase in dry mouth severity correlated with the metabolic R-desethyloxybutynin concentration, and no apparent relationship was observed with the R-oxybutynin concentration. This may be a possible explanation for the observed decrease in dry mouth severity with oxybutynin ER compared with IR. This suggests that the metabolite may contribute to the dry mouth. Oxybutynin does not appear to produce any significant adverse cardiac effects and adverse central nervous system (CNS) events were uncommon. Approximately 7% of patients treated with oxybutynin ER discontinued treatment because of adverse events.

The recommended dosage range for oxybutynin ER is 5-30mg, once daily. The poor tolerability of antimuscarinic therapy in elderly patients has been attributed to their predisposition to higher incidence of adverse effects, especially CNS effects. It is recommended to use a lower dosage of oxybutynin IR in the elderly. In contrast, the efficacy and tolerability of oxybutynin ER in the elderly are not significantly different from those in younger patients and the dosage does not need to be reduced. The ER may be administrated with or without food.

Oxybutynin is a very useful medication, with highly successful results to which other drugs should be compared. It is a first-line therapeutic agent for overactive bladder.

MY DRUG IS BEST FOR OAB - DARIFENACIN (NOVARTIS)

Joao Luis Amaro

The International Continence Society has defined the overactive bladder (OAB) syndrome as disturbance of bladder function that leads to urgency, with or without urge incontinence, usually with frequency and nocturia. The family of Muscarinic receptors consists of the 5 subtypes M_1 to M_5 which are encoded by 5 distinct genes. Contractile activity in human detrusor muscles is mediated by acetylcholine. It has been considered that the muscarinics receptor population involved is mainly of the M_2 and M_3 receptors subtypes. Despite the predominance of the M_2 receptors (66%) the M_3 receptors are mainly responsible for normal micturition contraction. M_3 receptors are also located in the parotid gland and in the gastrointestinal tract. The prevalence of OAB was found to increase with age. Anticholinergic therapy is the first line of medical treatment for the OAB syndrome. The major concern of clinicians prescribing anticholinergic for the treatment of OAB in the elderly patient is the side-effect profile. Observed central nervous system (CNS) side effects (e.g. cognitive adverse effects, which are M_1 - mediated) and cardiac effects (e.g. tachycardia, which is M_2 - mediated) are the main issues. The incidence and intensity of CNS side effects of anticholinergics is determined by 2 factors: the ability of the drug to pass the blood-brain barrier and the affinity of the drug for the muscarinic receptor subtypes present in the CNS (M_1). There are a number of clinical case reports of neuropsychological or cognitive adverse effects of Oxybutynin and Tolterodine. In contrast, Darifenacin do not appear to be associated with cognitive adverse events and effects on sleep architecture and quality.

Dry mouth and constipation continue to play a role in the patient's compliance with the medication, but are not as great a concern in the independence of patient. Among the drugs used for treating the symptom complex of OAB lack true specificity for the muscarinic receptors in the target bladder organ, except for Dariferacin, which is the first M_3 - selective agent. Cardozo et al observed that Dariferacin (30 mg) increases mean median and minimum warning time compared with placebo, allowing subjects more time to reach a toilet and potentially avoiding the embarrassing experience of incontinence. Many randomized, double-blind, controlled studies using Dariferacin (7,5 and 15 mg once daily) showed this drug is effective in the treatment of patients with OAB. As predicted by its M_3 selectivity and associated M_1 / M_2 - sparing profile, Dariferacin was well tolerated with no central nervous system or cardiovascular safety concerns.

MY DRUG IS BEST FOR OAB – TROSPIUM (INDEVUS)

Aparecida Pacetta

Trospium chloride is an orally active anticholinergic quaternary ammonium compound with predominantly peripheral nonselective antimuscarinic activity and thus has therapeutic value in treating patients with overactive bladder. It binds specifically to muscarinic receptors M1, M2 and M3. It is hydrophilic and has poor central nervous system penetration having minimal central antichoninergic activity. The time to the maximum plasma concentration (Tmax) is 5-6 hours. Food ingestion reduces trospium bioavailabity. Trospium chloride is not metabolised by hepatic cytochrome P450 and few metabolic drug interaction are known. The usual dose is 20mg twice daily. Comparative studies in patients with overactive bladder indicate that Trospium is at least as effective as Oxybutinin and Tolterodine. It has showed improving some urodynamics parameters and decreased the average number of daily toilet voids, urgency severity, urge frequency, and urge urinary incontinence episodes, besides it improves the health-related quality of life of the treated patients. The most frequent adverse events are dry month, constipation and headache. Several studies demonstrated that Trospium chloride is effective, safe and generally well tolerated.

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MY DRUG IS BEST FOR OAB – PROPIVERINE (APOGEPHA)

Helmut Madersbacher

PROPIVERINE – WHAT ARE THE MARKETING MESSAGES?

Propiverine, in contrast to other drugs indicated for detrusor overactivity, comprises a dual mode of action with neurotropic and musculotropic properties (Madersbacher & Mürtz, 2001). Efficacy has been proven in numerous studies conducted in Europe and Japan in Caucasian and Japanese / Korean patients covering a broad range of different indications: symptoms of the OAB, idiopathic and neurogenic detrusor overactivity in adults, idiopathic and neurogenic detrusor overactivity (myelomeningocele) in children. In elderly men with OAB and concomitant BPE/BPO propiverine and alpha-adrenoceptor antagonists were administered together.

In OAB propiverine and tolterodine are equieffective as was shown in a head-to-head study in adults (J¸nemann et al., European Urology, 2005). Furthermore, propiverine and tolterodine are equally tolerable. Furthermore, in long-term studies it was proven that adverse events decreased during the time-course following propiverine treatment (e.g. Madersbacher et al., ICS 2005). In unobstructed and obstructed male patients with OAB and BPE/BPO no clinically relevant increase of post-void residual, no acute urinary retention was observed (Lee et al., Journal Urology, 2005).

PROPIVERINE: WHAT IS THE SCIENTIFIC BASIS FOR THESE MESSAGES?

A complex dual mode of action is based on the parent drug propiverine hydrochloride comprising antimuscarinic and calcium≤+-modulating properties. Three major main metabolites were detected, the N-oxide is the main metabolite. In the experimental setting only the combination of atropine (antimuscarinic) and nifedipine (Calcium-channel blocker) achieved an extent of detrusor inhibition which was comparable to that of propiverine. In preclinical studies (in–vivo studies in the mini-pig) propiverine and tolterodine induced an equivalent decrease of salivation, thus suggesting comparable tolerability of both drugs also in humans (Scheepe et al., Aktuelle Urologie, 2000).

PROPIVERINE – WHAT IS THE DOCUMENTATION FOR THESE MESSAGES?

In regards to idiopathic detrusor overactivity J¸nemann and coworkers (European Urology, 2005) showed in a head-to-head study that the increase in maximum cystometric bladder capacity following propiverine and tolterodine was comparable. Also in regards to tolerability there was no difference between these two drugs, as was evidenced with respect to the overall adverse event incidence rate and with respect to the incidence rate of dryness of the mouth.
In regards to CNS adverse events cognitive, mental and motor functions in elderly patients with various neurological diseases (multiple cerebral infarction, M. Parkinson, M. Alzheimer) were not negatively affected during a 8-week treatment with propiverine (Uchiyama et al., ICS 2005).

In regards to neurogenic detrusor overactivity in a placebo-controlled study (St^hrer et al., Spinal Cord 1999) again the maximum cystometric bladder capacity increased, the maximum detrusor pressure amplitude during voiding decreased significantly following propiverine treatment compared to placebo.

Tolterodine, trospium, darifenacin and solifenacin are not registered for the use in children and only very few studies with these drugs are published. Additionally, oxybutynin has traditionally been used in children (Hehir & Fitzpatrick, European Urology 1985), however numerous reports evidenced an unfavourable adverse event profile. Propiverine, registered for the use in children in Germany and some other countries, exerts significantly less adverse events compared to oxybutynin according to a very broad paediatric data base (Marschall-Kehrel et al., Journal Urology 2004, Madersbacher et al., European Urology 2006, Alloussi et al., European Urology 2006). Therefore, propiverine proved to be significantly better tolerated compared to oxybutynin also in children suffering from idiopathic or neurogenic detrusor overactivity.

MY DRUG IS BEST FOR OAB – PROPIVERINE (APOGEPHA) (Cont.)

In several studies in men with OAB and concomitant BPE/BPO alpha-adrenoceptor antagonist monotherapy was compared to the combined usage of an alpha-adrenoceptor antagonist and propiverine: this combination regimen achieved higher rates of improvement in OAB-symptoms. In only one out of four studies 2 out of 75 patients (Saito et al., Japanese Journal Urology Surgery 1999) experienced urinary retention.

The advantages of a propiverine extended release formulation compared to the propiverine immediate release formulation have been shown, especially with respect to a further improved tolerability profile (J¸nemann et al., ICS 2004).

WHY IS PROPIVERINE THE BEST DRUG FOR OAB?

Propiverine is unique in regards to its dual mode of action. Numerous placebo- and/or reference-controlled studies as well as open-label studies evidenced excellent results in the following patient populations: idiopathic detrusor overactivity and neurogenic detrusor overactivity, both in adults and in children. Especially for children a dose formulation containing 5 mg propiverine (MictonettenÆ) has been designated. In men with OAB and concomitant BPE/BPO very promising results were achieved by combining alpha-adrenoceptor antagonists and propiverine.

In conclusion, propiverine comprises an excellent efficacy and tolerability profile, it is the market leader in Japan. However the marketing possibilities are according to a medium-sized family-owned company.

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MY DRUG IS BEST FOR OAB - OXYBUTYNIN PATCH (UCB PHARMA)

Linda Cardozo

Oral Oxybutynin has been used for many years in the treatment of overactive bladder syndrome (OAB). Its principal action is to block M3 muscarinic receptors, reducing detrusor contractility. However oxybutynin is also active against muscarinic receptors in the salivary glands, leading to an unacceptably high rate of dry mouth.

Problems with antimuscarinic side effects such as dry mouth, have led to the development of alternative agents and formulations. These include extended release oxybutynin, marketed as Ditropan or Lyrinel XL, and newer anticholinergics such as Darifenacin and solifenacin. All oral formulations of anticholinergics are subject to extensive hepatic and gastro-intestinal pre-systemic metabolism. Oxybutynin is rapidly metabolised to N-desethyloxybutynin.
This reduces bioavailability, and leads to troughs and peaks in drug concentration following administration.

Transdermal formulations of other drugs have been available for almost 25 years. They are popular with patients, and are used for a range of medications requiring continuous release, including oestradiol, fentanyl, and nicotine. This route of administration helps avoid first-pass metabolism, stabilising drug concentrations. The lower drug concentrations lead to a reduced rate of dose-related side effects, while maintaining therapeutic blood levels. The combination of fewer side effects and ease of administration increases patient compliance with therapy.

Oxybutynin is now available in a matrix-type transdermal patch, for twice weekly administration. It is marketed as Oxytrol or Kentera. The licensed dose is a 36mg patch, releasing an average of just 3.9mg oxybutynin/24 hours.

One Phase II study demonstrated that transdermal oxybutinin has equivalent efficacy, on both objective and subjective measures, to oral immediate release oxybutynin (max 20mg od). The incidence of anticholinergic side effects was much reduced, with 89% of patients reporting, "none", or "mild" effects only.
A further Phase III study has shown that transdermal oxybutynin and extended release tolterodine (4mg od) are associated with equal improvement in incontinence episodes, urinary frequency, mean voided volumes, and incontinence specific quality of life scores, with statistically significant benefit compared with placebo. Although these trials are powered only to detect a difference in efficacy, the rate of anticholinergic side effects is no higher for transdermal oxybutynin compared with placebo.

In common with other transdermal systems there is an associated rate of erythema and pruritus (up to 14%). These separate adverse effects may limit compliance in some patients.

Transdermal oxybutynin is a novel treatment for OAB, with significant benefits compared with existing oral medications. It offers the efficacy of these established anticholinergics, with an unprecedented low rate of adverse anticholinergic effects. Were cost not an issue, the combination of efficacy and acceptability should make it an obvious choice as a first line treatment for OAB.

MY DRUG IS BEST FOR OAB – PLACEBO

Pedro Araño

RCTs are valuable, however limited tools: they are carried out in a controlled setting, which gives them "great internal validity", but they present with a "questionable external validity" when their conclusions are applied to clinical practice, as the clinical and the experimental scenarios are not comparable. This seems to be clearly evident in studies on antimuscarinics for the treatment of Overactive Bladder Syndrome.

An argument has recently been brought forward in two systematic reviews and meta-analyses by Herbison P, Hay-Smith, Ellis G. Moore K: Effectiveness of anticholinergic drugs compared with placebo in the treatment of overactive bladder: systematic review. BMJ 2003; 326 (7394):841-4, and by Chapple Ch, Khullar V, Gabriel Z, Dooley JA: The effects of antimuscarinic treatments in overactive bladder: a systematic review and meta-analysis. Eur. Urol. 2005; 48: 5-26 on the real efficacy of anticolinergic agents.

Herbison's work concludes: "Although statistically significant, the differences between A.C. drugs and placebo were small, apart from the increased rate of dry mouth in patients receiving active treatment. For many of the outcomes studied, the difference between A.C. and placebo may be of questionable clinical significance as none of these studies provided data on long term outcome".

In Chapple's work, later than Herbison's, the argument is clarly stated thus: "...These objectives were included to address criticism of a previous Cochrane review of pharmacological therapies of O.A.B". Chapple's working objectives are: "To evaluate the tolerability, safety and efficacy of A.M. drugs used to treat O.A.B." But when the conclusions are drawn: "The A.M. have different tolerability and safety profiles, which are clinically significant Where is efficacy?"

- Where is efficacy indeed? Is this omission to be understood as an unspoken recognition that it is not their efficacy the main reason for antimuscarinic indication?

Are these changes statistically significant? Indeed they are; "but most of the responders would be admitted in the same R.C.T. of O.A.B. treatment because they still fulfill the inclusion and exclusion criteria"

At this point Dr. Chapple establishes an apparent but fake inconsistency between the results of both studies, when he states: "The results also suggest that A.M. confer a significant quality of life benefit to patients; in contrast Herbison concluded that the benefits are of limited clinical significance". Is QoL the same as Clinical Significance? I do not think so, and this gets highlighted if we try to answer these questions:

- Is the patient better? Does the patient feel better?
- If he is better, has this improvement clinical significance?
- If he is not better, why is he feeling better?

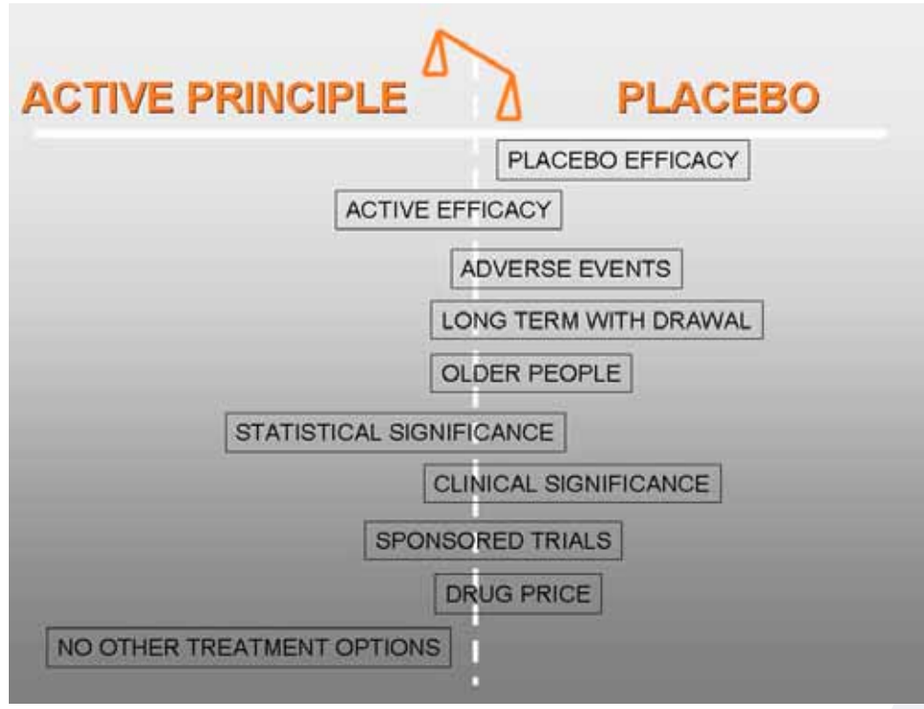
In my opinion:

- The distortion factor that determines the QoL is the patient's perception.
- The QoL is determined by the patient and it depends of many not-measured factors.
- Clinical significance is determined by the doctor and it depends on measured factors.

