

Educational Course



International
Continence
Society

ICS

Educational Course

Barcelona, Spain
November 11-12, 2005



ICS PARTNERS :



Medtronic

P R O G R A M M E



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Greetings

.....
Welcome to Barcelona and the first International Continence Society education course. 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, but this is the first time that the ICS has held a stand alone course outside of the annual meeting.

This non-profit making 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 who are keen to understand the important aspects of the ICS. The speakers are all internationally recognised in their field and have committed much time and effort to ICS activities over the years. It is hoped that those of you who are attending the course will be able to not only to listen to the lectures but also talk to the speakers and get to know us better.

At the end of the 2-day programme you should know something of the history of the ICS, its standards regarding good urodynamic practice, suggested evidence-based care pathways for the management of incontinence. In addition I hope that you will have a better understanding of which drug to prescribe for which patient with the common overactive bladder syndrome, and which of the many sub-urethral tapes is the most appropriate for patients with stress urinary incontinence. 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.

We have already made plans to hold courses outside Europe and next year we are going to run a course in South America in June, one in China in September and one in Abu Dhabi in December.

I hope that you will enjoy participating in this course and that it will encourage you to submit abstracts for and hopefully attend the forthcoming ICS annual meeting in future years

Linda Cardozo
Chair
ICS Education Committee

Sponsors & Exhibitors



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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.

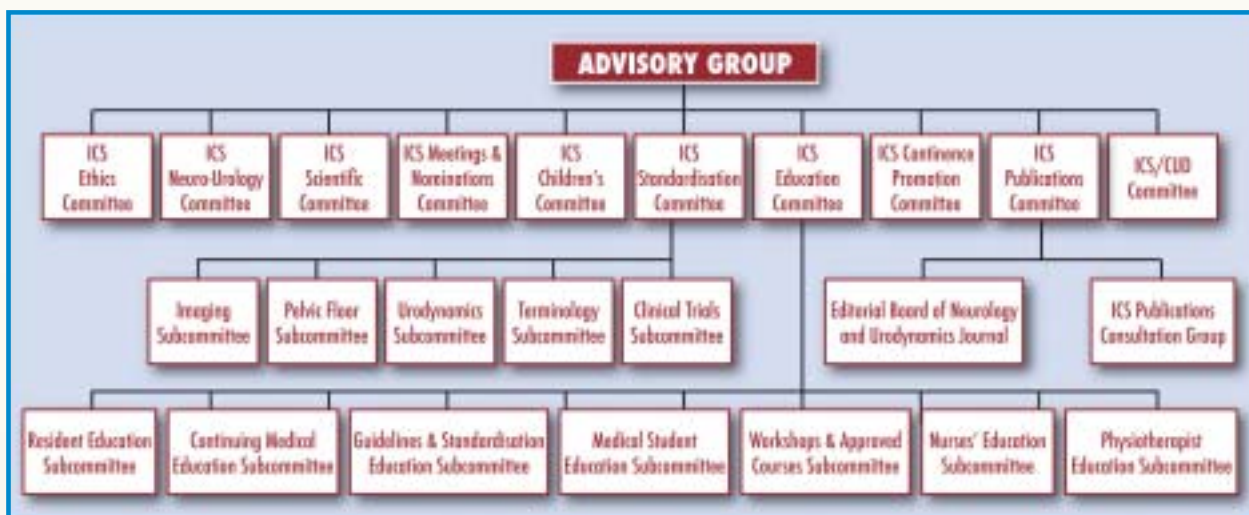
Our Annual Meeting is hosted by a different member each year, selected by members ballot four years in advance.

- 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
- Two bi-annual ICS newsletters
- Access to other members worldwide
- Information and education via our website, office, courses and meetings.

Today, the society employs three 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

Prof. Linda Cardozo (Chairperson)
 Prof. Walter Artibani
 Prof. Carlos Levi D'Ancona
 Dr. Roger Roman Dmochowski
 Dr. Michael Halaska
 Mr. Hashim Hashim

Dr. John P.F.A. Heesakkers
 Dr. Vikram Khullar
 Prof. Helmut Madersbacher
 Dr. Menahem Neuman
 Dr. Steven Peter Petrou
 Prof. Lavio Rogha

Dr. Peter K. Sand
 Dr. Ajay Singla
 Mrs. Marijke C. Ph.Slieker ten Hove
 Mrs. Amanda Wells
 Prof. Jean-Jacques Wyndaele

