International Continence Society

Educational Course

Mumbai, India

16th November 2007

WELCOME

It is a great pleasure to organise an International Continence Society Educational Course in conjunction with the Indian Section of the Société Internationale d'Urologie. Our aim is to provide high-quality education for Indian healthcare professionals taking into account local traditions and expertise. Also this is the first time that the ICS has been in India.

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 pre-meeting workshops and ICS educational courses. Now the ICS Education Committee 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.

These non-profit making courses are 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 and to interact with other ICS members and listen and learn from relevant topics.

We have designed this course to bring together international speakers of different disciplines to share their experiences with all the delegates adding to the value and effectiveness of the event. 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 enjoy the lectures but also get a chance to talk to the speakers and get to know us better.

Whether you are attending just the one day ICS course or the whole SIU programme we hope that your expectations are fulfilled and in return all we ask is that you complete your evaluation form so that we learn from our experiences to make better Educational Courses in the future. We hope that you will enjoy participating in this course and that it will encourage you to submit abstracts for and hopefully attend the future ICS annual meetings.

Linda Cardozo

Ajay Singla

ABOUT THE ICS

Visit our website: www.icsoffice.org

The International Continence Society (ICS) 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. We have more than 2000 members on our books from over 70 countries 1,800 delegates attended the 37th Annual Meeting of ICS in Christchurch, New Zealand at the end of 2006.

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.

2007	Rotterdam, The Netherlands	Ruud Bosch
2008	Cairo,Egypt	Sherif Mourad
2009	San Francisco, USA	Tony Stone
2010	Toronto, Canada	Sender Herschorn & Harold Drutz

Today, the society employs four fulltime staff at its head office in Bristol, UK. There is a Executive Board made up of the current Trustees and there is also an Advisory Group and many committees dedicated to various tasks ensuring the Society's charitable objectives are maintained.

BECOME A MEMBER OF THE ICS

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.
- Free membership to the EU-ACME programme for continuing professional development