As to adverse effects, the evidence does clearly support a greater incidence than in the case of placebo. Adverse effects, together with low efficacy, can be considered the cause of long-term dropouts observed in clinical practice, and this is another factor not reflected by the RCTs.

To finish with this issue, I think is is essential to quote the conclusions of a group of experts (R. Appel, L. Cardozo, Ch. Chappel, H. Drutz, J. Four Croy, R. Vela-Navarrete, O. Nishizawa, A. Wein) on the Pharmacological Treatment of Urinary Incontinence in the 3rd Internacional Consultation on Incontinence in 2004:

- "...It should be stressed that in many trials on O.A.B./D.O. there has been such a high response to placebo that meaningful differences between placebo and active drug cannot be demonstrated".
- "Many drugs have been tried, but the results are often disappointing, partly due to poor treatment efficacy and/or side effects".
- "The role of pharmacotherapy is even more contentious in older and particularly frail elderly people".
- "Drugs may be efficacious in some patients, but they do have side effects and frequently are not continued indefinitely".



WHAT CAN NURSES DO TO HELP IN THE MANAGEMENT OF INCONTINENT PATIENTS

Mandy Wells

This session will describe and discuss the role of both generalist and specialist nurses in the management of incontinent patients.

It will discuss the importance of the generalist nurse (either in the hospital or the community) setting in identifying the individual with incontinence. These nurses have a unique role in first line assessment and treatment planning.

This session will also discuss the advancing role of specialist nurses in the assessment, management and treatment of the individual with incontinence.

Specialist Nurses can use a number of techniques following an in-depth assessment. These can range from simple lifestyle changes to teaching bladder training and pelvic floor exercises. More advanced specialist nurses will also use biofeedback and electrical stimulation.

In a number of countries specialist nurses can now prescribe the same medications as medical colleagues. In a number of countries they can also request and or carry out investigations such as urodyamics.

DO WE STILL NEED INTESTINAL SEGMENTS TO TREAT VESICAL DYSFUNCTION – RISK USING INTESTINAL SEGMENTS

John Heesakkers

The use of intestinal segments for replacement of parts of the lower urinary tract is widespread and exists already for years.

The risks of doing so can be categorized in:

1. The procedure itself
2. The risks for the urinary tact for using a particular part of the GI tract
3. The risk for the GI tract to use some of its components for replacement of the urinary tract

1. The procedure itself has hazards because of the dissection of bowel, the reimplantation of the ureters in most cases, the length of the procedure. The percentage of perioperative complications because of bowel leakage, ileus etc is not known.

2. The risk for using bowel as reservoir for the urinary tract are:

- Maximal volume of the new bladder is created when a spheric configuration is constructed. For this the bowel should be detubularized. This also increases bladder compliance and therefore protects the upper urinay tract.Rhythmic contractions have been noted postoperatively with all bowel segments, although ileum seems the least likely to demonstrate remarkable urodynamic abnormalities, and stomach the most. This is also important with regard to upper urinary tract functioning.
- The storage of urine within intestinal segments can lead to hyperchloremic metabolic acidosis. Patients with this metabolic derangement have noted to have fatigue, weakness, anorexia, and polydipsia. Koch and McDougal (1985) demonstrated the mechanisms by which acid is absorbed from urine in contact with intestinal mucosa. Resorption in the form of ammonium results in chronic acid loading. Patients with normal renal function usually are able to handle the resorbed load of chloride and acid without frank acidosis. Essentially every patient after augmentation with an intestinal segment had an increase in serum chloride and a decrease in serum bicarbonate level, although full acidosis was rare if renal function was normal. Patients with acidosis should receive bicarbonate therapy.
- Although jejunum is rarely used for bladder reconstruction, storage of urine in this segment results in a unique metabolic pattern of hyponatremic, hypochloremic, and hyperkalemic metabolic acidosis. The problem is often associated with significant hypovolemia.
- Gastric mucosa is a barrier to chloride and acid resorption and, in fact, secretes hydrochloric acid .This difference was the primary factor in the initial consideration of stomach for use in the urinary tract. This secretory nature was shown to be of benefit in azotemic animals during acid loading. Serum chloride does decrease and serum bicarbonate increases slightly after gastrocystoplasty whether antrum or body is used in patients with normal or impaired renal function.
- Intestinal segments continue to produce mucus after placement in the urinary tract. The proteinaceous material can potentially impede bladder drainage during voiding or CIC, particularly in pediatric patients who must use small-caliber catheters. Mucus may serve as a nidus for infection or stone formation when it remains in the bladder for long periods. Mucus production often increases after cystoplasty in the presence of cystitis.

DO WE STILL NEED INTESTINAL SEGMENTS TO TREAT VESICAL DYSFUNCTION – RISK USING INTESTINAL SEGMENTS (Cont.)

- Bacteriuria is very common after intestinal cystoplasty, particularly among patients requiring CIC. The incidence of symptomatic cystitis after cystoplasty probably depends on the length of follow-up and the diligence with which symptoms are sought. All patients and families should be told to expect some signs or symptoms of cystitis. Recurrent episodes of symptomatic cystitis requiring treatment occurred in 23% of patients after ileocystoplasty, 17% after sigmoid cystoplasty, 13% after cecocystoplasty, and 8% after gastrocystoplasty at Indiana University (Hollendsbe 1992). Recurrent infections resulting in deterioration of renal function in the absence of other problems have been quite rare after effective augmentation. Not every episode of asymptomatic bacteriuria requires treatment in patients performing CIC. Bacteriuria should be treated for significant symptoms such as incontinence or suprapubic pain and perhaps for hematuria, foul-smelling urine, or remarkably increased mucus production. Bacteriuria should be treated if the urine culture demonstrates growth of a urea-splitting organism that may lead to stone formation. To minimize infection, patients who need CIC must perform it on a regular basis to avoid increased reservoir pressures and must work to empty the bladder completely.
- Another long-term complication of augmentation cystoplasty is bladder calculi. The majority of bladder stones in this patient population are struvite in composition, and bacteriuria has been thought to be an important risk factor. Any infection with a urea-splitting organism should therefore be treated aggressively.
- A well-recognized complication of ureterosigmoidostomy has been the development of tumors, primarily adenocarcinoma, at the ureterocolonic anastomotic site. In a review by Husmann & Spence (1990) of reported tumors after ureterosigmoidostomy, the latency for development of such tumors averaged 26 years and ranged from 3 to 53 years. Adenocarcinomas were the prominent tumors that developed, but benign polyps and other types of carcinoma were also found.
- Perhaps the most disturbing complication of augmentation cystoplasty is delayed bladder perforation. Patients presenting with spontaneous perforation after augmentation cystoplasty are usually quite ill with abdominal pain, distention, and fever. Sepsis has been common. Nausea, decreased urine output, and shoulder pain from diaphragmatic irritation have also been noted.

3. Complications for the GI tract

- Postoperative bowel obstruction is uncommon and occurs in approximately 3%.
- Reports of chronic diarrhea after bladder augmentation alone have been rare. Diarrhea can occur after removal of large segments of ileum from the gastrointestinal tract, although the length of the segments typically used for augmentation rarely are problematic unless other problems coexist. The much longer segments required for continent urinary diversion may increase the risk for chronic diarrhea. The use of a typical colonic segment for augmentation only rarely results in a change in bowel function and is less of a risk than the use of ileum. Removal of a segment from the gastrointestinal tract that includes the ileocecal valve is the most likely procedure to cause diarrhea.
- Ileum is the sole site of vitamin B12 absorption in the bowel. Removal of the distal ileum from the gastrointestinal tract may result in vitamin B12 deficiency and megaloblastic anemia. Certainly the terminal 15 to 20 cm of ileum should not be used for augmentation, although problems may arise even if that segment is preserved.

DO WE STILL NEED INTESTINAL SEGMENTS TO TREAT VESICAL DYSFUNCTION – HOW TO AVOID COMPLICATIONS

Nelson Rodrigues Netto Jr

Early bowel complications are usually related to the bowel resection and subsequent anastomosis. This can include anastomotic leak, enteric fistula, bowel obstruction, prolonged ileus and septic complications. A stricture of the conduit can occur as a late complication and is usually secondary to ischemia. Conduit necrosis is a rare but morbid complication which usually results from acute ischemia secondary to mesenteric injury.

Stoma complications, about 8.5%, are the most common problems. These complications include necrosis, obstruction, stenosis, retraction, prolapse and parastomal hernias. Contributing factors include obesity, advanced age, malnutrition, chronic cough and steroids. The incidence of ureteroenteric anastomotic leak has decreased significantly with the routine use of soft silastic stents. This diagnosis is suspected when there is increased drain output or urinary drainage from the wound.

Stones occur in 5 to 10% in pouches. Prevention is based on the treatment of chronic bacteruria, urinary stasis, mucous production, associated metabolic abnormalities, and exposed staples used in pouch formation.

Incontinence occurs in 0.6 to 5.8 % of the patients with continent urinary diversion. Pouch urodynamics are most helpful in categorizing the cause of the incontinence.

Additionally, false passage of a catheter can create a small fistula beyond the intussuscepted nipple valve causing leakage. Lastly, problems with the nipple valve including ischemia, fibrosis, or prolapse can also result in incontinence. Difficult catheterization occurs in about 3 to 18%. A tension free muco-cutaneous anastomosis avoiding angulation and kinking of the catheterizable channel should prevent complications. Antireflux mechanism to prevent reflux should be considered a relative risk of ureteroenteric stricture, pyelonephritis and renal deterioration.

Voiding dysfunction and urinary incontinence may be complications of orthotopic neobladder. Daytime incontinence may range from mild stress incontinence (15–25%) to total incontinence (5%). A total of 8% of patients may develop urinary retention requiring self catheterization. Four to 25% of patients with orthotopic neobladders will need intermittent self-catheterization. On the other hand, *if too small a segment is selected, the capacity will be low and may have the risk of incontinence and urinary frequency. Likewise, if too generous a segment of bowel is selected, poor emptying and urinary retention will occur.*

Although most operative techniques for urinary diversion are surgically well established, current interest is directed towards minimization of complications, as well as the selection of the ideal procedure.

DO WE STILL NEED INTESTINAL SEGMENTS TO TREAT VESICAL DYSFUNCTION – NEW TISSUES

Helmut Madersbacher

Over the past century, several bladder-wall substitutes have been tried: the first application of a free tissue graft for bladder replacement was reported by Neuhoff in 1917, when fascia was used to augment bladders in dogs. Since the first report, many investigators tried to achieve successful urinary bladder augmentation with a variety of auto-, homo- and heterologous tissues.

*Research projects on bladder regeneration can be cat*egorized into three main groups: (1) bladder autoaugmentation or detrusorectomy, (2) the use of tissue template, whether alloplastic or biodegradable and (3) a bladder bioengineering strategy using tissue culture and gene transfer.

(1) BLADDER AUTOAUGMENTATION

Detrusorectomy or "bladder autoaugmentation" is based on the idea reported by Couvelaire (1955) five decades ago and popularized by Cartwright and Snow (1989) in the USA and by M. Stoehrer (1999) in Europe. The idea of this method is to create a bulge or diverticulum in the dome of the bladder by partially excising detrusor muscle, while leaving the bladder epithelium intact. Histological evaluation of the autoaugmented bladder shows an intact epithelial layer along the detrusorectomy site, however there is no evidence of muscle regeneration, only a few thin muscle bundles are present just below the lamina propria that could have been left during surgery. In a recent retrospective study, Leng et al (1999) reported on 33 primary detrusormyectomies for different clinical indications. The failure rate was 27 %, followed in these patients by enterocystoplasty. Moreover, there is more and more evidence that after detrusorectomy the initial gains in capacity are lost with time, however a longer follow-up of more patients is needed to validate these assumptions.

SEROMUSCULAR COLOCYSTOPLASTY

Buson et al (1994) showed that, if the intestinal submucosa of a seromuscular colonic segment was preserved and this patch was applied over the exposed bladder epithelium after a subtotal detrusorectomy, not only was there no patch contraction or significant fibrosis, but the experimentally contracted bladder could also be enlarged. In 15 years of work in experimental models and clinical experience with close follow-up, Lima et al (2004) showed, that the demucosalized bowel fulfils the prerequisites for an ideal material. The long-term complication rate in this series was around 10 %, which is far distant from that reported for total intestinal patches.

(2) A BLADDER TEMPLATE ALLOWING REGENERATION

Experimental work has shown that a graft material can serve as a framework or template for the regeneration of host tissue. Ideally such a material should be completely biodegradable, i.e. completely eliminated by biological activity, should allow faithful regeneration with no adverse effects and a muscular bladder wall lined on its luminal surface by epithelium. Such a material should not act as a nidus for the crystallization of urinary salts, not be cytotoxic; should be technically strong, easy to handle surgically and should be available at low cost.

ALLOPLASTIC PROSTHESES

Polyethylene, PTFE (TeflonÆ) and silicone rubber were used as well as biodegradable prostheses, e..g polyvinyl sponge, collagen film, etc.,however the materials were soft and the handling difficult. So far, these procedures have never been applied in humans.
In regards to placental membranes, the possibility of rejection is a source of concern, when any organic material is used as a graft.

Small intestinal submucosa (SIS) is another collagen-based biomaterial developed by Badylak et al. in 1989. Kropp et al (1996) assessed the feasibility of promoting urinary bladder regeneration with SIS in rats. At 48 weeks all three layers of the normal bladder (urothelium, smooth muscle and serosa) were present, and were grossly and microscopically indistinguishable from the normal rat urinary bladder. SIS-regenerated bladder had contractile activity, expressed muscarinic, purinergic and ?-adrenergic receptors, and had functional cholinergic and purinergic innervation similar to that in normal rat urinary bladder. The studies so far support the potential use of SIS grafts for clinical bladder augmentation.

BLADDER ACELLULAR MATRIX (BAM)

It mainly consists of acellular collagen and elastin, which serve as a scaffold for the ingrowth of smooth muscle tissue and mucosa. Instead of using porcine SIS, Thanago and his group took a full-thickness bladder, from which all cells were extracted. The absence of stromal and epithelial cellular elements was confirmed histologically.

Experiments were undertaken in partially cystectomized rats: After 4 weeks all bladder wall components were evident hsitologically in the graft. At 12 weeks the bladder wall muscle structure in the graft was so well developed that it was difficult to delineate the junction between host bladder and acellular matrix graft. Neural regeneration continued to improve.

Dahms et al (1998) assessed the neurophysiological properties and molecular mechanisms of the BAM graft by cystometric and neurophysiological studies in rats. The work of Dahms et al (1998) confirmed that these bladder components are truly functional and that they can work in a coordination with the host components under the same neural influence and generate adequate intravesical pressure to produce sustained voiding with complete emptying. However, in these studies using acellular matrix free of cells the amount of tissue resected from the bladder has always been less than half.

Urakarni et al (2006) from Tanagko's team, recently demonstrated in spinal cord injury induced neurogenic bladders in rats that the voiding function in underactive bladders was improved by using BAM after partial cystectomy.

However, porcine acellular collagen matrix seems not to be a suitable material for bladder augmentation, because of resultant microcalcifications, thickening of the bladder wall and irregular development of detrusor regeneration (Ali-Ayyildiz et al, 2006)

(3) TISSUE ENGINEERING

Published work demonstrates the possibilities of tissue engineering, but what can be offered to the patient today? Tissue engineering is a young rising technology which is in many areas still experimental for most of the indications.

The main goals still are the search for the optium scaffold, which can be seeded by cells and the best way to differentiate cells to be used in lower urinary tract reconstruction. When the technique to differentiate stem cells approached the laboratories, they inspired the researchers to have the type of cell that is totipotent. Diffent kinds of adult mesenchymal stem cells and satellite cells, such as myeloblasts are used to continue the degenerative medicine research. With improved technique they can be differentiated into smooth and striated muscle cells and even nerve cells are reported.