Meet the Speakers



Paul Abrams



Jens Thorup Anerson



Karl-Erik Andersson



Pedro Aranyo



Walter Artibani



Bary Berghmans



Kari Bo



Ruud Bosch



Linda Cardozo



Mike Craggs



Montserrat Espuna



Derek Griffiths



Meet the Speakers



Francois Haab



Vik Khullar



Helmut Madersbacher



Rien Nijman



Peter Sand



Werner Schaefer



Tony Smith



David Staskin



Adrian Wagg



Jean-Jacques Wyndaele



General Information

Course Venue

Hotel AC Barcelona
Passeig Taulat, 278
Barcelona 08019
Spain
Tel: +34 934 898200
Fax: +34 934 898201

Language

The official language of the course is English.
Translation to Spanish will be provided in all sessions.

Clothing

Casual for all occasions.

Registration and Hospitality Desk

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

Friday November 11, 2005 11:00 – 20:00

Saturday, November 12, 2005 07:30 – 16:00

Welcome Cocktail

Friday, November 11, 2005 at the end of sessions in the exhibition area.



ICS
BARCELONA 05

PROGRAMME



PROGRAMME



INTERNATIONAL CONTINENCE SOCIETY
ICS EDUCATIONAL COURSE

FRIDAY, NOVEMBER 11, 2005

Chairman: *Linda Cardozo*

- | | |
|-------|--|
| 12:30 | Buffet Lunch |
| 13:15 | Welcome & Introduction by Chairman
<i>Linda Cardozo</i> |
| 13:20 | The ICS past & present
<i>Walter Artibani</i> |
| 13:30 | ICS standardisation & terminology
<i>Paul Abrams</i> |
| 14:10 | Discussion:
<i>Peter Sand</i> |
| 14:30 | Good urodynamic practice
<i>Werner Schaefer</i> |
| 15:10 | Discussion:
<i>Derek Griffiths</i> |
| 15:30 | Coffee Break |
| 16:00 | ICI algorithms
Coordinator & Initial assessment
<i>Paul Abrams</i> |
| 16:15 | Women
<i>Linda Cardozo</i> |
| 16:30 | Men
<i>Francois Haab</i> |
| 16:45 | Children
<i>Rien Nijman</i> |
| 17:00 | Elderly
<i>Adrian Wagg</i> |
| 17:15 | Neurogenic
<i>Jean-Jacques Wyndaele</i> |
| 17:30 | Discussion |
| 18:00 | Close & Drinks |



SATURDAY, NOVEMBER 12, 2005

Chairman: *Walter Artibani*

- 08:30 Introduction
Walter Artibani
- My drug is best for OAB
Coordinator: *Karl-Erik Andersson*
- Pfizer (Tolterodine)
Tony Smith
- Janssen Cilag (Oxybutynin)
Peter Sand
- Astellas (Solifenacin)
Francois Haab
- Novartis (Darifenacin)
Paul Abrams
- Indevus (Trospium)
David Staskin
- Apogepha (Propiverine)
Helmut Madersbacher
- UCB Pharma (Transdermal Oxybutynin patch)
Adrian Wagg
- Placebo
Jens Thorup Anderson
- Discussion:
Jean-Jacques Wyndaele
Walter Artibani
- 10:00 Coffee Break
- 10:30 What the physiotherapist can offer?
Speaker: *Bary Berghmans*
Discussion: *Kari Bo*
- 11:00 My tape is best for SUI
Coordinator: *Linda Cardozo*
- Gynecare**
TVT: *Peter Sand*
TVT O: *Vik Khullar*
- AMS**
SPARC: *David Staskin*
MONARC: *Tony Smith*
- Mentor Porges**
T.O.T. (Obtape): *Francois Haab*
- Neomedic**
Remeex System: *Pedro Aranyo*
- Discussion:
Kari Bo
Montserrat Espuna
Walter Artibani
Ruud Bosch
Jens Thorup Anderson



INTERNATIONAL CONTINENCE SOCIETY
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- 12:00 Debate: Urodynamics should be carried out prior to all surgery for SUI
Chairman: *Walter Artibani*
- For:** *Paul Abrams*
Derek Griffiths
- Against:** *Peter Sand*
Werner Schaefer
- 13:00 Buffet Lunch
- Chairman:** *Jean-Jacques Wyndaele*
- 14:00 Clinical Problems - introduction
Jean Jacques Wyndaele
- 14:15 How to deal with mixed incontinence
Vik Khullar
- Discussion:
Adrian Wagg
Montserrat Espuna
- 14:30 What are the options for co-existent stress urinary incontinence and urogenital prolapse?
Tony Smith
- Discussion:
Peter Sand
Montserrat Espuna
- 15:00 Neurourology Update
- Neurostimulation
Mike Craggs
- Neuromodulation
Ruud Bosch
- Discussion:
Jean Jacques Wyndaele
- 16:00 Close of Meeting