PROGRAMME

07:00 –08:00	Arrive – Register	
08:00 - 08:15	**Welcome**	
08:00 –0 8:05	Welcome and Introduction	Ajay Singla
08:05 –08:10	Aims and Objectives	Linda Cardozo
08:10 –08:15	Indian Continence Foundation – An overview	Srini S Vasan
08:15 - 09:30	**Session One**	**Chair: Shailesh Raina, Kiran Coelho**
08:15 – 08:30	ICS Standardisation & Terminology	Linda Cardozo
08:30 – 09:15	Good Urodynamic Practice	Werner Schaefer
09:15 – 09:30	Discussion	
09:30 - 10:30	**Session Two: Current Management of Neurogenic Bladder**	**Chair: Shirish Yande, Vanita Raut**
09:30 – 09:45	Need for Video UDS in Neurogenic Bladder	Shirish Yande
09:45 – 09:55	Clean Intermittent Catheterization – The Concept	Jayesh Dhabalia
09:55 – 10:10	Urological Management of Spinal Cord Injury	A Mohan
10:10 – 10:25	Surgical Management of Neurogenic Bladder	Narmada Gupta
10:25 – 10:30	New advances in NGB	Shailesh Raina
10:30 - 10.45	**Break**	
10:45 - 12:15	**Session Three Stress Urinary Incontinence – My Tape is Best**	**Chair: Ajit Vaze, Vilas Dhanu**
10:45 – 11:00	How & Why Tapes Work	Vik Khullar
11:00 – 11:15	Role of UDS in SUI	Mayank Agarwal
11:15 – 11:30	TVT	Sanjay Sinha
11:30 – 11:45	TOT	Ajay Singla
11:45 – 12:00	TVT Secur	Vik Khullar
12:00 – 12:15	Panel Discussion	
12:15 - 13:00	**Lunch**	
13:00 - 13:30	**Session Four Oration**	**Chair: Dr Ajit Virkud, Dr Vinita Salvi**
13:00-13:20	"Selection of ideal procedure for SUI; Management of complications and failed tape"	Chris Chapple
13:20-13:30	Questions and answers	
13:30 - 15:00	**Session Five Surgery For Pelvic Organ Prolapse**	**Chair: Sanjay Sinha, Aruna Kekre**
13:30 -13:45	Does UDS Change Management	Srini S Vasan
13:45 – 14:00	Vaginal Repair	Linda Cardozo
14:00 – 14:15	Surgical Correction – Abdominal Repair	Ajay Singla
14:15 - 14:30	Mesh or not to Mesh?	Rakesh Kapoor
14:30 - 14:45	Role of new devices – TVM Prolift, Apogee Perigee	Vikram Khullar
14:45 - 15:00	Panel Discussion	
15:00 - 15:15	**Break**	
15:15 - 17:15	**Session Six Overactive Bladder/Painful Bladder Syndrome**	**Chair: Ajit Vaze, Vilas Dhanu**
15:15 – 15:30	Pathophysiology	Chris Chapple
	A. New drugs for OAB	
15:30 – 15:40	1. Tolterodine	Chris Chapple
15:40 – 15:50	2. Solifenacin	Ajay Singla
15:50 – 16:00	3. Darifenacin	Vik Khullar
16:00 – 16:10	4. Transdermal Oxybutynin Patch	Linda Cardozo
	B. Refractory OAB	
16:10 – 16:30	1. Role of Botox	Chris Chapple
16:30 – 16:50	2. Role of Neuromodulation	Ajay Singla
16:50 – 17:05	**C. Painful Bladder – An Update**	Nitin Kekre
17:05 – 17:15	Discussion	
17:15 - 17:55	**Session Seven - Urological injuries**	**Chair: Srini S Vasan, CN Purandare**
17:15 – 17:25	Urological injuries during Gynaecological Surgery	Chris Chapple
17:25 – 17:35	Urological Injuries during Laparascopic Gynaecological Surgery	Rakesh Sinha
17:35 – 17:45	Prevention and Management of Urological Injuries	Deepak Kirpekar
17:45 - 17:55	Panel Discussion	
17:55 - 18:00	**Closing Remarks**	**Ajay Singla**

EU★ACME

CME Accreditation

E B U
European Board of Urology

EU-ACME – This Educational Course is accredited within the EU-ACME programme by the European Board of Urology Accreditation Committee with 6 credits. 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 ICS desk at the end of the course.

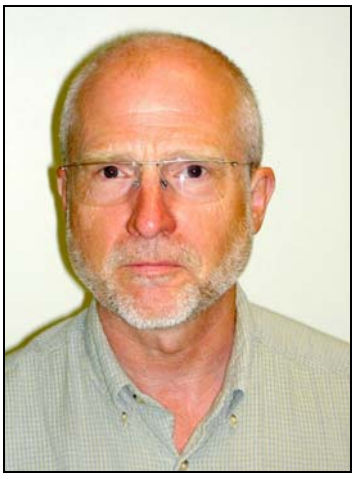
Meet the speakers

Ajay Singla

Linda Cardozo

Chris Chapple

Vik Khullar



Werner Schaefer

Session One:
Good Urodynamic Practice: Standardization 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 or enclosed CD.

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 lecture, 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 microtip catheters.
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 DO, 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.
9. Understand the specific problems of pressure recording in the urethra.

Session Three: Stress Urinary Incontinence - My Tape is Best
How & Why Tapes Work

Vik Khullar

Mid urethral tapes have been shown to stabilise the mid urethra allowing greater compression of the midurethra during coughing. It is not clear whether increased bladder neck mobility is of importance when seeking increased cure rates. The importance of the urethral pressure profile is controversial . some studies have shown a low urethral pressure predicts the poor outcome of

surgical procedures whereas others have shown the low pressure does not alter the outcome of continence surgery.
There has also been noted to be a slight change in the position of the bladder neck after this form of surgery. The bladder neck is elevated but it is not clear if this has any role in continence.