In the urinary tract one of the major issues is the avoidance of urine contact with the seeded or unseeded scaffold, because of its mediators for scarring. Now stratified multilayer urothelium layers can be cultivated in the dish from autologous urothelial cells from a bladder wash (Nagele et al., 2006). Others use buccal mucosa cells and grow tissue for urethral reconstruction (Bagawa and Chapple, 2006). At present the group of H. Strasser et al treats urinary stress incontinence with myeloblasts. This might be an option to treat age-related striated sphincter muscle degeneration.

A scaffold, which meets the needs to generate a functional bladder wall is hard to find. Commercial available scaffolds as small interstine submucosa inhibit in-vitro the urothral growth.Other labaratories investigate those scaffolds by adding mechanical stimuli in biochambers to improve results (Ram-Liebig, et al., 2006).

Currently, tissue engineered bladder reconstruction is not available for patients, apart from the Atala's institution: So far nine myelodysplastic children with low compliance bladder have received a tissue engineered bladder reconstruction by using the omentum to cover the seeded scaffold (Atala, 2006).

The tissue engineered bladder as a whole seems to be a long-term goal, but very difficult to obtain because of its complicated physiological function. Even more complicated is e.g. tissue engineering for the neurogenic bladder. If cells of a normal bladder are seeded on a biomatrix, there is regeneration of normal bladder, however if you take cells from neuropathic bladder, what will happen ? According to Kropp and co-workers (2005) neuropathic bladder smooth muscle cells have different characteristics in vitro in regards to contractility (decrease), cell proliferation (increase), cell adhesion (decrease), facts which raise concern for current tissue engineering techniques. Neuropathic cells may need to be manipulated prior to use in vivo involving gene therapy.

Both, acellular matrix and bladder bioengineering are promising methods, but several questions remain: Will the augmenting effect persist with time, would the procedure predispose to spontaneous bladder rupture ? Can it be applied to abnormal bladders in patients as it was to the normal bladder ? Once several patients have undergone the procedure these questions can be answered.

Because of these uncertainties of these attempts, present management still relies on the surgical augmentation with gastrointestinal (demucosalized) segments.

DO WE STILL NEED INTESTINAL SEGMENTS TO TREAT VESICAL DYSFUNCTION – NEW TISSUES (Cont.)

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DO WE STILL NEED INTESTINAL SEGMENTS TO TREAT VESICAL DYSFUNCTION – DOES RATIATION THERAPY PROCLUDE THE USE OF INTESTINAL SEGMENTS

Ubirajara Ferreira

Radiation therapy as a primary treatment for invasive bladder cancer and for gynaecological tumours has previously been shown to give reasonable cure rates. Despite these results, urinary diversion may be required to manage the complications resulting from pelvic irradiation of these types of cancer.

The field of radiation for pelvic malignancy includes the small intestine, ascending and descending colon. The potential side-effects if these portions of bowel are entero-enteric fistulae, uretero-intestinal anastomotic stenosis and poor healing. Therefore, it seems appropriate to use an intestinal segment which has not been exposed to irradiation.

A continent diversion may be considered for irradiated patients with a good prognosis, who are well motivated and have the dexterity and willingness to carry out self-catheterization. Herein, we report the results of a continent and nonrefluxing transverse colonic urinary reservoir construction, the Unicamp technique.

SURGICAL TECHNIQUE

A 40-cm segment of transverse colon is isolated and resected. The segment of bowel removed is irrigated copiously with saline solution. The proximal 30-cm of the segment is detubularized; the portion not detubularized is intussuscepted to create a 3-4 cm long nipple valve, according to a method described by Kock et al. A 1.5 cm incision is made in the midportion of the nipple throughout ali layers, directly opposite the pouch wall. An ellipse of the mucosa of the pouch wall is excised to match the opening in the nipple. Using 3-0 chromic catgut sutures, the muscularis of the pouch wall is approximated to the exposed inner nipple wall.

A 12 F catheter is placed through the undetubularized portion into the open pouch. With Babcock clamps placed on the antemesenteric border, the excess colon is excised. The efferent limb is reconfigured using a 3-0 polyglactin running suture. To achieve adequate ureteric length for submucosal tunnelling, the ureters should be mobilized to the lower pole of the kidney. A 3-cm submucosal tunnel is created and a single-layer ureteromucosal anastomosis completed with 5-0 inter-rupted chromic catgut sutures. The pouch is closed via a Heineke-Mikulicz type reconflguration in one layer.

Some patients with mild metabolic acidosis required no treatment because they had good renal function after surgery and the acidosis improved considerably by 6 months; such patients would be treated if the acidosis remained after this period.

Urodynamic studies have consistently shown that the transverse colonic reservoir is a stable system, with peak pressures of <35cmH20. A year after surgery the median functional capacity of the reservoir was 450 mL and the catheterization interval remained at 3-4 h. Thus, from our experience, we recommend the transverse colonic reservoir as an alternative form of urinary diversion in patients who have received high-dose pelvic irradiation.

WHAT IS NEW IN NEUROUROLOGY?

Helmut Madersbacher

In their foreword to the book "Neurourological Urology" E. Bors und A.S. Comar (1971) stated that Neuro-Urology can only be understood by combining thoughts and methods of Urology, Neurology, Neurourgery, Psychiatry,Traumatology and Rehabilitation Medicine.

The following topics will be discussed, Progress (1) in understanding physiology and pathophysiology of the lower urinary tract, (2) in diagnosis and (3) therapy of neurogenic lower urinary tract dysfunction and I'll finish with (4) some ideas on the future of Neuro-Urology.

PATHOPHYSIOLOGY

In the 1960's we only knew that via pathways from the CNS to the bladder bladder contractions are induced by activating cholinergic receptors, about 10 years later also the afferent reflex pathway became more evident, during the next decade it was realized that normally the afferent input from the bladder to the CNS is conducted in myelonated A-? fibres. But to convey afferent input under pathological conditions, e.g. after spinal cord injury, C-fibres are activated. It became clear, that such receptors can be blocked by intravesical instillation of capsacine and resiniferatoxine, thus relaxing the overractive detrusor. During the last 8 years much attention was paid to the urothelium, which is not just a barrier, but functions as a metabolic organ: it releases e.g. NO, ATP, Acetylcholin, expresses many receptors, incl. M2- and M3, and communicates extensively with the underlying structures.

Much of our understanding of cerebal structures to be involved in micturition and withholding micturition we are owing to 15 young volunteers, who were trained to achieve micturition by lying supine in the tube of an MRI. Blok and Holstage initiated these investigations in 1997. On the basis of these MRI studies it was confirmed, that there is a pontine micturition center in the dorsal pons (M-region) and that the pontine center for the external sphincter is located more laterally (L-region). They also found that afferent input from the periphery projects firstly to the periaquaeductal grey and from there ascending pathways originate to cortical and subcortical centers and descending neurons inhibit or stimulate the pontine micturition centre.

Own investigations in patients with Parkinson's disease revealed that with increasing duration and increasing severeness of the disease neurogenic detrusor overactivity occurs causing symptoms of the overactive bladder including overactive detrusor incontinence. The way this functions was elegantly shown by Seiff and co-workers from Kiel in 2003 on the example of Parkinson patients, who have received an implant for deep brain stimulation (SDN). Urodynamic studies with the brain stimulator on and off enlighted the inhibiting influence of the basal ganglia on the detrusor reflex: STN stimulation normalizes detrusor hypersensitivity in Parkinson patients, thus proving the concept of increasing detrusor overactivity with increasing severeness of the disease.

Functional MRI is able to detect structures involved in the cortical and subcortical control of bladder and sphincter: according to Reitz and co-workers, from Prof. Schurch's department, repetitive voluntary pelvic floor contractions with a full and an empty bladder activated areas known to be involved in the control of the bladder, they activated supplementary motor areas as well as the basal ganglia, confirming that pelvic floor contraction, which is recommended for inhibiting the urge to void, really inhibits detrusor activity centrally. This proves that the clinical effect of such manoevres is not only a mechanical one by occluding the bladder outlet.

DIAGNOSIS

New techniques in the field of diagnosis allow to define the dysfunctional pattern in the individual patient, moreover they also improved considerably our knowledge on neurogenic lower urinary tract dysfunction.

In regards to diagnostic procedures video-urodynamics are the State-of the-Art to evaluate the underlying pathophysiology, for follow-up urodynamics may be sufficient depending on the individual situation. With the help of these investigations we are able to define various dysfunctional patterns of detrusor and sphincter.

Neurophysiologic testing gives additional information on the function/dysfunction especially of afferent nerves: We have focused on the electrical stimulation of the bladder neck area, to prove whether electrical stimulation is able to evoke cortical potentials, allowing a judgement on the afferent activity at least to extroceptive stimuli. The results of this investigation are extremely helpful, when it comes to the indication of intravesical electrotherapy, which only works in patients, in whom at least some afferent fibres to the cortex are still functioning (see below).

We do know that only (video)-urodynamics can detect risk factors within the lower urinary tract, before they cause upper urinary tract damage.
In regards to follow-up (video-) urodynamics one may ask "how early is too late, however, the intervals have to be based on the risk factors being present as well as on the individual situation of the patient.

THERAPY

The aim of therapy in lower urinary tract dysfunction still is to preserve the kidney function and to control incontinence possibly to restore continence. Since about 20 years the therapy of choice to treat the spinal reflex bladder, according to the new terminology of the ICS, now called neurogenic (spinal) detrusor overactivity, is (1) to relax the overactive detrusor for controlling a high pressure situation during the storage (Low Compliance) and the emptying phase, mostly combined with (2) intermittent catheterisation to circumvent unbalanced voiding due to detrusor-sphincter-dyssynergia (DSD). This concept replaced the area of transurethral sphincterotomy,

which was inaugurated in 1958 by Ross et al. in the U.K. Transurethral sphincterotomy also nowadays has its place especially in the high tetraplegic man when intermittent catheterization is not possible. A good sphincterotomy - although re-sphincterotomies are necessary in about 40 % of our patients - guarantees preservation of the upper urinary tract in the vast majority, however, continence can not be achieved and a condom urinal is necessary.

Suprapubic triggering to empty the bladder is risky and should only be allowed if the urodynamic situation is safe. Basically it should be replaced by intermittent catheterisation.

Intermittent catheterisation (IC) was introduced by Sir Ludwig Gutmann in Stoke Mandeville for bladder emptying during the spinal shock phase already in the late 50's and was popularized on the other side of the Atlantic ocean by Jack Lapides. He recommended the clean technique also for long-term bladder emptying.
The experience, that IC really works also for long-term treatment, with an acceptable rate of urethral pathology and a low rate (3 %) of strictures needing treatment, was one of the greatest progress Neuro-Urology has made during the last 25 years, enabling also adequate bladder emptying e.g. in augmented bladders and bladder substitutes. In most European countries aseptic IC is used, in other area of the world clean IC is practised.

With the combination of IC and detrusor-relaxing therapy, with anticholinergics as the first line treatment, intravesical pressures can be controlled and continence be achieved in these patients in about 70 %.
In some centres, e.g. in New Zealand, and other areas of the world, there is a tendency to replace intermittent catheterisation by long-term suprapubic catheterisation, last but not at least due to economic reasons. Despite some optimistic reports, most neuro-urologists believe that a permanent suprapubic catheter can not be the solution for the future. However, a few patients may benefit from it.

If anticholinergics are not effective enough or are not tolerated in adequate dosages, the second choice nowadays is the injection of Botulinum Toxin A into the bladder wall. The European study, inaugurated by Prof. Schurch, in which our unit also participated as well as a recently published placebo controlled study, have proved the efficacy of this new therapy. The effect of Botulinum Toxin in the smooth muscle detrusor lasts much longer than in the striated muscles for reasons we do not know. In the mean after nine months the injections have to be repeated. Botulinum Toxin has been introduced into Neuro-Urology to relax the spastic external striated sphincter in patients with DSD, at least temporarely. This pharmacological sphincterotomy can be used as a test procedure to see what happens when a surgical sphincterotomy is planned, especially in patients, with a danger for incontinence in so far continent patients. Although it is not the topic of this lecture, I would like to mention, that instillations of Botulinum Toxin in the bladder have shown to be useful in interstitial cystitis and moreover, injections into the prostate cause apoptosis in the enlarged prostate: the size of the prostate decreases and obstructive micturition symptoms improve. Therefore the indications for Botulinum Toxin may become several and this substance, still the most poisoning substance on earth, may become something like the penicillin of the 21st century for the neuro-urologist.

Before the era of Botulinum Toxin the alternatives, if oral anticholinergics were not effective, were either intravesical instillation of vanilloids like e.g. capsacin or resiniferatoxin or surgical procedures, e.g. sacral deafferentation (posterial sacral root rhicotomy) or bladder augmentation. In regards to vanilloids capsaicin is more or less out already due to the side effects.
Resiniferatoxine has proved to be effective also in the spinal reflex bladder, however the substance is not registered for human medicine and can therefore only be applied within studies.

Sacral deafferentation is an elegant method: One has to cut all posterior roots from S2-S5 on both sides. The results to achieve detrusor acontractility are excellent and lasting, however there are major disadvantages: the procedure is destructive, and patients are more and more reluctant when nerves are cut, even if they are not useful for them. Moreover with sacral deafferentation they loose any sensation also for the bowls and constipation may be increased unless defecation can not be achieved by electrical stimulation by simultaneous implantation of a sacral anterior root stimulator. In the era of BotulinumToxin the indications for sacral deafferentation have become less.

Although IC is nowadays the state-of the-art to empty the neuropathic bladder, some patients can not do it, some patients have nobody who can do it for them and some do not accept this type of bladder emptying. For those with an intact sacral reflex arc, at least on the efferent side, sacral anterior roots stimulation (Brindley) is an option and mostly combined with sacral deafferentation. Based on his profound knowledge of neuro- and muscle physiology Prof. Giles Brindley in London designed stimulation in bursts with intervals in between: during stimulation sphincter and detrusor are activated, however during the interval the quickly reacting striated sphincter relaxes immediately while the slowly reacting smooth muscle detrusor stays still in contraction. Thus "post-stimulus" voiding is achieved. Although not ideal this technique has excellent results with a long-termin efficacy in 85 % after mean observation time of 10 years.

Sacral neuromodulation comprises (1) percutaneous nerve stimulation as a test period, during which the electrodes are placed to the relevant sacral roots - mostly S3 giving

WHAT IS NEW IN NEUROUROLOGY? (CONT.)

the best response - and are then connected to an external stimulator. If the test period reveals sufficient efficacy, in a second stage the stimulator (IPG) is implanted. Sacral neuromodulation results in detrusor relaxation, but at the same time also dysfunctional voiding may be improved. The results with this method in neurogenic lower urinary tract dysfunction are somewhat controversial.

For the combination of an acontractile detrusor with an acontractile (incompetent) sphincter, typically for conus-cauda-lesions, bladder expression by Valsalva or CredÈ has been used extensively. Due to the high intravesical pressures, created this way, associated with an enormous risk for upper urinary tract damage by vesico-uretero-renal reflux this method should only be used if urodynamically safe. Otherwise intermittent catheterisation should be performed or the patient persuaded to do it.

About 15 years ago, a sophisticated method was recommended to express the underactive detrusor with the help of a Latissimus dorsi muscle transfer: The latissimus dorsi muscle was wrapped around the bladder in a way that contraction of the latissimus dorsi squeezed the bladder. The nerves were anastomized in such a way that the patient could be trained to contract the transferred muscle voluntarily. Press conferences and articles in the newspapers predicted enthusiastically “no more intermittent catheterisation for patients with a weak detrusor”, thus creating, as we know nowadays, false hopes. It could only work if the outflow resistance is low or patients are able to relax the sphincter actively, but under these conditions voiding by Valsalva or CredÈ is mostly possible and patients do then not need a transferred Latissimus dorsi muscle.

Another attempt to empty weak neurogenic bladder is that of Prof. Chuan-Guo Xiaou, who recommends an artificial somatic-autonomic reflex pathway procedure for bladder control in children with spina bifida as well as in adults with neurogenic detrusor weakness: After limited laminectomy he performs lumbar ventral root (L 5) to sacral ventral root (S 3) microanastomosis; the dorsal L 5 root is left intact as the afferent branch of the somatic-autonomic reflex pathway after axonal regeneration. The bladder reflex is stimulated by scratching the skin of the L5 dermatom. Dr. Xiaou claims that the artificial somatic-autonomic reflex arc procedure is an effective and safe treatment to restore bladder continence and reverse bladder dysfunction. Interestingly enough, his method was published in the Journal of Urology only recently without any comment from the editors side, although the urodynamic curves published are really not convincing: Instead of a weak but normal compliant detrusor a low compliance bladder is present postoperatively and voiding is achieved only by abdominal straining and not by detrusor pressure.