ICS
BARCELONA 05



COURSE
MATERIAL



ICS STANDARDISATION AND TERMINOLOGY

Paul Abrams MD FRCS

Professor of Urology
Bristol Urological Institute
Southmead Hospital
Bristol BS10 5NB

The definitions used to describe lower urinary tract function and dysfunction, and the investigation methods, were collated by the International Continence Society (ICS) in 1988, Abrams et al (1988) and revised in 2002, Abrams et al (2002). In this abstract stress urinary incontinence is used as an example of the new definitions from 2002.

In a survey of 2000 women in the Bristol area, 60% had some leakage according to the 2002 definition "**Incontinence as any involuntary leakage of urine**" which is a definition suitable for epidemiological studies. Of the 60% who had some leakage, only a quarter had changed underwear, worn a protective pad or restricted social activities. Nevertheless this means that 15% of women over the age of 20 are bothered by their urinary incontinence - a huge number! This 15% would fit the previous ICS definition which included the phrase "**also causing a social or hygienic problem**" which encompasses the concept of leakage having an impact on quality of life.

Figure 1 illustrates the pattern of incontinence in women according to type. Stress urinary incontinence (SUI) is the commonest type of incontinence, occurring as either pure SUI or as mixed urinary incontinence (MUI) together with urgency urinary incontinence (UUI). SUI can be a symptom, a sign seen on physical examination, or a condition when seen during urodynamic studies. The definitions are as follows:

- The symptom: **Stress urinary incontinence** – "**the complaint of involuntary leakage on effort or exertion, or for example, on sneezing or coughing**".
- The sign: **Stress incontinence** is the "**observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing**" Stress leakage is presumed to be due to raised abdominal pressure.
- The condition: "**urodynamic stress incontinence**" is defined as: "**Urodynamic stress incontinence is noted during filling cystometry, and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction.**" USI is now the preferred term to "genuine stress incontinence". As the definition of USI implies, USI is diagnosed during the filling phase of pressure-flow studies.

In urodynamic stress incontinence (USI) urethral function studies are used, in some centres, to discriminate between intrinsic sphincter deficiency and bladder neck/urethral hypermobility, the two principle causes of SUI. The two techniques most commonly used are defined at follows:

- "**The urethral closure pressure profile is given by the subtraction of intravesical pressure from urethral pressure.**"
- "**Abdominal leak point pressure is the intravesical pressure at which urine leakage occurs due to increased abdominal pressure in the absence of a detrusor contraction.**"

SUI may occur as part of mixed urinary incontinence (MUI) which becomes increasingly common in older age, primarily due to the increase in urgency urinary incontinence and is defined as: **Mixed urinary incontinence is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.**

When UUI is seen during urodynamics then it can be termed "symptomatic detrusor overactivity incontinence" or "UUI due to detrusor overactivity". The symptom **Urgency Urinary Incontinence** is defined as **the complaint of involuntary leakage accompanied by or immediately preceded by urgency.**



When assessing incontinence, a bladder diary is important as it allows the severity of the incontinence to be defined according to frequency and severity. Severity is most easily assessed by asking the patient to record pad usage and/or changes of underwear/clothing on the diary. The bladder diary gives the greatest amount of information of the 3 types of charts defined by ICS:

- **Micturition time chart:** this records only the times of micturition, day and night, for at least 24 hours
- **Frequency volume chart (FVC):** this records the volumes voided as well as the time of each micturition, day and night, for at least 24 hours.
- **Bladder diary:** this records the times of micturitions and voided volumes, incontinence episodes, pad usage and other information such as fluid intake, the degree of urgency and the degree of incontinence.

In elderly persons, and particularly those who are frail two other terms are useful when treatment is being discussed, (Fonda and Abrams NUU, in press).