Trans-Obturator Tape

Ajay Singla

Associate Professor, Department of Urology & Gynecology, Wayne State University

Minimally Invasive Procedures

- Non-adjustable

—Trans obturator Tape (T.O.T)
—Percutaneous Vaginal Tape (PVT)
—Tension free vaginal Tape (TVT)
—Pre-Pubic Vaginal Tape

- Adjustable

—ACT
—Remeex

Preliminary Results of the New ARIS® Trans-Obturator Tape
Surgical Treatment of Female Stress Urinary Incontinence
Patient Characteristics
Pre-operative Urodynamic Assessment
Peri-operative Complications
Post-operative complications
Cure Rates
WSU Series

- Total Patients 30
- Mean Age 46.5 (29-69) yrs
- Follow up 18 (6-24)months
- Cured 16(80%)
- Improved 1(5%)
- Failed 1(5%)
- Removed 2(10%)

Which Procedure To Do?
Conclusion

- There has been a evolution in the surgical management of SUI
- The new minimally invasive procedure such as TOT appears to be safe and effective in the short term
- Long term follow up is needed to establish the durability of these novel procedures

TVT Secur

Vik Khullar

The TVT secur is a 8cm tape with insertion devices and a fixation method which obviates use of an exit for the tape. The tape can be inserted using local anaesthetic and either with the tape being inserted behind the symphysis pubis or behind the pubic bone. There is little data on the outcome data. However it does appear that the tape has a reduced success rate compared with other transvaginal tapes or transobturator tapes. However this is balanced by the reduced morbidity of the operation.

Session Four: Oration
Selection of the ideal procedure for SUI: Management of complications and failed tape
Chris Chapple

Stress urinary incontinence represents a consequence of reduced pelvic floor support and intrinsic sphincter weakness. It is important to weigh up these different aspects and individualize treatment to the specific patient. Clearly a proportion of patients will either fail to be improved by their surgery for stress incontinence, or develop a complication. Complications relating to the failure of a tape procedure are now being increasingly seen in clinical practice. This presentation will discuss the appropriate management of patients, in particular in the context of the patient who develops complications as the result of a failed tape.

Session Five: Surgery For Pelvic Organ Prolapse
Vaginal repair
Linda Cardozo

Aims: To review current evidence and best practice in the vaginal repair of pelvic organ prolapse.

Results: Pelvic organ prolapse is most commonly surgically approached via the vaginal route. Anterior colporrhaphy is the surgery of choice for anterior compartment prolapse, with success rate between 42-57%. Uterine prolapse maybe treated by vaginal hysterectomy as is most often the case, or by uterine preserving procedures such as sacrospinous hysteropexy. Additional procedures such as McCalls culdoplasty or uterosacralplication may be performed at the time of vaginal hysterectomy to prevent future enterocele formation and vault prolapse. Proven vault prolapse maybe approached vaginally by performing either a sacrospinous ligament fixation, intravaginal slingplasty or uterosacral ligament plication. Colpocleisis is used as a last resort in the frail elderly as it renders penetrative intercourse impossible and is associated with an increased risk of post operative stress incontinence.
Traditionally urogynaecologists perform posteror colporrhaphy through the transvaginal route and there is some evidence to suggest that this may be superior to the transanal route. Traditional levator ani plication posterior repair is associated with a high incidence of dyspareunia and apareunia as it restricts the capacity of the lower vagina. On the other hand fascial posterior repair is associated with no significant adverse effects on bowel, bladder or sexual function whilst significantly improving POP-Q parameters Ap and Bp.

Conclusion: Transvaginal fascial posterior repair would appear to be the best option for colporrhaphy in terms of native tissue options as it is associated with better anatomical results , improved overall patient satisfaction and no significant adverse effects on sexual, bowel or bladder function.