Intravesical electrostimulation is a method which is especially useful to improve/normalize the neurogenic hyposensitive/hypoactive detrusor. The efficacy of this method is discussed controversially, however in studies with disappointing results no attention was paid to inclusion criteria, which comprise most importantly at least some intact afferent fibres present.

What is the future of Neuro-Urology? Where do we need improvements? Where do we need innovations? In regards to intermittent catheterisation we do need controlled studies possibly with the patient as his own control in order to prove whether this catheter or this technique is better than the other. Of course innovations are always welcome and one can imagine that a lipstick-sized catheter for female patients makes intermittent catheterisation more attractive and more acceptable. Pharmacological relaxation of the detrusor will focus in the future on the afferent side since we know that the urothelium does not only produce important neurotransmitters, but has also cholinergic M2 and M3 receptors. It really makes sense to inhibit the detrusor reflex where it starts and this is on the afferent side. The substance Nociceptin/Orphanin is a good example for this strategy. The traditional way to apply Botulinum Toxin into the detrusor is to inject it into 20, 30 or even 40 locations of the bladder wall. The concept to inject Botulinum Toxin only in the trigonal area, makes sense and the first experience with this technique are promising. Allergic reactions to Botulinum Toxin A, even when injected repeatedly, were not yet a problem, but could be overcome by using Botulinum Toxin B instead of the type A.

I have already mentioned the disadvantages of sacral deafferentation.
M. Craggs (London), replaced it by combining anterior sacral root stimulation with posterior sacral root neuromodulation, a procedure, which he called SPARSI. It is possible to suppress the overactive detrusor with sacral neuromodulation and at the same time to empty the bladder with the Brindley method, detrusor-sphincter-dyssynergia is still a problem, however it can possibly be overcome in the near future.

Another question is that of tissue engineering, or in other words, can cells seeded from a neuropathic bladder on a biomatrix replace a neuropathic bladder. Prof. Kropp from the University of Oklahoma has characterised the neuropathic smooth muscle cells in culture and has found that neuropathic smooth muscle cells have different characteristics in regards to contractility - decreased, cell proliferation – increased and cell adhesion -decreased, facts, which raises some concerns for current tissue engineering techniques for the neuropathic bladder. Nevertheless, further initiatives should focus on avoiding destructive surgery, to improve symptomatic treatment for compensation of deficits and to induce more restorative therapy.

So far, and in the near future, proper initial management of the bladder during the spinal shock phase, adequate bladder rehabilitation and life-long neurological care are still the keys to ensure an almost normal life expectancy for tetraplegics and normal life expectancy for paraplegics as well as a high quality of life despite neuro-urological deficits.

NEUROUROLOGY UPDATE – NEUROSTIMULATION

Helmut Madersbacher

Electrical neurostimulation in Urology comprises intravesical electrotherapy, anterior sacral root stimulation, pelvic floor electrostimulation and transrectal electrostimulation for ejaculation. Electrical neurostimulation is characterised, that, in contrast to electrical neuromodulation, the stimulated nerves directly elicit an answer in the relevant organ(s).

1. INTRAVESICAL ELECTROSTIMULATION FOR BLADDER REHABILITATION IN NEUROGENIC AND NON-NEUROGENIC DETRUSOR DYSFUNCTION

In 1887 the Danish surgeon Saxtorph described intravesical electrical stimulation (IVES) for the "atonic bladder" by inserting a transurethral catheter with a metal stylet in it and with a neutral electrode on the lower abdomen. In 1899 two Viennese surgeons, Frankel-Hochwart and Zuckerkandl stated that intravesical electrotherapy was more effective in inducing detrusor contractions than external faradization. In 1975 Katona introduced and popularized this method for the treatment of neurogenic bladder dysfunction. He stressed the importance of vegetative afferentation as the first and main step to rehabilitate the dysfunctional detrusor. Ebner et al (1992) found in cat experiments that intravesical electrostimulation activated the mechanoreceptors of A-delta afferent fibres. He recognized that the receptors of bladder afferents are stimulated by IVES within the bladder wall thus proofing Katona's working hypothesis. Jiang (1998) demonstrated in another animal experiment that IVES induced modulation of the micturition reflex due to an enhanced excitatory synaptic transmission in the central micturition reflex pathway.

The "vegetative afferentation" results in the sensation of bladder filling/urge to void with subsequent enhancement of active contractions and possibly also voluntary control over the detrusor. According to Colombo et al (2000) IVES also induces electrical changes on higher micturition centers, measured by electroencephalography (EEG).

However, intravesical electrical stimulation of the bladder is still a controversial therapy, although basic research during the last decade has evidenced the mechanism of its action as well its efficacy and, at least, in animal experiments, optimal parameters have been determined.

In the following our experience with intravesical electrostimulation, not only in children, but also in adults, will be presented and the controversy about its value will be discussed.

TECHNIQUE

The technique involves a catheter with a stimulation electrode (cathode) in it, being introduced into the bladder and connected to a stimulator. Saline (0,9 %) is used as the current leading medium within the bladder. The anode (neutral) electrode (14 x 8 cm) is attached to the skin in an area with preserved sensation, usually in the lower abdomen. According to Ebner et al (1992) the following stimulation parameters have proved to be most effective in the animal experiment: pulse width: 2 ms; frequency: 20 Hz; current: 1-10 mA. Some clinicians use square unipolar pulses for continuous stimulation (Gladh et al, 2003), whereas others and we use intermittent stimulation with bursts and gaps that can be varied (1-10 s) along with the rise time and the time of the plateau within the burst. With intermittent electrostimulation, each therapy session takes 60-90 min., with continuous stimulation 20 min., on a daily basis, five days a week, until the maximum response is reached. For patients, who have never experienced the urge to void – e.g. children with myelomeningocele or patients who have lost this ability – IVES is combined with a biofeedback training: on a water manometer attached to the system the patient is able to observe the change in the detrusor pressure (Katona, 1975). This way the patient is able to realize that the sensation experienced is caused by a bladder contraction. This external feedback also facilitates the achievement of voluntary control.

PATIENTS SUITABLE FOR IVES

There are almost no publications so far on the effect of IVES in adults with neurogenic and non-neurogenic detrusor dysfunction: partial peripheral denervation of the bladder after gynaecologic or rectum surgery when resulting in a hyposensitive and underactive detrusor, is another excellent indication for IVES. Another interesting group for intravesical electrostimulation are elderly patients with unbalanced voiding (PVR > 50 % of bladder capacity) due to underactivity of the detrusor.

Intravesical electrotherapy is able to improve neurogenic and non-neurogenic bladder dysfunction, primarily by stimulating A-delta mechanoreceptor afferents inducing bladder sensation the urge to void and consequently increasing the efferent output with improvement of micturition and conscious control. The ideal indication is the hyposensitive and underactive (acontractile) detrusor due to an incomplete nerve lesion.

We have applied intravesical electrostimulation for non-neurogenic and neurogenic detrusor dysfunction in children and adults, the results in three groups of patients will be presented, 1) in children with non-neurogenic dysfunctional voiding. 2) in women with neurogenic detrusor dysfunction after pelvic surgery and 3) in a group of elderly with unbalanced voiding due to detrusor weakness for various reasons.

RESULTS

(a) Children with dysfunctional voiding

In 21 children with a Lazy Bladder Syndrom the mean decrease of cystometric bladder capacity (in cc) as a sign of improved sensation for the bladder) was from 300 to 220, the mean increase of max. detrusor pressure amplitude during voiding was from 30 to 54 cm H2O (p=0.002) and

NEUROUROLOGY UPDATE – NEUROSTIMULATION (CONT.)

the mean decrease of PVR was from 150 to 25 cc. Clinically all six children being on intermittent catheterization before achieved balanced voiding, the rate of urinary tract infections decreased almost to 0 in all 19 children, in whom IVES was successful. Follow-ups so far showed stabilization in 19. Two children relapsed between three and six months after the treatment was finished, therefore a re-stimulation was performed (Madersbacher, 2004). From our and others experience (Gladh et al, 2003) IVES is an excellent method for bladder (re-)habilitation in children with dysfunctional voiding, due to a hyposensitive and underactive detrusor.

Regarding children with myelomeningocele, one must take into account that myelomeningocele bladders may have already at birth substantial structural changes: Nevertheless, from our results, two third of the myelodysplastic children benefit from induced/improved bladder sensation, half of them from increased detrusor contraction amplitude and 40 % gain some control over the bladder. These results can further be improved by longterm IVES, over years, according to Katona and BerÈnyi (2005).

(b) Women with persisting unbalanced voiding after gynaecological surgery
In group I (start of therapy within the first twelve months postoperatively) the mean maximum detrusor voiding pressure (cm Hd2O) increased from 6 to 35 (p= 0.003); the mean PVR decreased from 314 to 35 (p=0.0077); in group II (start of therapy later than 12 months postoperatively) the maximum detrusor voiding pressure increased from 7.2 to 17.8 (p=0.0277), the PVR decreased from 240 to 84.4 (p=0.0077); in group I all patients achieved balanced voiding, eight with detrusor contraction only, in two still assisted by abdominal straining; in group II 6/9 achieved spontaneous voiding with detrusor only, in one assisted with abdominal straining and two remained on intermittent catheterization.

(c) Elderly with unbalanced voiding due to detrusor weakness
Voiding dysfunction with or without urinary incontinence is one of the most frequent health problems in the elderly. In 30 % of the geriatric population a combination of a hyperactive, but weak detrusor is present, causing unbalanced voiding (post-void residual urine > 50 % of the functional bladder capacity) combined with urgency, urge and/or overflow incontinence.

Nineteen women and six men, mean age 78,2 (72-88) years with underactivity/acontractility of the detrusor and a post-void residual urine above 50 % of bladder capacity were treated with intravesical electrostimulation. The underlying pathophysiology of the detrusor dysfunction were partial peripheral bladder denervation after pelvic surgery in eight, autonomic neuropathy in three, incomplete spinal cord lesions in seven, a supraspinal lesion in four and chronic urinary retention in three. The mean follow-up was 22,3 (6-50) months.

Intravesical electrical stimulation of the bladder is still a controversial therapy for patients with neurogenic and non-neurogenic detrusor dysfunction, although basic research during the last decade has evidenced the mechanism of its action and its efficacy.
Almost none of the published papers really focused on inclusion and exclusion criteria. According to Katona's concept and the results of basic research only those patients with some intact afferent fibres from the bladder to the cortex, with still intact mechanoreceptors within the bladder wall and a detrusor which is basically able to contract, are suitable for this treatment. The value of viscerosensoric cortical evoked potentials form the bladder neck to prove the existence of functioning afferent fibres was demonstrated by Kiss et al (1998). In incomplete spinal cord lesions the presence of pain sensation in the sacral dermatoms S3 and S4 is a prerequisite for successful IVES, as, according to Nathan and Smith (1951) , the pathways of bladder proprioception and for pain lie close together.

Intravesical electrotherapy is able to improve neurogenic and non-neurogenic bladder dysfunction, primarily by stimulating A-delta mechanoreceptor afferents inducing bladder sensation the urge to void and consequently increasing the efferent output with improvement of micturition and conscious control. The ideal indication is the hyposensitive and underactive (acontractile) detrusor, due to an incomplete nerve lesion (Madersbacher, 2004).

2. ANTERIOR SACRAL ROOT STIMULATION (BRINDLEY)

Spinal cord injured patients with a suprasacral lesion usually develop an overactive bladder. The overactivity of the detrusor and of the external sphincter causes unbalanced voiding and incontinence and threatens those patients with recurrent urinary tract infections, renal failure and autonomic dysreflexia.

If conservative means of treatment fail the situation can be well managed by sacral deafferentation (SDAF), followed by implantation of an anterior root stimulator (Brindley). Mostly the operative treatment consists of two steps, (1) sacral deafferentation with complete transsection of all afferent dorsal roots S2 to S5 using microsurgical technique, intraoperative urodynamics and arterial blood pressure registration allowing to differentiate between dorsal and anterior roots by electrostimulation. SDAF restores a normal reservoir function and urinary continence by interrupting the reflex activity. (2) The second step is the implantation of the anterior root stimulator which allows patients to void voluntarily by means of an external transmitter. G.S. Brindley developed the implant and the external device (1969-1978). We have treated in our unit 70 patients between 1985 up till now, however the largest series in one hand is that of D. Sauerwein in Bad Wildungen with 440 patients between 1986 and 2003, still in continous follow-up for a mean time of 6.6 years (Kutzenberger et al., 2004). The results are very similar, continence was

achieved in 83 % in Sauerwein series and in 85 % in our series (Madersbacher et al., 1996) and almost the same percentage are able to void voluntarily by SARS with a daily frequency of between 85 % in our series and 90 % in Sauerwein series. SARS is also used for defaecation. Urinary tract infections are diminished from 6.3 preoperatively to 1.2 postoperatively, kidney function did not change, indeed it did not deteriorate. Autonomic dysreflexia disappeared in almost all cases.

Complications are rare with adequate skin desinfection, infections of the implant occurred in 1 %. However more often late complications related to the implant occur. Failures of SARS may be caused by a defect of the external transmitter, a defect of the implant or by neurogenic or myogenic deterioration. Repairs are possible, however myogenic damage due to overdistentions requires clean intermittent catheterisation for months, sometimes forever and the same is true for neurogenic failures which have been very seldom.

Accurate adjustment of stimulation parameters allows a post-stimulus voiding with low resistance. However, efforts are undertaken to modify the electrical current in such a way that efferent fibres to the detrusor and to the external sphincter are not activated simultaneously.

The number of these procedures has decreased recently, firstly because Botulinum toxine injections are a useful alternative to control detrusor-overactivity if anticholinergics fail, secondly because patients have become quite reluctant to have nerves cut, even if they are not useful to them, having in their mind regeneration and repair of the spinal cord. However, it is still not known, how soon repair and regeneration within the CNS will be possible. Craggs et al (2000) therefore tried to replace sacral afferentation by electrical neuromodulation through sacral posterior roots and combine it with sacral anterior root electrostimulation. They call the procedure SPARSI, which stands for sacral posterior and anterior root stimulation. So far, five patients have been treated this way with some success, however detrusor-sphincter-dyssynergia is still a problem.

3.ELECTRICAL STIMULATION OF PELVIC FLOOR MUSCULATURE (PFM)

The value of electrical stimulation of the PFM for urinary stress incontinence is still discussed controversially (Sand et al., 1995; Yamanishie et al, 1997). More prospective, randomised studies with sufficient power are needed to compare the efficacy of electrical stimulation with pelvic floor muscle training programmes.

However, electrical stimulation makes women more aware of the pelvic floor muscle. This is important because 30 % of stress-incontinent women do not know initially what it means to contract the pelvic floor muscles. Additional electrical stimulation by vaginal plugs helps the woman to realize that there is a PFM which can be contracted voluntarily. Electrical stimulation should therefore be used in these women before or in combination with a pelvic floor training programm. Longterm electrical stimulation is indicated in some patients with neurogenic stress urinary incontinence due to incomplete nerve lesions.

4.TRANSRECTAL ELECTROEJACULATION

It comprises the induction of seminal emission (rarely or a real ejaculation) by electrical stimulation of sympathetic fibres of the hypogastric plexus through electrodes in the rectum. Electro-ejaculation has been used in domestic animals since 1938 and sporadically in men since 1948. The first life births were reported by Francois et al (1978) and Brindley (1980).
The sympathetic fibres are stimulated at the “obturator point” which can be reached easily via the rectum. The equipment that is usually used for this purpose (Seager) works with sinusoidal current and avoids thermal damage to the rectum by monitoring the temperature of electrodes and automatically switching off the stimulus if the temperature rises too high. For results read the paper of Le Chapelain et al (1998). However, due to other methods of fertilisation available nowadays, the importance of transrectal electrostimulation to retrieve sperms for spinal cord injured patients has decreased considerably.