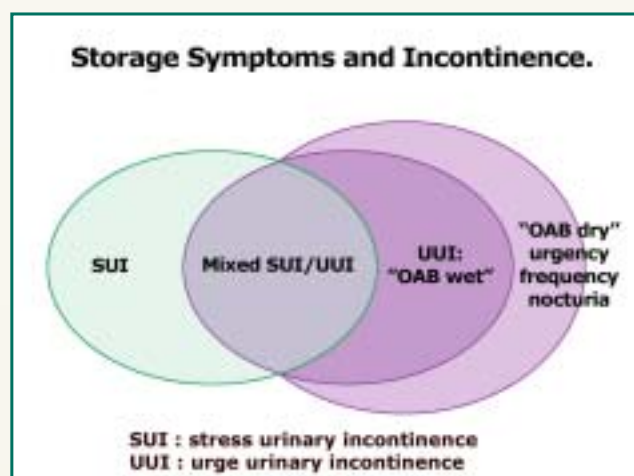
“Dependant Continece” to mean the situation where the individual would suffer a recurrence of incontinence if management was withdrawn. Examples would be, assisted toileting in the frail elderly, and successful antimuscarinic treatment for urgency incontinence. “Contained Incontinence” means that incontinence is controlled by being contained within an absorbent product or a collecting device. This term is preferred to the term previously used, “social continence”, which is felt to be misleading.

The importance of the ICS nomenclature is the precise definitions used, allows accurate description of the patients symptoms, signs and conditions, and urodynamic assessment. This assures unequivocal communication between health care professionals.

References

1. P Abrams, J G Blaivas, S L Stanton, J T Anderson. The Standardisation of Terminology of Lower Urinary Tract Function. Scan J Urol Nephrol. Suppl 114, 1988
2. P Abrams, L Cardozo, M Fall, D Giffiths, P Rosier, U Ulmsten. The Standardisation of Terminology of Lower Urinary Tract Function: Report from the Standardisation Sub-committee of the International Continence Society. Neurourology and Urodynamics 21: 167-178 2002.

Fig 1





GOOD URODYNAMIC PRACTICE: STANDARDISATION AND QUALITY CONTROL IN MEASUREMENT AND DATA ANALYSIS

Werner Schaefer

Geriatric Continence Research Unit, University of Pittsburgh, PA, USA wes11@pitt.edu

Description:

The widespread application of urodynamics seems to be still hampered by the common believe, that good urodynamics is difficult to perform and to interpret, prone to artifacts, time consuming, and its invasiveness makes it at least unpleasant to the patient. This practically orientated course will show, that urodynamic studies, from free flow to pressure/flow are easy, reliable, and not at all lengthy troublesome procedures, when properly prepared and performed strictly standardized with inherent quality control, following the guidelines of "good urodynamic practice, GUP" of the International Continence Society, ICS. See **NEUROUROL URODYNAM 21:261-274, 2002** or <http://www.icsoffice.org/documents/standardisationreports.asp>.

Good studies are easy to interpret. On different levels of sophistication, all methods of data analysis e.g. for bladder outflow obstruction provide very similar results, when used within their originally intended application. The most relevant methods can be performed in a simple manual graphical format. Computer application is helpful, but plausibility control of computer results is indispensable and requires comprehensive understanding of the underlying concepts and algorithms. Participants are invited to bring their own original urodynamic studies for discussion.

Objectives: At the conclusion of this course, the attendee should be able to:

1. Select suitable urodynamic equipment and catheters.
2. Understand the technical and physiological limitations of uroflowmetry.
3. Understand the differences between pressure recordings with fluid or air-filled systems, external transducers and microtips.
4. Prepare the equipment and perform filling cystometries and pressure/flow studies in standardized form.
5. Detect and correct, - but mainly avoid - , common errors and artifacts in intravesical, abdominal, and detrusor pressure.
6. Analyze cystometry curves for overactivity, and understand and determine compliance in a meaningful way.
7. Analyze pressure/flow data with simple graphical and numerical methods: such as the provisional ICS or the Schaefer nomogram. Concepts for females are discussed.
8. Understand the theoretical potential and practical limitations of computerized methods: PURR/DURR, CHESS, 3-parameter-model, OBI, and analysis of detrusor contractility.
9. Understand the specific problems of pressure recording in the urethra.



WHAT THE PHYSIOTHERAPIST CAN OFFER?

Bary Berghmans, PhD MSc RPT

Pelvic physical therapy focuses on the prevention and the treatment of all kinds of functional disorders of the abdominal, pelvic and low back region, like urinary incontinence, that is considered as a high prevalent health problem in women, men, children and the elderly.

Using the International Classification of Functions (ICF)¹, the physical therapist tries to influence the *consequences* of urinary incontinence 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).