References:

1. Weber et al.Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001 Dec;185(6):1299-304
2. Kahn MA, Stanton SL.Posterior colporrhaphy: its effects on bowel and sexual function. Br J Obstet Gynaecol. 1997 Jan;104(1):82-6.
3. Robinson D, Wadsworth S, Cardozo L, Bidmead J, Balmforth J. Fascial posterior colpoperineorrhaphy: A five year follow- up study. Journal Of Pelvic Medicine and Surgery 2003 9(6); 279-283

4. Maher et al.Uterine preservation or hysterectomy at sacrospinous colpopexy for uterovaginal prolapse?
Int Urogynecol J Pelvic Floor Dysfunct. 2001;12(6):381-4

Management of vault prolapse
Ajay K Singla

- Conservative
- Pessaries
- Surgical
- Obliterative (colpocleisis)
- Reconstructive
- vaginal (sacrospinous fixation, iliococcygeus suspension, uterosacral suspension, culdoplasty)
- abdominal or laparoscopic (sacral colpopexy – **Straight-In**)
- trans-gluteal (IVS, Apogee)

Abdominal Sacral Colpopexy

- Elevation of vaginal vault to sacral promontory (S3) utilizing a mesh bridge
- Abdominal or laparoscopic approach
- Results in most physiologic vaginal axis
- High proven success rates, especially for younger patients
- Known risks, minimized in experienced hands
- Mesh erosion - 3 %

Sacral Colpopexy: variables

- Approach (open v. laparoscopic)
- Mesh choice (biologic v. synthetic)
- Method for sacral attachment (suture v. bone anchor)
- Degree of tension
- Associated reconstructive procedures
- Post-operative care

Sacral Colpopexy Procedure
Abdominal Approach

- Midline abdominal or Pfannenstiel incision
- Dissect down to the sacrum
- Graft material bridge is placed between the sacrum and the vaginal cuff

Sacral Colpopexy
Procedure Obstacles

- Difficult to insert a needle through the sacrum
- Risk of disrupting the presacral veins and nerves
- If bleeding occurs, difficult to locate source
- Decreased visualization within the pelvis due to the combination of blood rapidly filling the abdomen, and the deep sacral location of the presacral veins
- Stainless steel thumbtacks or corkscrews may be used to stop the bleeding.

Straight In

- Only system on the market for sacral colpopexy procedure

- Bone screws allow for minimal clearing of the sacrum
- Facilitates quick fixation of the IntePro Y-graft to the sacrum
- Proprietary, innovative, pre-formed Y-graft is sutured to the vaginal cuff
- The vaginal distender facilitates suturing of the Y-graft to the vaginal cuff
- Indicated for open abdominal and laparoscopic procedures

AMS Straight-In™ System
Surgical Procedure Steps

- Prophylatic antibiotics
- Regional or general anesthesia
- Low lithotomy position
- Bowel prep
- Anterior abdomen, vagina prep
- Insert foley catheter into bladder

Surgical Procedure Steps

- Midline abdominal or Pfannenstiel incision
- Pack bowel to patient's left side
- Retract sigmoid colon laterally

SCP Surgical Procedure Steps
Surgical Procedure Steps

- Identify right ureter
- Incise posterior peritoneum
- Clear off sacrum
- Avoid disruption of presacral veins and nerves
- Place 2 bone anchors
- S3 -> Promitory
- 1-2 cm apart, verticle or horizontal
- Insert the vaginal distender
- Secure anterior and posterior segments of the vaginal apex with 6-10 interrupted sutures (braided nylon)
- Use sutures from bone screws to fixate graft to sacrum
- NO TENSION on graft between vagina and sacrum

IntePro Y- Graft

- Large pore polypropylene
- Pre-formed into Y-shape

Inserter and bone screws
Vaginal Distender
Packaging

- All Straight-In components are individually boxed and placed into one large box to be shipped as a system.
- System contains:
- Inserter
- Shaft
- 2 bone screws