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NEUROUROLOGY UPDATE – NEUROMODULATION

Homero Bruschini

Neuromodulation and neurostimulation has its beginnings in the eighteenth century, when Caldani in 1756 and Galvani in 1786, produced muscle contraction by nerve stimulation. During the nineteenth century, further experiments discovered the urinary and erectile functions of the sacral nerve roots and hypogastric nerves, hypothesizing a micturition center in the S2-S4 region. The first attempt to stimulate the bladder by an electrical stimulation date back to 1878, by the Danish surgeon Saxtorph through a metal electrode inserted transurethrally. It was not until the second half of the twentieth century that further studies and efforts were undertaken in this area.

In the 1950s, McGuire performed direct bladder stimulation in dogs to evaluate the parameters required for detrusor contraction, which results were only commented 14 years latter. Katona reused the transurethral electrical stimulation in 1958, similarly to Saxtorph, process utilized and presented by Mardersbacher and his group in humans, by 1982. A large number of researchers were involved with these processes since then, trying pelvic nerve stimulation, pelvic floor stimulation, spinal cord stimulation and sacral root stimulation. The best practical results were obtained by sacral root stimulation, basically developed by Emil Tanagho and a group of doctors who did postdoctoral fellowships in San Francisco with him, including Rick Schmidt.

SELECTION OF PATIENTS FOR NEUROMODULATION

Two groups of patients have been basically implanted:

- Idiopathic detrusor overactivity who have failed all conservative and medical treatments
- Idiopathic urinary retention unavailable to intermittent self catheterization.

In both indications, sacral roots have to be neurologically intact. The FDA approved its use for urge incontinence in October 1997 and for urgency-frequency and nonobstructive urinary retention in 1999.

SURGICAL TECHNIQUES

Three surgical techniques can be utilized for electrode implantation: a two-stage, one stage implant and bilateral sacral implantation. The two-stage process, has been the one developed by Tanagho and Schmidt originally. Consists of a temporary stimulations applied through a simple removable and temporary electrode (percutaneously inserted under radiological guidance and local anaesthesia), during a test period. In case of success (more than 50% reduction of pads or incontinence episodes), a permanent electrode is implanted in a second procedure. The one stage implant consist of insertion of the permanent electrode, kept in place when test is positive. The bilateral implant offered similar results in a comparative trial, and its use should be reserved for those who unilateral test fails.

RESULTS

Actually, around 20,000 Interstim systems have been implanted around the world. The process is minimally invasive and offers success and improvement in 61% to 90% of patients test responders. There are some multicenter studies and two prospective randomized studies supporting these numbers. The 3rd Consultation in Incontinence, in 2004, gave level of evidence 1 and 2 and recommendation B for patients with idiopathic detrusor overactivity who have failed all conservative and medical treatments.

CONCLUSIONS

Sacral neuromodulation is an effective and mini-invasive treatment for patients with intractable OAB (level 1-2) or Idiopathic Urinary Retention (level 2-3), but indications must be carefully weighed according to risk/benefit and cost/benefit ratios.

MEN WHO LEAK - THE IMPACT ON QUALITY OF LIFE

Walter Artibani

Health-related QoL (HRQoL) consists not only of the patient's physical and psychologicalwell-being, but also of their ability to work, live and act in a normal social setting. HRQoL can be perceived differently by patients of different ages, race, education, religion or from different social classes.

Because urinary incontinence may cause social isolation, loss of sexual function, and other psychosocial problems it could have significant impact on patients' psychosocial well-being and quality of life, as well as on depression, anxiety and satisfaction (1). Moreover, coping mechanism can significantly affect patient's life (2).

Due to the need of measures objectively subjective issues such as those related to quality of life, several questionnaires have been developed, validated (including translations). Generic questionnaires are those validated, and useful to assessing a broad range of populations and ages in many different disease states (including healthy populations). Although this kind of questionnaires can be insensitive to the specific condition measured, failing to address many of the issues relevant to the specific disease, they allows comparisons of quality of life issues among different diseases as well as with healthy population. Vice versa, disease-specific tools are more sensitive than generic ones in detecting changes as a result of treatment. Due to these reasons, the concomitant use of a selection of generic and disease-specific questionnaires should be recommended. RAND SF-36, SF-20, European Quality of Life Scale, Sickness Impact Profile, General Health Index, Nottingham Health Profile, Health Utility Index, Mental Health Index are among the most commonly used generic questionnaires, while, in the field of incontinence, Incontinence Impact Questionnaire (IIQ), Urinary Distress Inventory (UDI), York Incontinence Perception Scale, Incontinence Quality of Life Index, King's Health Questionnaire (KHQ), and ICI-Q are among the most employed disease-specific instruments.

According to the epidemiological data provided by the 3rd International Consultation on Incontinence, male patients more likely to leak are elderly men, those men with functional or cognitive impairment, patients with neurological disorders, and patients after prostate cancer therapy (e.g., radical prostatectomy) (3).

With regard to elderly patients, in a large survey involving more than 140,000 patients, the Medical Health Outcomes Survey, Ko et al. (1) showed that, after adjusting for age, sex, race, marital status, education level, and other comorbidities, urinary incontinence remained a significant predictor of all domains of SF-36 and 2 summary scores (Physical component and Mental component summaries). In the 8 domains of SF-36, the incontinent group scored 2.9 to 4.2 points less than the non-incontinent group, while the presence of urinary incontinence reduced Physical component and Mental component summaries 3.7 and 3.0 points (1).

Regarding incontinence after prostate cancer therapy, Several studies assessed patient's health-related quality of life, although most of them were comparative studies among different therapeutical options (surgery, EBRT, brachitherapy). The most relevant experiences were those of the Prostate Cancer Outcomes Study (PCOS), That study analyzed patients undergoing different prostate cancer treatments (surgery, radiation therapy, hormonal ablation therapy, or watchful waiting), showing a relevant effect of urinary incontinence on five SF-36 domains at 2 years after the primary treatment (4).

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MEN WHO LEAK — INJECTABLE PROCEDURES

John Heesakkers

The technique of intraurethral injection of material to increase outflow resistance in patients with urinary incontinence is not new. The first report was from Murless in 1938. Sachse treated in 1963 24 patients with postprostatectomy incontinence of whom 12 were reported as cured. All available materials try to be optimal with regard to efficacy and durability. The complications that one tries to avoid are migration of particles, allergic reactions and formation of abcesses and granulomas. The currently available materials are among others:

- GAX- Collagen. Bovine dermal collagen has long been recognized as a biocompatible biomaterial. Cross-linking with glutaraldehyde results in a fibrillar collagen with resistance to collagenase digestion and significantly enhances persistence, with stabilization preventing syneresis. This material does not cause granuloma formation, and migration of particles to distant body sites does not appear. It can however cause allergic reactions.

- Durasphere. This material consists of nonresorbable pyrolitic carbon-coated zirconium beads that are much larger (200 to 500 ?m) than either PTFE or silicone polymers and are transferred in a beta-glucan water-based gel. The beads encapsulate within the tissue and retain bulky for at least 2 years. The use of carbon beads does not require skin testing, because there is no associated antigenicity. In addition, owing to the larger particle size, they do not migrate.

- Autologous materials like blood and fat can also be injected but do not have reported efficacy.

- Macroplastique concs of polydimethylsiloxane macroparticles (>100 ?m) suspended within a bioexcretable carrier hydrogel of polyvinylpyrrolidone (povidone) in which the solid particle content is 33% of the total volume. The biggest issue here is also migration of the macrospheres.

- Zuidex consists of detranomer sugar molecules in hyaluronic acid as a carrier. It is inert and easy to administer.

- Tegress is a copolymer of demethyl sufloxide / ethylene vinylalcohol. Upon implantation, the Tegress implant solution forms a soft hydrophilic implant that reinforces the integrity of the urethra's mucosal seal.

INJECTION TECHNIQUES IN MALES

The injections can be performed suburothelially through a needle placed directly through a cystourethroscope while observing the manipulation endoscopically per urethra or by an ultrasound probe per rectum. The patients are positioned in a semilithotomy position. A 20 or 21 Ch cystoscopic sheath is employed using a 0-degree or 30-degree lens.

The postprostatectomy urethra is frequently scarred and less pliant; thus, several needle positions are frequently needed to deposit sufficient material to produce urethral coaptation. The needle must be positioned proximal to the external sphincter, because injection into the sphincter has been associated with sphincter spasm and failure. The needle is advanced under the urethral mucosa with the beveled portion of the needle facing the urethral lumen to allow for layering of the material. The injectable material is then delivered, creating a bulb under the urethral mucosa that protrudes into the urethral lumen. This is performed in a circumferential manner in four quadrants. After completion, the urethral mucosa should be completely coapted and creates the appearance of an obstructed urethra. Extrusion of the injectable agent into the urethral lumen as the needle is withdrawn may occur. This may be prevented in most cases by leaving the needle in place for some time after the injection is completed. The loss of additional material is diminished by preventing advancement of the cystoscope proximal to the injection sites.

Because of the difficulty of localizing the injection by means of cystoscopy one can also use the suprapubic antegrade approach. This approach has been described employing a flexible cystoscope (Klutke 1996) placed suprapubically. The antegrade approach has the advantage of direct visualization of the bladder neck and the injection of material into more supple, less scarred urethra. This approach offers an excellent view of the bladder neck and proximal urethra. The needle is placed just under the urethral mucosa at the level of the bladder neck and advanced proximally, meaning it is pulled back toward the bladder. The bladder neck closes off completely as the material is injected. It is optional to place a suprapubic cathether to avoid the possible necessity of urethral catheterization.

In the treatment of postprostatic resection incontinence, the injection is in proximal membranous urethra and laterally beside the utriculus to give the impression of replacing "apical" tissue, and it should visually appear obstructed at the conclusion of the injection. Injections in patients after radical prostatectomy are more difficult especially in irradiated tissue or those with more scarification, and considerable practice is needed to reach correct tissue depth with the needle.

MEN WHO LEAK – URETHRAL CONSTRICTOR

Salvador Vilar Correia Lima

The mechanism of voiding involves a complex neuromuscular apparatus, which needs to work in perfect synchronism in order to allow bladder filling and emptying at appropriate time and place. Lesions that interfere with this mechanism lead to impairment of vesico sphincteric function, as well as deterioration of the upper urinary tract.

It is well known that the AS-800 artificial sphincter offers satisfactory results in treating urinary incontinence of various etiologies. There is an over 30 years experience accumulated in the literature with the use of this device in the treatment of urinary incontinence The complexity of this 3-piece device with connections and a variety of cuff sizes and especially the high cost imposes some restrictions to its use. Patients with
some disabilities have difficulties in emptying the cuff by pressing the control pump.

THE DEVICE: The periurethral constrictor is a 2-pieces device with an adjustable cuff to be placed around the bladder neck or bulbous urethra. A subcutaneous port allows filling and emptying of the cuff by direct puncture. The characteristics of the cuff which is wider than the usual AS-800 and consequently takes more fluid allows spontaneous micturition when applied around the urethra.

ACTIVATION: The device is activated 6 to 8 weeks after the implantation. The continence is obtained by injecting saline inside the system by puncturing the subcutaneous port. The idea is to obtain continence with a pressure inside the cuff not superior to 70cm of water which is the safer level according to experience gained with 61-70cm regulating balloon of the AS-800. Fluid can be added or removed in order to achieve continence.

This device has been implanted in 76 male patients suffering mostly from urinary incontinence after prostatic surgery. Most of them had undergone radical prostatectomy.Five patients had a penile prosthesis implanted simultaneously and 2 had the penile prosthesis implanted previously. To validate this idea twelve volunteers including staff urologists, residents and medical students were asked to produce uroflowmetry in normal conditions and in full erection.

RESULTS: The mean folowup of patients implanted with this device is 60 months with a median of 65 months. All patients with the device in situ are continent. Table 01 shows the overall results of the implantation of this device. Patients with the penile prosthesis seem to achieve continence with lower pressure inside the cuff and this may be an indicative of better prognosis with the use of this device.When analyzing uroflowmetry data in the volunteer¥s group a significant decrease in flow rates during erection was observed when compared to the normal condition.

CONCLUSIONS: Long term results with the use of the periurethral constrictor show a significant improvement in continence with the use of this device. The simultaneous use of penile prosthesis may improve results in continence rates in the long term.

TABLE 01- RESULTS OF THE LONG-TERM USE OF THE PERIURETHRAL CONSTRICTOR

Diagnostic	Cases#	Site of impl.	Failure (%)	Fup (Mo)	Success rate (%)
Prostate (RP)	47	BU=46	34.8	M=46.7 Med=29	66
Prostate (TURP)	05	BN=05	0	M=97.8 Med=86.0	100
Neurog> Bladder	24	BN=22 BU=02	37.5	M=80.6 Med=72.5	62.5
Megalourethra	01	BN=01	0	111	100
Total	77	76	32.5	M=61.8 Med=63.0	67.5

BN=Bladder neck BU=Bulbous urethra RP= Radical prostatectomy TURP=Transurethtral resection of prostate

MALE SLINGS

Luis Augusto Seabra Rios

Urinary incontinence after prostatectomy is still a significant and disabling problem. The real prevalence is dificult to know because different definitions used in the recent literature. Terms such as “occasional leakage” “less than one pad/day”, “socially dry” among others, make the incidence and prevalence of PPI vary enormously in the literature.

The treatment of choice for patients with intrinsic sphincter deficiency and normal bladders is the artificial urinary sphincter (AUS).

The male sling unlike the AUS promotes a passive external compression and utilizes a concept similar to that described by Kaufman in 1970. The procedures rely on ventral compression of the bulbar urethra rather than the circular compression achieved with the AUS.

A few thecnical variations have been described but the more popular alternative is the bone anchored perineal sling with synthetic materials.

The procedure is entirely done by a perineal approach and the sling itself is attached to the ischial rami bilaterally.

Most of the authors refer a 60 to 80% cured / improved rate but results are still limited by short term followup and small series reported in the literature.

To date the AUS remains the gold standard for the treatment of PPI. The perineal sling is a promising alternative specially for less severe cases and for patients who refuse to have a mechanical device implanted.

MEN WHO LEAK – ARTIFICIAL SPHINCTER

Flavio Trigo-Rocha

INTRODUCTION

Post radical Prostatectomy Urinary Incontinence (PRPUI) represents a serious late complication of radical prostatectomy. It compromises significantly quality of life even when compared to impotence1. Although PRPUI is very common in the first months after surgery the majority of the patients will recover their urinary control during the first twelve months after surgery2. After one year three to eight percent of the patients submitted to radical prostatectomy will remain with significant urinary incontinence3 and 6% will need surgical treatment4.

As the sphincter deficiency isolated or in association with detrusor overactivity represent the cause of incontinence in the major part of the cases5 the treatment of sphincter deficiency will result in significant improvement in the vast majority of the cases6.

Some authors defined the artificial urinary sphincter (AUS) as the main treatment option for post prostatectomy incontinence7 and many papers have addressed the efficacy and safety of the AUS 800 sphincter for the treatment of PRPUI. However, the large series analyzing efficacy and safety of the artificial sphincter include patients suffering from incontinence secondary other conditions like congenital abnormalities or trauma. Some other series included patients suffering of incontinence after trans urethral resection of the prostate, post radiation therapy and many published series included previous models of the artificial sphincter AMS 8009.

Few papers in the literature evaluated prospectively the safety and efficacy of the current version of the artificial urinary sphincter the AMS 800Æ exclusively for patients suffering from post radical prostatectomy urinary incontinence (PRPUI). A prospective study addressing just this particular population may be helpful in advising patients about the results, advantages and complications in this specific group of patients.

CASUISTIC AND METHODS:

From May 1997 to April 2003, we conducted a prospective study evaluating the efficacy and safety of the AMS 800Æ device in 40 consecutive patients with severe PRPUI due to sphincter deficiency treated at Sao Paulo University. The patients' age ranged from 53 a 83 years (m = 68,3 ± 6,33 years). The time between radical prostatectomy and AMS sphincter implantation varied from 12 a 108 months (m = 32,05 20,41). The inclusion criteria were: time from prostatectomy longer than one year, good cognitive function, patients wearing three or more pads per day, sphincter deficiency demonstrated in the urodynamic evaluation and significant impact of the incontinence in the patient's quality of life.

Preoperative evaluation included personal perception of incontinence, pads count, urodynamic evaluation with Valsalva Leak Point Pressure (VLPP) and the use of a visual analogue scale to determine the impact of the incontinence in quality of life. The parameters observed were: personal perception of incontinence, number of pads used/day and quality of life score. These parameters were obtained in the follow up and compared to baseline measurements using the "t of student test". Statistical significance was defined by a p value lower than 0,05.