For patients with urinary incontinence physical therapy is often considered as the first-choice treatment, due to its non-invasive character, the results in terms of symptom relief, the possibility of combining physical therapy with other treatments, the low risk of side effects and the moderate to low costs. Important restrictions are that the success depends on the motivation and perseverance of both the patient and the therapist and the time needed for physical therapy².

The armentum of the pelvic physical therapist is based on specific knowledge and skills, and contains interventions such as physiotherapeutic diagnostics, education and information of patients, pelvic floor muscle (PFM) training, bladder training (BIT), training with vaginal cones, electrical stimulation, biofeedback, etc.

Several forms of urinary incontinence such as stress urinary incontinence, mixed incontinence and incontinence due to detrusor overactivity can be differentiated².

DeLancey has suggested that an effective PFM contraction may press the urethra against the pubic symphysis, creating a mechanical pressure rise. PFM contraction also supports the pelvic organs³. Timing might also be important; Bø has suggested that a well-timed, fast and strong PFM contraction may prevent urethral descent during intra-abdominal pressure rise⁴.

So, in stress incontinence, to improve the extrinsic closing mechanism of the urethra, physical therapy is especially aimed on strength improvement and coordination of the peri-urethral and pelvic floor muscles. For these patients treatment modalities are PFM training, with or without biofeedback, electrical stimulation and vaginal cones. In particular, PFM training is effective².

Different from the mechanism in stress incontinence, for detrusor overactivity physical therapy is aimed at the reduction or elimination of involuntary detrusor contractions through reflexinhibition. Treatment modalities are information and education, electrical stimulation, bladder training, behavioural therapy and/or PFM training, with or without biofeedback. Especially, electrical therapy appears to be an effective treatment modality².

In mixed urinary incontinence the physiotherapeutic diagnostic & therapeutic process focuses on the predominant factors.

Radical prostatectomy is the most important cause of incontinence in men. Recently, Van Kampen showed that an adequate program of PFM training, after radical prostatectomy, decreased the duration and the extent of incontinence and improved the quality of life⁵.

Conclusion: physical therapy is in many cases of incontinence an effective treatment option.
References:

1. WHO. International Classification of Impairments, Activities and Participation: a manual of dimensions of disablement and functioning. Geneva: 1997
2. Wilson PD, Berghmans B, Hagen S, *et al.* Adult conservative treatment In Abrams P, Cardozo L, Khoury S, Wein A (eds). Incontinence. Paris, France. Health Publication Ltd 2005: 855-965
3. DeLancey JOL. Structural aspects of urethrovesical function in the female. *Neurourol Urodyn* 1988; 7: 509-519
4. Bø K. Pelvic floor muscle exercise for the treatment of stress urinary incontinence: an exercise physiology perspective. *International Urogynecology Journal and Pelvic Floor Dysfunction* 1995; 6: 282-291
5. Van Kampen M, De Weerd W, Van Poppel H, *et al.* The effect of pelvic floor re-education on duration and degree of incontinence after radical prostatectomy: a randomised controlled study. *Lancet* 2000; 355(9198): 98-102



HOW TO DEAL WITH MIXED INCONTINENCE

Dr Vik Khullar

Mixed incontinence is a common disorder affecting a large number of women and men. The disorder can be classified symptomatically and urodynamically. This talk will give an overview of the pathophysiology of mixed incontinence and how it is diagnosed. The problems of treatment will be highlighted, as will the different methods of conservative and surgical treatment with their outcomes.

The difficulty of defining mixed incontinence is that the condition consists of two different pathological processes, which co-exist to produce a new pathological condition. This new condition behaves differently from its two component processes. Mixed incontinence is a process of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.

It has been demonstrated for patients with mixed incontinence, that the urge component is significantly more bothersome than the stress component, both in terms of psychosocial factors and the overall sickness impact profile¹. As a result of this, therapy targeting the urge component has a greater impact on overall symptomatology.

It has been proposed that the management of mixed incontinence should initially be conservative i.e. behavioural modification and pharmacotherapy, for each component.

Surgical correction may cure between 35 to 50% of women of their detrusor overactivity, but unfortunately some women will have worsening of their detrusor overactivity after surgery.

Key learning points in this session are to understand the pathophysiology of mixed incontinence, to learn about different methods of diagnosing mixed incontinence and how it alters management, to understand the different conservative methods of treating mixed incontinence and the outcomes, and to discuss the place of surgery in the treatment of mixed incontinence.