- Vaginal Distender
- Y-graft

Benefits of Straight-In

- Bone screws
- Accurate placement
- Minimal pre-sacral trauma
- Self-tapping titanium screws requires minimal clearing of the anterior sacrum
- Vaginal distender allows to distend apex for safer and easier suture placements
- Pre-assembled Y-Graft saves OR time
- Small inserter diameter allows for the device to be used laparoscopically

Reduced bleeding risk without loss of strength

SSF vs. ASCP

- Retrospective review, follow-up 6 mo. - 5 yrs.
- SSF - 125, ASCP - 80
- ASCP - Marlex mesh, Prolene sutures
- SSF - Unilateral, PDS or Prolene sutures, all had posterior repair

		SSF	ASCP
post-op fever (%)	10	6	
recurrent vault prolapse (%)		2.4	1.3

Hardiman, Drutz. Am J Obtet Gynecol 1996;175:612-16.

Abdominal Sacro-Colpopexy: Benefits

- Results in most physiologic vaginal axis

CCF Straight-In ASC data

64 consecutive patients
Mean age: 64.8 (38-81)

- 33 had pre-op stage IV POP-Q score
- 27 had pre-op stage III POP-Q score
- 4 had pre-op stage II POP-Q score
- Average follow up 11.1 (1-53) months.
- Mean EBL: 219 (100-500) cc.
- No cases of significant pre-sacral bleeding
- Post-operative evaluation
- 1 mesh erosion into posterior vagina
- Treated successfully in office with estrogen cream
- No osteitis or osteomyelitis
- 63 patients with POP-Q stage 0 prolapse
- 1 patient with 3rd degree enterocele

Session Six: Overactive Bladder/Painful Bladder Syndrome Pathophysiology
Chris Chapple

The ICS terminology for overactive bladder and bladder overactivity are discussed. A critical overview of the recent developments in our understanding of the pathophysiology underlying detrusor overactivity and the relationship of detrusor overactivity to overactive bladder

symptom complex is presented, with reference to existing pharmacotherapy for these clinicians and the potential for new therapies in the future.

New drugs for OAB
Tolterodine
Chris Chapple

Tolterodine is currently the most commonly used anticholinergic in many countries and there is a wealth of experience related to its use. This presentation will review some of the pertinent features of the use of tolterodine in the management of patients presenting with overactive bladder symptom complex.

Solifenacin
Ajay K Singla

- Bladder selective antimuscarinic
- Demonstrates specificity for M3 over M1 and M2
- Hepatic metabolism
- Half Life: 45 -68 hours
- Once daily dosing
- Flexible dosing regimen

Launched in 2004
Currently 64.3 million treatment days since launch

Solifenacin Clinical Development Program

Solifenacin
- Double-blind multinational trial of 857 patients
- Randomised to:
  Solifenacin 5mg Solifenacin 10mg Placebo
- Significant reduction in:
  frequency urgency incontinent episodes
- Significant increase in volume voided
- Significant improvement in QoL
- Gradual increase in efficacy during the trial with maximum effect at 12 weeks
- No difference in withdrawal rates across groups

Cardozo et al 2003

Solifenacin
- Double-blind multinational trial of 1077 patients
- Randomised to:
  Solifenacin 5mg Solifenacin 10mg Tolterodine 2mgbd Placebo
- Significant reduction in frequency in all arms
- At end of study continence rates were:
  Solifenacin 5mg 51.1% Solifenacin 10mg 50.6%
  Tolterodine 2mg bd 48.4% Placebo 37.3%
- Dose dependent increase in antimuscarinic adverse effects
- No difference in adverse events between groups

Chapple et al 2004

Solifenacin: STAR Study
Solifenacin and Tolterodine as an Active comparator in a Randomised Trial

- Prospective, double blind, double dummy, two-arm parallel group study
- 12 week duration
  Solifenacin 5mg/10mg Vs Tolterodine ER 4mg od
- Flexible Dosing regimen
- 1200 patients recruited in 117 sites in 17 countries
- Primary outcome measure
  Solifenacin is non-inferior to tolterodine ER in change from baseline in mean number micturitions/24hrs