Clinical and surgical complications were assessed. Patient's satisfaction with the procedure was estimated. Preoperative urodynamic parameters were correlated with the surgical outcome.

RESULTS:

Urodynamic evaluation confirmed sphincter deficiency as the etiology of the incontinence in all the surgical candidates. Four patients with leakage due to isolated bladder overactivity were excluded. Table 1 summarizes the data of urodynamic evaluation.

TABLE 1:DATA FROM URODYNAMIC EVALUATION

Parameter	Finding	No	%
Bladder compliance	Low	8	20,0
Normal	32	80,0	
Detrusor overactivity	No	30	75,0
Yes	10	25,0	
Detrusor hypocontractility	No	36	90,0
Yes	4	10,0	
Bladder outlet obstruction	No	34	85,0
Yes	6	5,0	

The follow-up ranged from 27 to 132 months (mean = 53,4 ± 21,49 months). Sphincter activation was done after 6 weeks in all patients but the one who have the prosthesis removed due to infection and erosion. At the last follow up 36 patients (90%) reported a significant reduction in their incontinence degree. Twenty patients (50%) described themselves as completely dry 16 (40%) reported mild incontinence and three moderated, incontinence.

When we evaluated quality of life all of the 36 patients who became continents defined their quality of life as good or excellent. In the visual analogue scale the final evaluation ranged from 1 to 5 points, mean= 1,4 ± 0,93 ($p < 0,001$).

Complication represented by erosion occurred in three patients (7,5%), mechanical failure in two (5%) and urethral atrophy in two (5%). There was also one case of no improvement after the surgery due to incorrect choice of the cuff during the surgery. These adverse events led to surgical revisions in seven patients, in six of them (15%) related to problems in the sphincter or in the urethra and in one to improve bladder compliance. Conversely 90% of the patients were satisfied with the treatment and the satisfaction was not influenced by the necessity of reoperations. When objectively asked 95% would accept the sphincter implantation again if they were incontinent. Table 2 compare our continence rates and table 3 compares our complication rates with literature

TABLE 2:CONTINENCE RATES AFTER ARTIFICIAL SPHINCTER IMPLANTATION IN PATIENTS WITH PRPUI

Author	Number	Follow-up (years)	Continence rate (%)
*Montague et al., 2001	166	3,2	75,0
*Perez; Webster, 1992	49	3,7	85,0
*Martins; Boyd, 1995	28	2,0	85,0
*Fleshner; Herschorn, 1996	30	3,0	87,0
*Mottet et al., 1998	96	1,0	86,0
Trigo-Rocha, 2005	40	2,5	90,0
*Marks; Light, 1989	37	3,0	94,5
*Light; Reynolds, 1992	126	2,3	96,7

TABLE 3: COMPARISON OF OUR COMPLICATION RATES TO OTHER SERIES IN THE LITERATURE *

Series	year	Number	Infection(%)	Erosion(%)	Mechanical failure(%)
Elliot e Barrett	1998	160	1,8	1,0	9
Litwiller	1996	65	6,0	3,1	NR
Singh e Thomas	1996	28	10,0	0,0	NR
Gundian	1989	117	2,5	7,0	16
Marks e Light	1989	16	5,4	8,1	NR
Trigo-Rocha	2005	40	2,5	5,0	5

* Adapted from Petrou, 200010.

MEN WHO LEAK – ARTIFICIAL SPHINCTER (CONT.)

As described by other authors the necessity of surgical revision did not decrease the satisfaction with the treatment 11.

More recently we have used the transcorporal approach in reoperations due to urethral erosion. This consists in placing the cuff 3 centimeters distally to its original site. As the urethral diameter is smaller and the dissection of urethra is harder in this point we place the cuff around the urethra and though the cavernous corpora. This may avoid urethral ischemia and may prevent new erosions. Some authors have reported good results in more than 80% of the patients treated with this approach12.

CONCLUSIONS:

Although the AMS 800 has a significant cost it represents a good and safe alternative for PRPUI with acceptable levels of complications. Other alternatives like bulking agents, sling procedures 13,14 and periurethral balloons (ProACT TM)15,16 may represent alternatives to AMS sphincter in selected cases.

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DEBATE – PHYSICAL THERAPY IN STRESS URINARY INCONTINENCE – FOR

Bary Berghmans

In women with stress urinary incontinence (SUI) the aim of the physiotherapeutic diagnostic process is to assess, analyse and evaluate the – often unclear - nature and severity of the healthproblem SUI and to determine if and to what extent a physiotherapeutical intervention can be effective. What is the nature of the underlying pathology, are there any local or general obstructing factors for recovery and improvement, and to what extent can these factors be influenced by physiotherapy?

Using the International Classification of Functioning, Disability And Health (ICF) (WHO 2002), the physical therapist tries to influence the consequences of this health problem on 3 different levels: organ level (impairment level, e.g., urine loss while coughing)), persons level (disability level, e.g., sanitation) and social-societal level (restriction of participation, e.g., social isolation).

Pelvic floor muscle dysfunction related to SUI often involves failure of external supporting mechanisms. Poor functioning of pelvic floor muscles may be due to weak pelvic floor muscles resulting from inactivity or misuse, to lesions in local nerve fibers supplying the pelvic floor, to lesions in the endopelvic fascia, which may be due to traumatic partus, or to a combination of these factors. The objective of physiotherapy i.c., pelvic floor muscle training (PFMT) in this group of patients is to improve the pelvic floor muscles' ability to provide external support. In addition, there may be some compensation of possible internal urethral closing mechanism dysfunction. Concurrent dysfunction of the internal urethral closing mechanism can influence prognosis and effect of physiotherapy.

PFMT has proven to be effective in women with SUI and is graded A, level 1 by the International Consultation of Incontinence (Wilson et al. 2005). Nowadays there are more than 50 RCTs reporting good short and long term effects (Wilson et al. 2005).
Motivated, compliant patients with SUI, due to weak pelvic floor muscles and/or hypermoblity of the urethra might have best prognosis.

When there is pelvic floor muscle dysfunction without awareness of pelvic floor muscles (i.e., in terms of their contraction and relaxation), electrostimulation, biofeedback, digital assessment by the patient or physical therapist, or some combination of these techniques may be indicated. After awareness has been successfully restored using these interventions, PFMT alone is possible. First, isolated contractions of the pelvic floor muscles are practiced, followed by contractions during the performance of normal daily activities, initially with awareness. Activities are then increased in complexity from single to multiple tasks so that, ultimately, automatic functional use of the pelvic floor during normal daily activities and sports can be achieved (Berghmans et al. 1998).

When there is SUI without any pelvic floor muscle dysfunction, internal urethral closing mechanism dysfunction is clearly the cause. It is unlikely that physiotherapy can influence internal urethral closing mechanism dysfunction. Only compensation is possible.

The effect of pelvic floor muscle training is strongly dependent on neuromuscular tracts being intact. It is important that there are no serious defects in interconnections between different components of the pelvic floor. A serious defect caused, for example, by a traumatic lesion in the endopelvic fascia could interfere with normal functional recovery.

IN CONCLUSION: Based on relevant medical and physiotherapeutic diagnostics, physical therapy is effective, also long term. Therefore, physical therapy should be considered as first line treatment for SUI.

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DEBATE – PHYSICAL THERAPY IN STRESS URINARY INCONTINENCE – AGAINST

Marcos Tcherniakovsky

The approach of stress urinary incontinence (SUI), even today, presents difficulties regarding its diagnosis and therapeutic conduct, since besides the new propaedeutic modalities and distinct surgical techniques described, failure rates reach between 10% to 20%, during the five years following the surgery, no matter the kind of procedure and/or the surgeon's ability. Success in stress urinary incontinence (SUI) depends on the accurate diagnostic, aiming to correct the dysfunction or alteration that causes urine loss. Patient's clinical history and complete physical exam are fundamental for the evaluation of these cases, having the POP-Q (1996) as a parameter.

Besides these aspects, it is known that patient's treatment depends on various factors: the quality of colagens present in tissues that envelop the inferior urinary tract, sedentary habits, the age, and the use of hormonal therapy. Patients with a favorable clinical history: young in age, normal BMI, absence of previous vaginal surgeries or UI correction and altered urodynamic patterns, however not in an intense form, have greater chances of success for clinical treatment. For the treatment of UI by physiotherapy, it is indispensable the follow-up of a multidisciplinary team – physicians, nurses, physiotherapists and psychologists – what becomes a barrier for the adequate treatment of the patient, since there are few specialized medical centers for this purpose. Another important aspect is the lack of full knowledge, from the physicians that actuate in this specialty, in relation to the UI treatment by physiotherapy, in comparison with the surgical treatment, a situation in which the same ones feel more at ease to indicate and to obtain a more immediate satisfactory outcome. Should the physiotherapy be indicated, a greater effort from the patients will be necessary for the adhesion to the treatment, therefore with the enlightenment of patients, since the period of treatment is prolonged, with repeated sessions and greater abandon chance.

If we compare the evolution of physiotherapy treatment for urinary loss, started with Arnold Kegel in 1948, until the present moment, we conclude that the advance in the arsenal of physiotherapeutic procedures has grown very little, in comparison to the surgical treatment, where the therapeutic success reaches, today, about 90%, depending on the technique. Another important detail is that, in cases of SUI caused by sphincterian deficiency, physiotherapy treatment does not present good results, and would not be indicated.

Although the medical literature reports several studies about the physiotherapy conservative treatment in relation to SUI, few of them are meta-analysis controlled and randomized, until the present moment. Likewise, until this date, there are scarce comparative works randomized in relation to other non-invasive techniques (medicamental clinic treatment) and invasive ones (colposuspension and slings). Literature concludes that, after a judicious evaluation of the studies methodologically correct, there is no possibility to judge the real efficacy and benefits of physiotherapy techniques for the treatment of SUI, due to the heterogeneity of the methods employed for the studies.

It is necessary to carry out a greater quantity of randomized studies, controlled, and with a wider amplitude, and also with a major quality and reliability, in order to avoid surgical interventions in patients.

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WHAT DULOXETINE CAN OFFER IN THE TREATMENT OF SUI

Linda Cardozo

Stress urinary incontinence (SUI) is the complaint of involuntary leakage upon effort or exertion, or upon sneezing or coughing.(1) It is common among women of all ages and can have a negative impact on quality of life (QoL).(2) To date, SUI has been treated conservatively by means of pelvic floor muscle training (PFMT) and lifestyle interventions such as weight loss, regulating fluid intake and smoking cessation.(3)

Until recently, the pharmacological treatment options for stress urinary incontinence (SUI) have been limited to the off-the label use of several medications including oestrogens, ß-adrenergic receptor agonists, ?-adrenergic receptor antagonists, tricyclic antidepressants and anticholinergics. However, these medications have questionable efficacy and are associated with adverse effects.(4) Duloxetine is a potent and relatively balanced serotonin and noradrenaline reuptake inhibitor (SNRI) and is the first drug to be licensed for use in the treatment of SUI.

Its efficacy relative to placebo in the treatment of moderate to severe SUI has consistently been demonstrated in various phase 2 and phase 3 controlled studies.(5-8) Duloxetine has been shown to be significantly more effective then placebo in reducing incontinence episode frequency (IEF) and improving QoL score. It was equally effective in women with and without intrinsic sphincter deficiency. All duloxetine responses were observed within 2 weeks. Importantly, 20% of the duloxetine-treated women indicated that they were no longer interested in SUI surgery.

Although PFMT remains the first line therapy for SUI, its efficacy depends on motivation and compliance. Unfortunately, the latter is often poor in the long term with few women continuing with PFMT.(9) The combination of PFMT and duloxetine might be helpful as the former can strengthen and support the pelvic floor, while the latter can improve sphincter function. PFMT and/or SNRI are now recommended as a first line therapy for the initial management of SUI in women in the guidelines of the third international consultation on incontinence (ICI).(10) SNRI use has received a grade A recommendation. A recent study comparing the effect of combined treatment with no active treatment found that combination therapy was significantly better for all outcomes, including frequency of SUI episodes, pad use, improvements in QoL and global impression of improvement scores. (11)The data suggest that combination therapy might provide another treatment option for SUI symptoms in women.

As with almost any other treatment, the benefits of duloxetine in the treatment of SUI can be accompanied by adverse effects. Nausea is the commonest side effect and occurs in around 23% of women.(5-8) However, nausea tends to be of mild to moderate intensity and resolves within 1 month in the majority of women. Other frequently reported adverse events comprise dry mouth, fatigue, insomnia, constipation, headache and dizziness occurring in 9-13% of women. These adverse events are consistent with duloxetine's receptor physiology and are typical for 5-HT reuptake inhibition.(12,13) The most common adverse event-related treatment discontinuations were due to nausea, dizziness, fatigue and insomnia(1-6% of women).(5-8) The fact that most women affected by nausea continued the study indicates that nausea is not perceived as a serious adverse event by most women. In addition, counselling about potential transient nausea may improve treatment compliance. A dose-escalation study showed that some women may benefit from starting treatment at a dose of 20mg twice daily for 2 weeks before increasing to the recommended dose of 40mg twice daily.(14) Dose escalation may decrease, although not eliminate, the risk of nausea and dizziness.

In conclusion, duloxetine is an effective treatment for a wide variety of women presenting with moderate to severe SUI symptoms. In addition if compliance with PFMT can be improved by the addition of duloxetine, then this combination might improve the outcome of conservative measures for SUI.

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MY TAPE IS THE BEST FOR SUI – TVT/TVTO (GYNECARE)

Telma Guarisi

The aim was creating an artificial neoligament to elevate the urethra and restore the urethral-vesical angle, through the retropubic space. The initial results suggested the procedure was safe once there were few minor complications such as retention of urine, and few major complications such as hematoma and bladder perforation.

Based on the "Integral Theory" of Incontinence and aimed at creating a neoligament, the technique uses a prolene mesh sling, nonabsorbable, placed without tension at the mid-third of the urethra, and can be performed under local anesthesia. Major complications are due to lesions of neurovascular structures leading to hematoma or perforation of structures such as bladder and bowels.
The first publication by Ulmsten of a 3 year follow-up included 50 patients evaluated with a 24 hour pad-test, quality of life questionnaire and urodynamic test showed 86% were cured and 12% improved. 90% of the patients urinated spontaneously at the same day. Patients did not report complications such as bleeding, urinary retention and erosion.

A more recent series compiled 23 studies, reporting worldwide experiences, totaling 1392 patients, among which, 90% were cured, 5% improved and only 7% had minor complications. A prospective randomized series, comparing Burch and TVT, in a 3 year follow-up included 316 patients and showed similar cure rate (60%). It was observed in this study less than 30% of urinary dysfunction. The major risk factors were pre-operative abnormal voiding and prolapse.The lack of a clear view makes it comparable to all needle procedures requiring caution and safe surgical principles.

Recent data including more than 250.000 patients show extremely low complication rates. Questionnaires were used to evaluate the quality of life of 809 participants until 24 months post-operative, and it was observed an improvement of the quality of life of women treated of SUI by TVT. A new surgical instrument, the TVT-O, was developed in pursuit of an ideal surgical technique. TVT O enables the course of a synthetic sling from the lower portion of the urethra through the obturator foramen towards the thigh root, fixing it at the transition between the medial and distal portion of the urethra. The anatomical path is strictly perineal, keeing it at a certain distance of the obturator neurovascualr structures, femoral and saphena. Cystoscopy is not needed since it does not reach the pelvic region at any time of the procedure. The major complications comprise lesions of the obturator neurovascular blundle and the dorsal nerve of the clitoris.

The distance between the TVT O needle and the dorsal nerve of the clitoris is similar to the TVT (approximately 11mm) and is different in regard of the obturator canal. In a series of more than 500 patients treated by TVT-O, there were no injuries of the bladder or urethra, hematoma, heavy bleeding nor neurological complications. Medium-term results have suggested that TVT-O is as efficient as retropubic tension-free slings for treatment of female SUI, with about 90% complete cure rates after one-year follow up Twenty-one patients from the TOT group and 12 from the TVT group had ultrasonographic evaluation, and there were no significant difference in the tape position between TOT and TVT. No correlation was found between ultrasonographic findings and postoperative voiding troubles for both techniques After comparing patients who underwent TVT and TOT throught ultrasound, the conclusion was that the angle of TOT is more open. However, it remains sufficiently oblique and allows the tape to be put with light tension if needed in low-pressure urethra. In spite of larger urethrovaginal dissection in TOT, the tape does not migrate close to the bladder neck and remains at mid-urethra.