1. Hunskar S, Vinsnes A. *J Am Geriatr Soc.* 1991;39:378-382.



WHAT ARE THE OPTIONS FOR CO-EXISTENT STRESS URINARY INCONTINENCE AND PROLAPSE?

A. R. B. Smith

1 Introduction

This lecture will cover:

1. The aetiology of stress incontinence and prolapse
2. Treatment options for women who have both stress incontinence and prolapse
3. Treatment options for women who have prolapse and “occult” incontinence.

2 Aetiology of stress incontinence and prolapse

- A. Pelvic floor weakness
 - a. Pelvic floor muscle denervation
 - b. Fascial weaknessRelevance of congenital, childbirth and ageing factors
- B. Lifestyle issues
 - Weight
 - Chest disease
 - Occupation

3 Treatment options for women who have stress incontinence and prolapse

- A. Lifestyle measures
- B. Conservative treatments
 - a. Ring pessary
 - b. Pelvic floor physiotherapy
 - c. Duloxetine
- C. Surgery
General points:
 - a). Women with prolapse and stress incontinence have a lower cure rate from surgery for stress incontinence than women who have stress incontinence alone
 - b). Prolapse surgery may:
 - (i) lead to development of OAB
 - (ii) cause denervation of the urethral sphincter
 - (1) Anterior vaginal wall prolapse
 - a. Anterior colporrhaphy with urethral buttress
 - b. Colposuspension
 - c. Anterior colporrhaphy with TVT
 - (2) Vault prolapse
 - a. Sacrospinous fixation + TVT
 - b. Sacrocolpopexy + TVT
 - c. Sacrocolpopexy + colposuspension
 - (3) Posterior vaginal prolapse
 - a. Posterior repair + TVT
 - b. Posterior repair + colposuspension

4 Treatment options for women who have “occult” incontinence

- A. Pre-operative evaluation
Evaluation of different methods of determining whether stress incontinence will develop after surgery
- B. Surgical procedures
Outcomes from prophylactic procedures to treat stress incontinence

NEUROSTIMULATION UPDATE: THE PROSPECTS FOR RESTORATION OF LOWER URINARY TRACT FUNCTION FOLLOWING SPINAL CORD LESIONS

Michael Craggs

Institute of Urology, University College London & Spinal Research, Functional Assessment & Restoration Unit London Spinal Cord Injuries Centre, Royal National Orthopaedic NHS Hospital Trust, Stanmore, Middlesex, UK

Complete spinal cord injury leads to various dysfunctions of the lower urinary tract including loss of voluntary control of the pelvic sphincters and bladder sensation, detrusor hyperreflexia (neurogenic detrusor overactivity - NDO) with sphincter dyssynergia and incontinence (Figure 1). Excessive bladder pressures can result in renal failure if not treated properly.

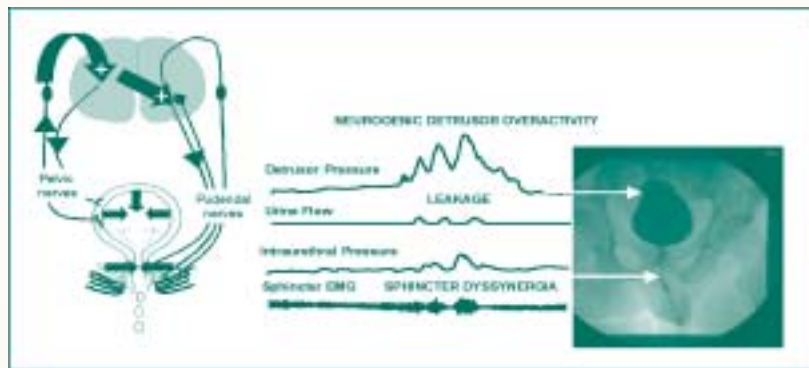


Figure 1 – Neurogenic Detrusor Overactivity with Sphincter Dyssynergia.

During the past 20 years, two key developments using implantable neural prostheses have had a significant impact on treating and managing patients with a neurogenic bladder. The first of these developments was the Brindley sacral anterior root stimulator implant (SARSI – Finetech Medical, UK) developed in the 1970's for efficient bladder emptying in spinal cord injury. Later it was combined with cutting of the sacral sensory nerves (posterior rhizotomy) to prevent NDO and incontinence ¹ (Figure 2). This device has now been implanted in nearly 3000 patients worldwide with considerable success. It has an extremely low failure rate and has been used for over 20 years in some patients. The second was the sacral (foramen) nerve stimulator (SNS) developed by Tanagho and Schmidt ² in the 1980's for suppressing detrusor hyperreflexia and controlling incontinence by neuromodulation with electrical stimulation through the intact mixed sacral nerves. Neuromodulation has become a very significant therapy in the treatment of the overactive bladder and urinary retention, and many thousands of sacral nerve stimulators (Interstim, Medtronic, US) have been implanted for this purpose (Figure 3).