Chapple et al 2005

Solifenacin: SUNRISE Study
Solifenacin in the treatment of UrgeNcy symptoms of overactive bladder in a RISing dose, randomised, placebo controlled, double blind, Efficacy trial

- Prospective, placebo controlled, double blind
- Rising dose study; 16 weeks duration
- Two randomisations
- 973 patients recruited in 105 sites in 14 countries
- Primary outcome measure
  Change from baseline in mean urgency episodes/24 hrs
  Evaluated using PPIUS

Cardozo et al, 2006

SUNRISE: Study Plan
SUNRISE PPIUS: Urgency Assessment
Patient Perception of Intensity of Urgency Scale
Validated; Completed at V2, V3, V4, 12 wk, V5
Rating at each void during 'diary period'
0 No urgency: I felt no need to empty my bladder but did so for other reasons
1 Mild Urgency: I could postpone voiding as long as necessary without fear of wetting myself
2 Moderate Urgency: I could postpone voiding for a short while without fear of wetting myself
SUNRISE
Primary Variable
SUNRISE
Urgency Episodes Per Diary Day 1 - 3
SUNRISE Study
% patients requesting dose increase at 8 weeks
Comparative Reduction in Urgency

Darifenacin
Vik Khullar

Darifenacin is a highly selective M3 muscarinic receptor antagonist for once-daily treatment of overactive bladder syndrome (OAB). Darifenacin has been shown to have a potent and specific muscarinic receptor antagonist with a 59-fold higher selectivity for muscarinic M(3) receptors relative to other muscarinic receptor subtypes. This should produce clinical efficacy in the treatment of OAB but with less adverse effects related to blockade of other muscarinic receptor

subtypes. Thus it should not have any effects on cognitive function and heart-rate variability (1). This is particularly important for the elderly who can have a higher rate of cognitive side effects due to increased permeability of the blood brain barrier. Large-scale clinical trials have confirmed that darifenacin (at doses of 7.5 and 15 mg/day) results in central nervous system and cardiac adverse events comparable to placebo, and provides early and meaningful improvement across a range of OAB symptoms including incontinence episodes, urgency and urinary frequency (2).

This suggests that darifenacin will be an effective treatment of OAB, that is efficacious, well-tolerated and, more importantly, minimises the risk of safety-related adverse effects.

References

1. Assessment of cognitive function of the elderly population: effects of darifenacin. J Urol. 2005;173:493-498. Lipton RB, Kolodner K, Wesnes K.
2. Darifenacin, an M3 selective receptor antagonist, is an effective and well-tolerated once-daily treatment for overactive bladder. Haab F, Stewart L, Dwyer P. Eur Urol. 2004 ;45:420-9

Transdermal Oxybutynin Patch
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.

Refractory OAB
Role of Botox
Chris Chapple

Botulinum toxin injection therapy is now being increasingly used for the management of patients with symptoms related to detrusor overactivity, either idiopathic or neurogenic. The scientific basis for the use of this agent is discussed, with reference to some of the recent peer-reviewed literature.

Role of Neuromodulation
Ajay K Singla

What is SNS?

- Implantable stimulation system
- Targets sacral nerves (S3)
- Modulates reflexes between bladder, sphincter, and pelvic floor

What are SNS Indications?

- Refractory OAB
  - Failed drugs and behavioral therapy
- Urinary Retention
  - Idiopathic non-obstructive
- Non-neurogenic etiology
- Bowel dysfunction

Mechanism of Action

- somatic afferent inhibition of sensory processing in the spinal cord
- pudendal afferent signaling serves as a common crossroads in the neurologic wiring of the system
  - can turn on voiding reflexes by suppressing the guarding reflex pathways
  - can turn off supraspinally mediated hyperactive voiding by blocking ascending sensory pathway inputs

Retention: MOA

- NOUR/Fowler's syndrome
- Used PET scan to study changes in brain activity of controls vs. retention patients
- Showed attenuated brainstem activity in women with retention
- Suggest that neuromodulation achieves its therapeutic effect at the level of functional interactions between midbrain and limbic cingulate cortex

Mechanism of Action

How is it done?