Both procedures (in-out e out-in) have been reported with a few complications. Anatomical dissections have shown that these two procedures can be very safe, but that the tip of the tunneller could injure the bladder, the urethra or the obturator pedicle. Surgeons have to respect the key points of the procedures. There is a need of long-term follow-up studies, including cohorts of patients to compare in-out e out-in techniques. The learning curves were comparable to TVT and TVT-O in-out. The safety and cost-effectiveness of the TVT are well-established. The TVT-Obturator was designed to overcome some of the TVT-related operative complications that seem to be occurring. Long-term comparative data collection is required prior to drawing solid conclusions concerning the two operative techniques.

MY TAPE IS THE BEST FOR SUI – SPARC/MONARCH (AMS)

Irineu Rubinstein

SPARC

In recent years, sub-urethral sling placement has become a standard treatment for stress urinary incontinence (SUI). Slings are used when hypermobility exists alone or in combination with intrinsic urethral sphincter deficiency respectively.

The SPARC system treats female stress urinary incontinence by placing a sling to support the urethra. This system uses a suprapubic approach in which narrow sling carriers are passed from above the pubic bone to the vagina. The sling mesh then is attached to the carriers and pulled into place. A self-fixating polypropylene sling cradles the urethra and gives it support during normal daily activities. Placement of the SPARC is a minimally invasive procedure that typically takes less than 30 minutes. Most patients are continent immediately following the procedure and can resume normal, non-strenuous activities within a few days.

MONARC

The Monarc subfascial hammock treats female stress urinary incontinence by placing a narrow strip of mesh to support the urethra. With the transobturator approach, narrow mesh carriers are passed through an area near the groin at the obturator of the pubic bone. The mesh is then attached and pulled into place under the urethra. Once placed, the hammock cradles the urethra and gives it a point of support. By avoiding the vessels and nerves of the retropubic space, the Monarc system offers a relatively quick procedure that proves to be safe and effective. The results show that the transobturator approach may be safer than the traditional retropubic approach to the tension free mid-urethral sling. Most patients are continent immediately following the procedure and can resume normal, non-strenuous activities within a few days.

MY TAPE IS THE BEST FOR SUI – REMEEX SYSTEM (NEOMEDIC)

Pedro Arañó

Over the last few years, sling techniques have turned to be the most widely used surgical treatment for correcting female urinary incontinence. The tension to be given to the sling at the time of placement has been a topic of debate from the very beginning - at that time they were tensioned until nowadays, when we place them in a tension-free fashion. However, the decision of placing the sling with or without tension is a result of previous data (type of incontinence, urethral mobility, local history...) depending upon the surgeon's objective assessment and lacking support from medical evidences.

Also, the tension given to the sling is decided at the time of surgery, with the patient on the operating table, immobile and in decubitus. For these reasons, an easy-to-use adjustable system, with the patient standing, walking and under stress, provides the tension that particular patient really needs in order to be continent without obstruction, without being taken for granted and in the course of her routine physical activity. The adjustability system will be even more desirable if it allows for long-term regulation (months, years).

The Remeex system satisfies all of these requirements. Its indication received FDA approval in 2004, and currently there are 4,700 systems implanted all over the world (35% of this figure in Spain). We are presenting Fundació Puigvert (Barcelona)'s experience in 105 women operated using this system.

PROSPECTIVE EVALUATION OF 105 WOMEN:

- Indications: Recurrent urinary incontinence with hypermobile urethra (40%).
  Incontinence due to intrinsic sphincter deficiency (60%).
- Mean follow-up: 24 months.
- Sphincter insufficiency repair: 88%.
- Pending from adjustment: 12 %.
- Detrusor overactivity: 15% (8,5 % de novo).
- Short-term postoperative adjustment: 52 %
- Long-term adjustment: 15% (mean at 9 months).
- System withdrawal: 1 patient.
- Satisfied patients according to questionnaire (King's Health): 84%
- Patients on anticolinergics: > 15%
- No patient on intermittent catheterisation.

CONSIDERATIONS ON THE CAPACITY OF ADJUSTABILITY BY MEANS OF THE REMEEX SYSTEM, BASED ON OUR OWN EXPERIENCE:

- A sphincter insufficiency can be corrected by adjustability, i.e. increasing sling tension.
- A bladder outlet obstruction can be corrected by adjustability (surgical hypercorrection), i.e. decreasing sling tension.
- Detrusor overactivity (not secondary to bladder outlet obstruction) cannot be corrected by adjustability, but it is indeed possible to increase the detrusor leak point pressure.
- We have no data on whether adjustability enables to improve results in type II urinary incontinence.
- By means of adjustability we succeed in improving results in type III urinary incontinence.
- By means of adjustability we succeed in correcting the sphincter insufficiency component in cases of urodynamically mixed incontinence, but not the detrusor overactivity component.
- By means of adjustability we succeed in correcting urinary incontinence due to recurrent sphincter insufficiency several months following the previous surgery.
- By means of adjustability, and by adjusting the sling tension "to the minimum level of continence", we succeed in reducing postoperative voiding alterations.

MY TAPE IS THE BEST FOR SUI – SAFYRE (PROMEDON)

Cassio Riccetto

The use of synthetic slings transform major surgeries into minimally invasive procedures and also reduces operative time and hospital stay as well as postoperative discomfort and the recovery period. The readjustable and self-anchoring SAFYRETM sling has recently been added to the existing therapeutic arsenal. It is a tension-free, synthetic sling, placed at the mid urethra that makes urethral erosion unlikely. Should postoperative urinary leakage or retention occurs, this innovative device allows for tension readjustment. SAFYRETM consists of a polypropylene mesh that acts as a urethral support, held between two self-anchoring tails made of polydimethylsiloxane polymer. These tails are the basis of the readjust able self-anchoring system. In order to minimize the surgical damage to pelvic floor natural support structures, a special 3.5 mm in diameter needle, allows for both suprapubic and transvaginal approaches,according to the surgeon best skills. The versatile needle is assembled for transvaginal approach when the hooked extremity is introduced inside the needle holder, and for supra pubic approach when assembled the other way. Recently, a specially designed spiral needle is introduced, allowing for transobturator technique, fitting the device to all surgical approaches.

As opposed to TVT? or other polypropylene minimally invasive slings, the smooth surface of SAFYRETM mesh allows for easy primary adjustment during the implant and even during eventual readjustment, besides keeping its resistance and shape due to its low deformity rate. Moreover, the elasticity of polymetylsyloxane tails can provide fine movements according to the changes of patient's abdominal pressure, acting as a dynamic support. Furthermore SAFYRETM self-anchoring system is unique as far as postoperative readjustibility is concerned, as showed in experimental studies.

Its readjustability allows for late adjustments of sling tension in patients presenting persistent incontinence or urinary retention, avoiding major surgeries such as urethrolysis or the need for another sling insertion, reducing costs.

Following the new trends and in order to compare the transvaginal and transobturator approaches, a total of 226 patients with clinical and urodynamic diagnosis of SUI underwent SAFYRE sling procedure, which was performed either by transvaginal (group 1; 126 patients) or transobturator approach (group 2; 100 patients). The mean age was 63 years, in group 1 and 61 years in group 2. Physical examination, stress and pad test and urodynamic assessment were performed before the surgery. The average follow-up period was 18 months in group 1 and 14 months in group 2. There was no difference in cure rate in both groups. Bladder injury was significative greater in transvaginal group [respectively, 12/126 (0%) versus 0/100 (0%)]. Postoperatively, 20.6% of the patients presented transient irritative voiding symptoms in group transvaginal group as opposed to 10% in transobturator group. This results showed that SAFYRE sling performed by transobturator approach is as effective as the transvaginal procedure. Fewer complications and less operative time were additional advantages of the transobturator approach.

The coherence of the physiological principles involved in female urinary incontinence, cure rate over 90% and the uncontestable benefits of postoperative tension readjustments make this procedure a promising step forward in the surgical management of SUI.

DEBATE – VAGINAL PROLAPSE – TO MESH

Walter Artibani

The lifetime risk of surgery for prolapse or stress urinary incontinence was 11%, with 29% of the patients experiencing surgical failure and requiring repeated surgical procedure (1). This issue can support the use of mesh graft, with the aim to reduce the number of patients who will need further surgery for recurrent prolapse

ANTERIOR VAGINAL WALL PROLAPSE SURGERY

In 1996, Julian and colleagues published an interesting RCT in which the use of Marlex mesh was assessed in a cohort of 24 patients with recurrent anterior vaginal wall. The authors demonstrated significantly better outcome in patients where mesh grafts were used (recurrence rate 0% Vs. 34%), but mesh erosion occurred in 25% of the patients, needing surgical excision (level 2 of evidence) (2). In 2001, Sand et al. analyzed 143 women with cystoceles, comparing anterior endopelvic fascia plication with and without using a folded vicryl mesh. The authors reported significantly higher objective success rates in cystocele repair with the use of the mesh (75% Vs. 57%, p=0.02), without any mesh-related complication (level 1b of evidence) (3). In the same year, Weber et al. compared classical anterior repair, ultralateral repair (with a larger lateral dissection towards pubic rami), and the use of a vicryl mesh. At a mean follow-up of 24 months, the three techniques yielded statistically overlapping cure and complication rates (level 1b of evidence) (4). A nice RCT was recently published by Gandhi et al., assessing the efficacy of a patch of cadaveric fascia lata in an adequately-powered cohort of patients with recurrent anterior vaginal wall prolapse. At a median follow-up of 13 months, the authors showed similar rates of prolapse recurrence (21% in the patch group and 29% in the control group, p=0.229), failing to show any statistically significant benefit for biological graft in anterior vaginal repair (level 1b of evidence) (5). However, the short follow-up time and the lack of reliable data regarding reoperation and complication rates limited the quality of the evidence. A few large retrospective surgical series, in fact, reported very high cure rates (75-100%) associated with variable incidence of infections, erosion, fistula formation, and other mesh related complications (0-16%) (level 3 of evidence) (6-9).

APICAL VAGINAL PROLAPSE

Several materials have been used, either homologous (cadaveric fascia lata, rectus sheath), autologous (dura mater, fascia lata) or synthetic (Prolene, Mersilene, Marlex, Teflon, Gore Tex). A landmark RCT was recently published by Culligan et al., who compared cadaveric fascia lata and polypropylene mesh in a cohort of 100 patients undergoing abdominal colposacropexy. At a median follow-up of 12 months, the authors demonstrated higher success rate in the mesh arm (91% Vs. 68%, p=0.007), defining objective anatomic failure as a POP-Q stage of 2 or greater at any postoperative interval (level 1b of evidence) (10). Data on mesh-related complications were not provided in the report, but a large review on abdominal colposacropexy reported only 70 cases of mesh erosion out of 2,178 procedures (3.4%). In the that review, specifically, cadaveric fascia and Prolene mesh were followed by very low rates of erosion (0 and 0.5%, respectively), while Mersilene (3%), Gore-Tex (3.4%), Marlex (5%), and Teflon (5.5%) performed less well (level 2 of evidence) (11). Those figures might support the use of polypropylen mesh graft in this setting. However, data at longer follow-up and the ongoing analyses on secondary end-points such as quality of life from Culligan's trials could further reinforce those statements.

POSTERIOR VAGINAL WALL PROLAPSE

At the 28th International Urogynecology Meeting, Gandhi et al. reported preliminary data at a 12-month follow-up of a randomized trial comparing colporrhaphy alone Vs. colporrhaphy with fascia lata graft, showing similar success rates (76% the graft group Vs. 89% in control group, p=0.54)(level 2 of evidence) (12). Sand et al., in an RCT analyzing the use of mesh in anterior colporrhaphy, performed accessory posterior colporrhaphy with and without mesh in 67 and 65 patients, respectively. Although the rectocele recurrence rate was not the primary end-point of the study, the authors reported overlapping objective failure rates in both arms (10% Vs. 9%) (level 2 of evidence) (3).

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DEBATE – VAGINAL PROLAPSE – TO MESH

Paulo Palma

Introduction: Anterior vaginal wall prolapse is a frequent condition affecting 11% of American women. The incidence of cystocele doubles each decade of life. There are 2.9 million of women with grade III and IV cystocele in USA. Because of anterior vaginal prolapses recurrence rate is 30% in the first year, new approaches were developed to repair these defects. New bio-materials and the introduction of the transobturator approach were the driven force behind the new procedures and devices.

THERE ARE TWO BASIC APPROACHES TO MESH VAGINAL WALL DEFECTS:

- Site specific- correction associate with mesh
- Mesh without site-specific correction

AS FAR AS THE MESH DESIGN, THERE ARE TWO DIFFERENT TYPES:

- Non anchoring mesh (Tension-free Cystocele repair or bulking)
- Self-anchoring meshes (Apogee, Nazca, Prolift, Swing, etc)

Because of the poor results obtained with non anchoring meshes, we will address only the self-anchoring meshes.

Selecting patients for mesh procedures: Because using mesh adds some risks, such as, mesh exposure, infection and dyspareunia, care should be taken in the proper selection of patients (Table 1).

Vaginal Erosion – Mesh for POP

Mesh	Patients (n)	Erosion N (%)	Occurrence Period of Erosion	Notes	References
Gynemesh (90 g/m²) and **Gynemesh Soft** (42.7 g/m²) Ethicon	138	27 (20%)	16(59%) : < 3 months 7(26%) : 3 - 6 months 3(11%): 6 - 12 months 1(4%): 12 - 21 months	• Gynemesh soft does not decrease the incidence of vaginal erosion of the mesh. • 75 % of the erosion were asymptomatic.	X Deffieux et al "Vaginal Mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 Women: a compa- rative study ", International Urogynecology Journal 2005.
Prolift (or Gynemesh Soft) Ethicon	687	46 (6.7%)	There is no data, they report only that the mean Follow up is 3.6 months	•Granuloma formations and vaginal erosion were subsequently decreased thanks to technical improvements, consisting in short incision of vagina and avoiding simultaneous hysterectomy.	Cosson M et al " Prolift (Mesh (Gynecare)) for pelvic organ prolapse Surgical Treatment using the TVM group technique: A retrospective study of 687 patiens" (abstract 121) ICS Ago 29th to Sept 2th, Montreal, 2005
Apogee AMS	55	8 (15%)	8 (100%): 0.5 - 8.2 months	6(11%): Exposure of the mesh without granulation tissue. 2(4%): Granulation tissue reaction to the mesh.	Davila G.W et al " Restoration of Vaginal apical and posterior wall support with the apogee system"(abstract). Int Urogynecol J 2005 ; 16 (Suppl 2) :S118

For the anterior compartment, there are some accepted indications such as:
1 Positive prolapses (POP-Q)
2 Obesity
3 Chronic pulmonary diseases
3 Poor tissue qualities (Eller –Danlos)
5 Recurrent prolapses

Mesh Types: For there are different types of meshes, with different properties, one should be aware of the mesh features in order to make a proper choice (table 2)

COMPARISION BETWEEN GYNEMESH AND NAZCA MESH

	Gynemesh PS/ Prolift	Nazca	TCRemarks
Density	42.7 g/m2	85g/m2 in arms 60g/m2 in central part	(1)
Pore Size	1.5 - 2 mm	0,5 – 1mm + 16 holes of 6mm diameter	(2)
Mesh Thickness	0.42mm	0.47mm	(3)
Monofilament PP Diameter.	0.10mm	0.14mm	(1)
Net Break resistance	7.58 Kg/cm2	11Kg/cm2	(4)

(1) a) **High density of the mesh in the arms section + Adequate diameter of the filaments (0.14 mm) of polypropylene:**

b) **Intermediate density in the central zone:** it avoids the shrinkage of the mesh. The 16 holes of 6 mm in center of the mesh make diminish the density of the mesh from 85 to 60,5 g/m2. In the meshes of low density there is a high risk of shrinkage.

(2) **Macropore:** 500 - 1000 microns, this assures a good integration between tissues and the mesh.