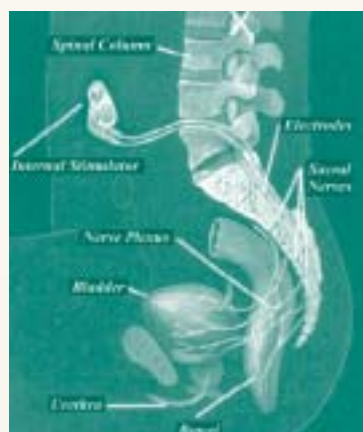


Figure 2 – The Finetech-Brindley Sacral Anterior Root Stimulator (SARS) Implant

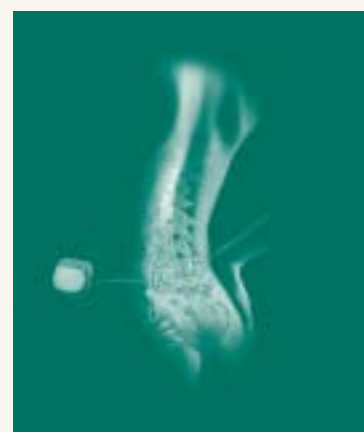


Figure 3 – The Medtronic Interstim Sacra Nerve Stimulator Implant



However, not only is sacral foramen stimulation used less often for NDO in spinal cord injury but posterior rhizotomy associated with SARSI is being shunned by many male patients. Perhaps this is not surprising as the disadvantages of posterior rhizotomy (bilateral S2-S4) include the loss of reflex erections and reflex ejaculation, and may predispose to pelvic floor weakness. Therefore, some patients are now understandably reluctant to accept this procedure despite the clear clinical benefits of SARSI. They have the hope that the development of a 'cure' for SCI involving neuroregeneration and repair is imminent and understandably do not wish to undergo further damage to their spinal pathways.

At Stanmore we are less sure about a short time-scale for these developments in neural repair and so have looked for new approaches to sacral root stimulation which avoid deliberate nerve destruction. Now we are combining the techniques of sacral anterior root stimulation for bladder emptying (Figure 2A) with posterior root stimulation for suppression of NDO and incontinence using an intrathecal electrode implant (SPARSI – Sacral Posterior and Anterior Root Stimulation Implant) (Figure 2B).

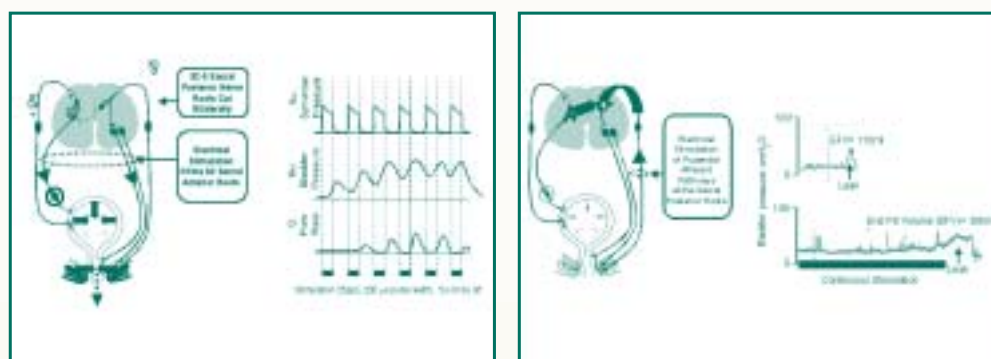


Figure 2. SPARSI – Differential sacral root stimulation using a single implant. A. Bladder emptying through sacral anterior root stimulation. B. Neuromodulation of NDO and increasing bladder capacity by sacral posterior root stimulation.