- Test stimulation (PNE)

- Percutaneous placement of S3 lead
- Office based, local anesthesia
- Use of external stimulator for several days
- Temporary application of SNS

- Objective effect on voiding diary parameters
- Subjective improvements
  - Pain, sleep, sex, bowel function

Staged Implant

- First stage
  - uses potentially permanent lead
  - Placed under local with sedation with fluoroscopy
- Allows longer time to gauge response
- Better predicts long term benefit
- Second stage
  - Same lead can be used with INS
  - Lead removal if not successful

Peripheral Nerve Stimulation

- Needle placed at S3
- Bellows and toe response
- Genital/anal sensation
- Patient comfort
- Identifies nerve location, integrity

Tined Lead Placement

- Minimally invasive
- Permanent lead
- Local/sedation
- Uses Fluoro
- As trial (staged)
- Together with INS

INS
SNS: Clinical Efficacy

Urge Incontinence:

Sustained Results Over Time [1]
Urgency - Frequency:
Sustained Results Over Time [1]
SNS for Bowel Dysfunction

- Leading diagnoses for therapy in EAU
- Multicenter trials pending FDA review
- Mechanism same as for GU conditions
- Present indications*
  - Fecal incontinence
  - Fecal urgency-frequency (IBS)
  - Idiopathic chronic constipation

SNS for Pediatric Patients

- Hoebeke P, JOU 2004;171:S56
- De Gennaro M, JOU 2004;171:1911
- Humphreys M, JOU 2006;176:2227

- Roth AUA
  - Dysfunctional elimination syndrome
  - Includes both GU and GI symptoms
- SNS used in those resistant to drugs/behavioral tx
- 18/22 patients had successful trial/implant
- Significant improvements seen in UI, frequency, enuresis and constipation
- Potential for cure after withdrawal of tx in this population?

SNS for IC/Pelvic Pain

- Several series have shown dramatic reductions in urinary symptoms, pain VAS, and narcotic use
  - Siegel S, JOU 2001
  - Comiter CV, JOU 2003
  - Feler CA, Anesth Clin NA 2003
  - Peters KM, BJU Int 2004
  - Everaert, Eur Urol 2004
- Treats pain as central disorder due to upregulation of of dorsal horn

Complications

- Reoperation rate 33%
  - Infection
  - Pain at lead or IPG site
  - Loss of efficacy
- Expected improvement
  - Smaller IPG, buttocks placement
  - Ability to test for longer period
  - Trial lead = permanent lead
  - Increased use of fluoro

SNS vs. Botox

- Restores function
- WYSIWYG
- Treats retention
- If fails, can use Botox
- Long term benefit
- Infrequent re-operation
- Cost
- Reimbursement
- Takes away function
- Not
- Causes retention
- 9 months before SNS
- Temporary
- Multiple re-treatments

SNS Versatility

- OAB
- Non-obstructive urinary retention
- IC/painful bladder syndrome

- Bowel dysfunction
  - Fecal incontinence
  - Fecal urgency-frequency
  - Idiopathic chronic constipation
- Pediatric voiding dysfunction
- Sexual dysfunction
  - PSAS, anorgasmia

Session Seven - Urological injuries

Urological injuries during gynaecological surgery
Chris Chapple

Injuries to the ureter, bladder or urethra can occur during gynecological surgery. The appropriate management of these injuries is essential to restore anatomical continuity and ensure appropriate restoration of function. A brief overview of this field will be covered, with particular reference to the management of the injured ureter, vesico-vaginal fistulae and damage to the urethra. The basic surgical principles will be emphasized.