16 holes of 6 mm: Amongst its holes or perforations grows the interconnective tissue between the vaginal flap and the bladder, which leads to a great integration of the implant without a loss of vascularization between the bladder and the vagina. As a matter of fact, since there is normal vascularization in the area of the implant integration, the risk of necrosis and postoperative erosion and mesh shrinkage diminishes. Additionally, the holes make the mesh softer and more flexible, which is particularly favorable because it reduces the effect of possible mesh folds that may form during implantation. Also it diminishes the risks of dyspareunia due to the folding and high fibrosis of the mesh.

(3) **Thickness of the mesh:** Adequate to avoid shrinkage. The low thickness of the mesh favors the shrinkage.

(4) The weft of the mesh has a high net break resistance that gives security during implantation.

Obturator Anatomical Background: The inner face of the obturator foramen is divided horizontally by the arcus tendinous fascia pelvis in two parts. The superior part of this foramen is pelvic and contains the obturator canal located superolaterally. The inferior part of the obturator foramen is perineal, that is below the white line, At this level, where the needles should be introduced, there are only potential structures at risk of perforation is the urethra (fig1).

OBTURATOR MANAGEMENT OF CYSTOCELES

Combined Obturator-prepubic approach is a new procedure for the concomitant repair of SUI and anterior vaginal wall prolapse, specially for high grade or recurrent cystoceles. The prosthesis which consists of a mesh made of polypropylene in which the central body has especial features, so that the superior part is designed to be place suburethrally at the mid urethra, two lateral triangular shape parts in order to support the bladder laterally (correction of lateral defects) and base of the mesh to be placed underneath the bladder base, for correction of the central defect (Fig 2)

DEBATE – VAGINAL PROLAPSE – TO MESH (CONT.)

Surgical Technique:

The patient is placed in the lithotomy position, an Allis forceps is applied at the level of the mid urethra and another to the lower most part of the cystocele.

A midline incision is made between the two Allis forceps. The dissection should be done laterally to the medial edge of the ischio-pubic ramus The superior needles are inserted transvaginally in a pre-pubic manner, towards the previously made marks on each side.

The arms of the graft are connected to the tip of the needles and pulled the length until the Armpits take the superior part of the body of the mesh to the mid urethra with no tension.

Next, the inferior needles are inserted parallel to the ascending ramus of the pubic bone, and turning the wrist and guided by the surgeon index finger, exit through the vaginal incision.

After connectors fixation the inferior tapes are pulled through until the lateral edge of the cystocele. Vaginal incision is closed using overlap technique to avoid contact of the suture line with the mesh. A Foley catheter and is let in place overnight. Tridimentional CT discloses the device (fig3).

The multicentric Nazca protocol involved 74 patients in four countries (Argentina, Brazil, Italy and Czech Republic). The demografics and results are showed below.

Pre-Surgical data

- Total Number of cases: 74
- Mean Age: 61,3 (41 to 81 years)
- Mean Vaginal Deliveries: 3,7 (1 to 9)
- Previous Surgeries: Histerectomy 16% Anterior Repair 30%
- Previous SUI: **42% (31 patients)** Mean ICIQ-SF: 10,2 (8 to 18)

Preliminary Report

- Median Prolapse degree (B-W):
  Anterior Wall >= III grade : 74 patients
  Posterior Wall >= II grade: 15 patients
  Apical >= II grade : 7 patients

Post-Surgical data

Mean Follow-up: 6 (1 to 12 months)

- Prolapse recurrence: 1 patient
- Post. Op. SUI: 6,7% (5 patients) Mean ICIQ-SF: 2,91 (0 to 13)
- Complications: Extrusion / Erosion : 3 Patients(4 %)
  Bladder outlet obstruction: 2 Patients(2,7%)
  Dysurria : 1 patient (1,4%)
  Vaginal Pain : 1 Patient (1,4 %)
  Dyspareunia : 2 Patients (2,7%)
  Developed enterocele : 1 Patient (1,4%)
  Developed Vault prolapse: 1 Patient (1,4%)

Data on project file I2005-008 March 2005

The good results obtained so far, make this combined approach a promising alternative in the management of anterior vaginal prolapse even in cases associated with stress urinary incontinence.

Mesh Impact On Sexuality: Meshes, specially in posterior compartment may led to dyspareunia. Besides, Cianci & Caruso, in Italy, reported reduced blood flow to dorsal artery of the clitoris after Retropubic slings with negative impact on sexuality (4), as disclosed in tables e and 4.

TABLE 3 . QUALITATIVE AND QUANTITATIVE ASPECTS OF SEXUALITY BY PEQ AFTER TRANSVAGINAL UROGYNECOLOGICAL PROSTHETIC SURGERY

Sexual Activity	Baseline	After Surgery	P
Desire	3.9 (0.5)	4 (1.3)	NS
Arousal	3.7 (0.5)	2.9 (1.2)	<0.01
Orgasm	3.8 (0.8)	2.8 (1.4)	<0.05
Enjoyment	4 (0.5)	3.5 (1.1)	<0.05
Frequency of intercourse	1.2 (0.5)	1.4 (1)	NS
Frequency of fantasies	2.3 (0.4)	2.1 (0.8)	NS
Dyspareunia	1.4 (0.8)	2.3 (1.1)	<0.05

P value determined by non-parametric Wilcoxon's rank sum test

Values are means ±SD. NS = No Significant

TABLE 4 TRANSLABIAL COLOR DOPPLER SONOGRAPHY OF CLITORAL BLOOD FLOW AFTER TRANSVAGINAL UROGYNECOLOGICAL PROSTHETIC SURGERY

	Baseline	After surgery	P
PSV cm/sec	11.8±0.3	6.2±0.7	<0.001
EDV cm/sec	2.7±0.3	0.7±0.2	<0.001
RI	0.8±0.1	0.9±0.1	<0.004
PI	1.9±0.2	1.51±0.3	<0.001

Note: RI = Resistance Index; PI = Pulsatility Index;
PVS = Peak Systolic Velocity; EDV = End Diastolic Velocity;
Values are means ±SD.

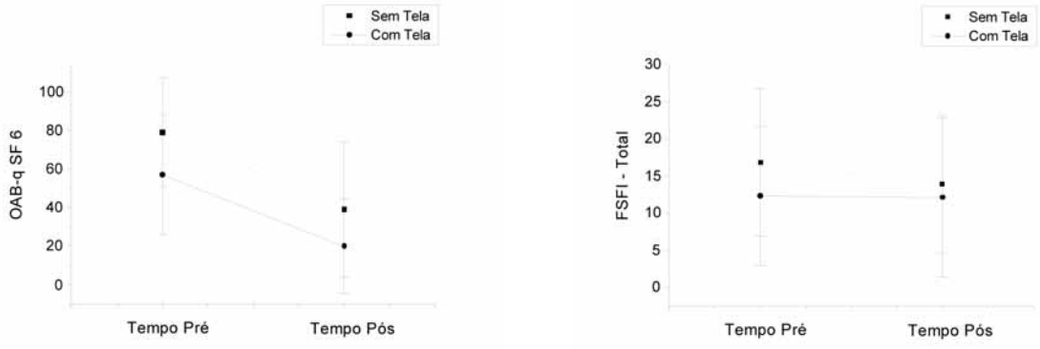
We compared the impact of pelvic floor reconstructive surgery for anterior vaginal prolapse with and without mesh.

A total of 31 women underwent colporraphy for grade III or higher vaginal wall prolapses. The surgical technique was anterior colporraphy with mesh in 54.17% of patients and without mesh in 16.7%; posterior colporraphy with mesh in 25% and without mesh in 4.17%. Mean follow up was 8.15 months (2 to 16) at the mesh group and 11 months (2 to 23) at the no mesh group. The mean age was 55, range from 39 to 75 years). Questionnaires were applied pre and post operatively to assess quality of life (QoL), lower urinary tract symptoms (LUTS-OABq-SF), and the female sexual function index (FSFI). Statistical analysis was performed using the ANOVA and Tukey's Post-hoc for p ≤0,05.

Results: Mean surgical time was 50 minutes at mesh group and 95 minutes at no mesh group (statistically difference). The improvement of stress urinary incontinence, stress test, prolapse degree and dyspareunia was similar in both groups. There was improving of pelvic pain in the group without mesh. The subjective analysis of patient improvement was: 60% cured, 20% ameliorate and 20% failed at the repair with mesh; 80% cured and 20 % failed at the repair without mesh. Mesh exposition occurred in 5 patients: 3 with the tension free technique, 1 with posterior colporraphy and 1 mesh using a combined pre- pubic and transobturator approaches.

Quality of life, LUTS and sexual function index improved in both groups, despite the technique used.

DEBATE – VAGINAL PROLAPSE – TO MESH (CONT.)



We concluded that surgical correction of vaginal wall prolapse improves QoL, LUTS and sexuality. The use of meshes do not adversely impact the results. This allow us to speculate that Cianci and Caruso's results may be related to the retropubic approach and not to the mesh.

Conclusion: There is reasonable evidence for the use of mesh in pelvic floor reconstructive surgery, specially for the anterior compartment and medium compartments, allowing for uterus sparing procedures in selected cases. Despite some controversies on the posterior compartment, properly selected patients may be good candidates as well.

FIGURES

Fig 1 The inferior part of the obturator foramen is perineal Where the needles should be introduced

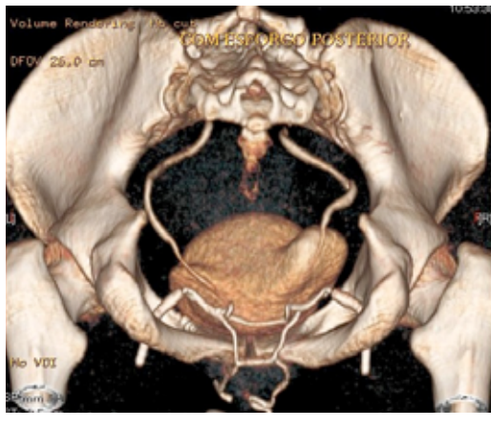


Fig Tridimentional Helical CT discloses the prepubic and obturator Anchoring tails and the body reinforcing the urogenital hiatus.

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DEBATE – VAGINAL PROLAPSE – NOT TO MESH

Telma Guarisi

The incidence of vaginal prolapse is variable, but can reach 20%, and frequently occurs after a hysterectomy. The cause is usually the weakness of the tissues that normally support it, and the symptoms depend on the type of prolapse. The type of surgery to correct it depends on the prolapse. The best surgery for restoration of the vaginal support should include low morbidity, and economic aspects. A single approach or procedure based on the surgeon's preference is not always optimal. Procedure selection should be individualized based on the patient's age, comorbidities, prior surgical history and level of physical and sexual activity The surgeon should be familiar with various methods of repair in order to provide appropriate individualized patient care. The safety of procedures should be balanced against the need for anatomic correction The transvaginal uterosacral ligament vaginal vault suspension is increasingly the procedure of choice for management of the apical defect due to its versatility, reduced postoperative morbidity and excellent short-term results.

Vaginal surgical approaches such as sacrospinous suspension, although shown in the past to have slightly less success than abdominal approaches such as sacrocolpopexy, continue to have good safety and efficacy profiles, and may be used in appropriately selected patients. Randomized clinical trials are still required to compare the differences between both techniques.

In a recent systematic literature review , abdominal sacrocolpopexy was found an effective procedure to correct vaginal vault prolapse. However, prospective trials are needed to understand the effect of sacrocolpopexy on functional outcomes. The association with culdoplasty can be helpful to prevent the persistence or development of an enterorectocele. There is no evidence of the use of grafts or collagen. It is a safe and simple technique, but the surgeon should be experienced and be able to solve intraoperative complications. The review of trials demonstrated that abdominal sacro colpopexy may be better than the vaginal sacrospinous colpopexy.

In another series of 1004 patients, this data could be confirmed, and there were lower rates of recurrent vault prolapse, with less dyspareunia. However, vaginal sacrospinous colpopexy was quicker and cheaper to perform and women had an earlier return to activities of daily living. The use of slings to complement corrections could lower recurrent cystoceles, but data on morbidity and other clinical outcomes was too little for reliable comparisons. Also, the meta-analyses to verify recurrent rectocele were insufficient. Patients with occult SUI could benefit from the use of tension-free vaginal tape. The risk of recurrent cystoceles could be lowered, but there should be trials to prove it.

Similarly, there should be more studies to evaluate laparoscopy techniques. Up to now, laparoscopic approach appears to be the least used, because of the great degree of technical difficulty associated with laparoscopic suturing. Although there is interest in the use of meshes to correct vaginal prolapses, randomized controlled trials are required to evaluate the role of surgical procedures in reconstructive surgery to determine which type of prosthesis is most suitable. Therefore, the use of slings as a minimally invasive surgery requires further evaluation before being used in routine clinical practice.

DEBATE – VAGINAL PROLAPSE – NOT TO MESH

Márcia Salvador Gèo

Until recently the goal of prolapse surgeries were the restoration of anatomy. Lately, the knowledge about the neurophysiology and anatomy of the pelvic floor, gave us another concept and a challenge. As postulated by the Integral Theory (Petros, 1990), the functions are intrinsic related with the form, and vagina elasticity and form, has an important hole on the function of the pelvic floor.

The debate about using mesh or not mesh, has it basis on the fact that woman with prolapse has poor tissues, an impaired healing process with her autologous tissue of bad quality or insufficient quantity. Those facts make the use of mesh, in theory, a good option. In the other hand, complications like infection, erosion, extrusion, dyspaureunia, that can occur with all kind of mesh available in the market, and the fact that we do not know yet how the meshes will behave in the vagina years after placement, can not be disregarded.

What to do when dealing with a pathology that is age-related, and reaching for less morbid procedures?

The main challenge of the pelvic surgeon when dealing with prolapse nowadays is to restore form, urinary, sexual and fecal functions with minimal adverse effects, as well as to analysis the results under the patient's perspective of improvement, and not only under the physician's perspective.

"In the era of evidence-based medicine, high-quality healthcare should imply a practice that is consistent with the best available evidence"
(Evidence– Based Medicine Working Group. JAMA 1992).

The highest grade of evidence is consider to be the meta-analysis of randomized clinic trials (level 1a) followed by an adequately sampled single randomized clinical trial (level 1b), and observational studies (level 2). Lower grade of evidence is provided by cases series (level 4). In the surgical treatments for genital prolapse, with or without mesh, has few controlled clinical studies comparing different techniques, which makes the long term success rates variable with lack of information on the criteria results, as well as function and patient satisfaction results.

There are recent reviews about surgery for prolapse in the anterior, middle and posterior compartments focusing results and complications.

We don't have enough evidence yet to offer a surgery using mesh as the first option for a patient with a health vagina elastic tissue. In patients with poor quality tissue - that have undergone multi-procedures with low elasticity of the vagina, especially in the anterior compartment, and making sure that the patient is aware of procedure's risks and benefits, and that a follow-up will be administered - we can use mesh. Nevertheless, the use of mesh is this case is based more in our clinical expertise and observation, than in good evidences because "without clinical expertise practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, practice risks becoming rapidly out of date, to detriment of patients. Evidence-Based Medicine builds or reinforces, but never replaces, clinical skills, clinical judgment and clinical experience, and it is not a "cook-book" medicine. Because integrates the best external evidence with clinical expertise and patient choice."(Evidence–Based Medicine; ; Richardson ;Rosenberg; Haynes)

HOW TO DEAL WITH MIXED INCONTINENCE

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Mixed urinary incontinence (MUI) is defined by the International Continence Society (ICS) as the complaint of involuntary leakage associated with urgency and also exertion, effort, sneezing or coughing. The initial management can be based on the symptoms presented but preferably will be adapted to the specific condition of the individual patient. This may necessitate a more extensive analysis of the problem including urodynamics.

As a general principle initial treatment will aim at the predominant symptom which can be either incontinence with urgency/frequency or incontinence on physical activity.

For either of these elements, conservative treatment is the mainstay with additional pharmacotherapy for the majority of individuals with MUI. In case of failure of this initial therapy, more specialized therapeutic modalities may be proposed. These will always have to be evaluated in view of the combination of symptoms and pathophysiological background.

For detrusor overactivity incontinence, additional modalities are intravesical instillations and injections as well as minimal invasive or more invasive surgical procedures. The urodynamic stress incontinence can be addressed by several surgical interventions such as injections, suspensions, slings or artificial urinary sphincter implant.

Based on the complexity of the problem, individual tapering of the therapy and the eventual combination of therapies must be considered.

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