This talk will discuss the use of differential sacral root stimulation. It will also outline the possibilities for a more advanced implant for complete control of the neurogenic bladder³ in which it is hoped to include conditional neuromodulation for reflex incontinence and selective neurostimulation for smoother bladder emptying. In these new developments, a European Union consortium (REBEC) has been working on a more advanced control for NDO using conditional neuromodulation in which suppression only occurs when it is required by providing a feedback signal of bladder pressure rises. A discussion of adjuvant therapies combining drugs and stimulating devices to facilitate neural control of pelvic dysfunction generally will also be included. By preserving all sacral reflexes, including those for erection, ejaculation and bowel control, as well as those essential to guard against stress incontinence, we will hope to reassure people with a spinal cord injury that this technology will improve their quality of life until the time comes when neural repair becomes a realistic possibility for them.

Key References

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NEUROMODULATION UPDATE: WHAT HAVE WE LEARNED AND HOW BRIGHT IS THE FUTURE?

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Sacral neuromodulation has been used for the treatment of (refractory) urge incontinence (or OAB wet patients, according to the most recent ICS terminology) since the early nineteen-nineties. Subsequently, other indications have been explored such as urge-frequency syndrome (OAB dry) and non-obstructive urinary retention. In the USA, FDA approval has been gained for these indications. Currently, the use of the Interstim device in other urologic indications such as interstitial cystitis, pelvic pain syndromes and neurogenic voiding dysfunction is investigational. Despite fifteen years of experience world wide, most reports on the results of the technique deal with relatively short follow-ups. Success rates of more than 70-80% have been reported after 0.5-1.5 years of follow-up, for all the approved indications. Interstim therapy for detrusor overactivity incontinence (or urge incontinence with urodynamically proven detrusor instability, using the older ICS terminology:) has the longest history, starting around 1990 in a few European centers. Although we have a 15-year history of this therapy, it is of some concern that several basic questions remain to be answered:

Why does it work? For whom does it work? How do we know that it will work (or not) in a particular patient? If it does work: how long does the effect last?

An inhibitory effect on the voiding reflex due the electrical stimulation of sensory afferent nerve fibers from the genito-perineal area, represents the most widely accepted theory about the mode of action of neuromodulation, although it is not completely clear how neuromodulation works in non-obstructive urinary retention. It also remains to be clarified whether an effect on centers located in the brain or brain stem is involved.

A complete 5-year follow-up in a personal series of S3 spinal nerve stimulation with an implantable electrode and pulse generator in 51 consecutive patients with refractory urge incontinence, shows that 65% were still a success at 5 years. Success was defined as a more than 50% decrease in incontinence episodes as compared to baseline. Of these 51 patients, 27.6% were dry at 5 years. Originally, 103 patients underwent a percutaneous test stimulation (PNE) of which 51 continued to the implant phase; this indicates that of all tested patients with refractory urge incontinence, 13.7% were dry after 5 years and 32.2% had an improvement of more than 50%.

One should also take into account that the selection of patients for a PNE not only involves the application of defined in- and exclusion criteria but also the personal bias of the investigator. This indicates that these results are not easily generalizable to the total population of patients with refractory voiding dysfunction. It also partly explains the differences in results between different series. Nevertheless, other investigators [Voskuilen et al] have confirmed the results in urge incontinence (64.2% success at 5 years) although about 45% of the originally included subjects were missing at 5 years in this world wide clinical study. In the urge-frequency and nonobstructive retention groups success rates of 66.7% and 76%, respectively were reported by these authors.

Despite several efforts, it has not been possible yet to define pre-treatment factors that are predictive of a durably successful implant. With the introduction of the tined lead in combination with the two-stage implant, the selection process has recently changed. This has increased the implantation rate after the test period from about 50% or less to about 80% in some series. It is not clear whether this will improve or maybe even worsen the long-term success rate.

Theoretically, direct pudendal nerve stimulation could be a more effective approach because more sensory afferent nerve fibers will be stimulated than with S3 spinal nerve stimulation. There are preliminary indications that implantation of a novel minimally invasive pudendal nerve mini-stimulator (Bion device) can be effective when other types of neuromodulation (including Interstim technique) have failed. Further clinical trials in larger groups of patients will have to confirm these results. Future trials of neuromodulation will also involve the oldest anatomical approach already used by Caldwell in the nineteen-sixties, i.e placement of a permanent electrode in the periurethral area of the pelvic floor (Miniaturio-I). This will certainly be the easiest approach for a permanent implant, but the efficacy remains to be determined.

Earlier studies of sacral nerve (S3) neuromodulation in neurogenic patients have shown mixed results. A systematic evaluation of the effect of direct pudendal nerve stimulation, which holds the promise of a greater efficacy, in patients with neurogenic voiding dysfunction is also expected in the near future.

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