



AUA NEV **2017 ANNUAL** MEETING HIGHLIGHTS Female Urology/Voiding

Dysfunction

Course #008IC Botulinum Toxin: Why Use It, How to Do It, What are the Results?

Course #026IC Contemporary Pharmacotherapy for OAB

Course #033IC Foundations of Female Urology

Course #067IC

AUA/SUFU Guidelines 2017: Surgical Management of Female Stress Urinary Incontinence

Course #070IC The Role of Sacral Neuromodulation in **Urological Practice**

Course #074IC

The Practical Management of Overactive Bladder: Integrating the SUFU Overactive Bladder Clinical Care Pathway into Your Practice

AUANews Editor Manoj Monga, MD, FACS

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AUA2017 ANNUAL MEETING HIGHLIGHTS

Female Urology/ **Voiding Dysfunction**

CME Credit

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CME INFORMATION

2017 AUA Annual Meeting Highlights: Female Urology/Voiding Dysfunction

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Estimated time to complete this activity: 1.25 hours Release Date: October 2017 Expiration Date: October 31, 2018

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Statement of Need

Over the past several years there has been an evolution in the diagnosis and management of urologic conditions such as overactive bladder (OAB) and stress urinary incontinence (SUI). Technological and pharmacological advances are constantly occurring. Thus there is an educational need for increased knowledge, particularly related to advances in the specialty and understanding of current guidelines for the management of patients with these conditions.

Target Audience

Urologists, urologists in training and non-physician providers involved in urology.

Course #008IC: Botulinum Toxin: Why Use It, How to Do It, What are the Results?

Learning Objectives

At the conclusion of this CME activity, participants should be able to:

- Cite the mechanism of action of botulinum toxin
- Describe the role of the toxin as a form of treatment for the bladder, sphincter and prostate
- Identify limitations and potential complications of botulinum toxin treatment
- Examine patient types who may benefit from treatment with botulinum toxin
- Compare and contrast injection techniques

Faculty

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Course #026IC: Contemporary Pharmacotherapy for OAB

Learning Objectives

At the conclusion of this CME activity, participants should be able to:

- Understand the similarities and differences between the various oral pharmacotherapies for overactive bladder (OAB)
- Review the principles of physiology and pharmacotherapy for currently available agents, including the antimuscarinics and beta-3 agonists
- Realize the importance of setting proper patient expectations regarding treatment of OAB and the potential need for sequential and even additive therapies
- Analyze the clinical (and theoretical) advantages and limitations of currently available agents
- Learn about potential future pharmacological pathways and therapies for OAB

Faculty

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Course #033IC: Foundations of Female Urology

Learning Objectives

At the conclusion of this CME activity, participants should be able to:

- Cite the basic concepts of pelvic floor anatomy, and how certain defects cause pelvic organ prolapse
- Distinguish the different prolapse surgeries, and the certain types of pelvic floor defects they correct
- Interpret the latest concepts regarding the pathophysiology and surgical treatment of stress urinary incontinence, and integrate guidelines into clinical management
- Enumerate the basic principles of urodynamic testing in women with pelvic organ prolapse, and integrate

guidelines into clinical management

• Incorporate the diagnosis and management of OAB, and integrate guidelines into treatment

Faculty

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CME Information

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Course #067IC: AUA/SUFU Guidelines 2017: Surgical Management of Female Stress Urinary Incontinence

Learning Objectives

At the conclusion of this CME activity, participants should be able to:

- Analyze the latest evidence on the management of female stress urinary incontinence as outlined in the AUA guidelines
- Improve the therapeutic decision making processes by illustrating the application of these guidelines in urological practice
- Acquire in-depth knowledge on the process by which evidence is used to develop scientifically rigorous, yet actionable, guidelines

Faculty

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Course #070IC: The Role of Sacral Neuromodulation in Urological Practice

Learning Objectives

At the conclusion of this CME activity, participants should be able to:

- Summarize the basic elements of sacral neuromodulation (SNM)
- Translate the theory of neuromodulation to the pathophysiology of voiding dysfunction
- Differentiate when SNM may be appropriate for patients in clinical practice
- Review new and potential future indications and weigh therapeutic alternatives
- Exemplify troubleshooting and best practice techniques

Faculty

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Course #074IC: The Practical Management of Overactive Bladder: Integrating the SUFU Overactive Bladder Clinical Care Pathway into Your Practice

Learning Objectives

At the conclusion of this CME activity, participants should be able to:

- Review the purpose of using clinical care pathways (CCPs) in the treatment of patients with overactive bladder
- Classify the steps along the SUFU Overactive Bladder Clinical Care Pathway
- Utilize the Clinical Care Pathway Modules to educate patients about their overactive bladder disease state
- Apply the CCP Modules for administering behavioral treatments, dietary modifications and pelvic floor exercises
- Employ the CCP and Roadmap to improve the quality and efficiency of care in the treatment of overactive bladder patients. This should include improving patient compliance with first line therapies, improving compliance and maintenance with drug therapy, help those patients who should consider more advanced or third line therapies, and minimize the number of patients who fail to meet their expectations

Faculty

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- Introduction of a debate format with an unbiased moderator (pointcounterpoint)
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COURSE #008IC

Botulinum Toxin: Why Use It, How to Do It, What are the Results?

Michael B. Chancellor, MD, Course Director

Injection of botulinum toxin (BoNT) into the bladder for the treatment of refractory overactive bladder (OAB) was a game changer when onabotulinumtoxinA (onaBoNTA) was approved by the FDA (Food and Drug Administration) in 2011 for the treatment of urinary incontinence due to detrusor overactivity associated with a neurological condition.1 It was only in 2013 that onaBoNTA was approved for the treatment of OAB with symptoms of urinary incontinence, urgency and frequency in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication.²

The approval of bladder BoNT injection ushered in a paradigm shift in the treatment of OAB. Anticholinergic drugs are the first line therapy for OAB and most physicians will try several different anticholinergics before moving on to another therapy. Yet anticholinergic drugs, as a class, have one of the lowest refill prescription rates. One study in which I participated showed that in the real world of clinical practice, less than 10% of patients still refill their anticholinergic prescriptions after 6 months.³ Cycling through 2, 3 and even up to 6 different anticholinergics did not fare any better.

In this AUA course we had a lively discussion on the practical aspects of the who, when and how of bladder botulinum toxin injection. The course included case studies, a video presentation and open dialogue with questions and answers.

Patient Preparation for Bladder BoNT Injection

Urinalysis should be checked at the time of the procedure (if the patient has a history of chronic bacteriuria, appropriate preoperative antibiotic coverage is indicated). Anticoagulation medicine should be stopped temporarily and informed consent obtained. The bladder should be empty and local anesthesia should be applied (1% lidocaine) with or without sedation. The bladder should be partially filled to approximately 150 to 200 ml for visualization but over distention should be avoided.

Injection Paradigm

For patients with neurogenic detrusor overactivity (NDO) the recommended dose is 200 U onaBoNTA, reconstituted in 30 ml sterile injectable saline. Volume per injection is 1 ml at a depth of approximately 2 mm intradetrusor at 30 sites spaced approximately 1 cm apart starting 1 cm above the trigone. For idiopathic OAB the recommended dose is 100 U onaBoNTA reconstituted in 10 ml saline and injected into 20 sites at 0.5 ml per site. Flexible and rigid cystoscopic techniques work well for BoNT injection. Surgeon preference and institutional practice usually affect the decision about technique (see Figure).

Flexible cystoscope. I use flexible cystoscopy in the office in the majority of men and women. The flexible scope accommodates a 27 gauge, 4 mm long flexible injection needle. Office procedures with only local anesthesia are adequate for most patients and they appreciate the convenience of an office procedure.

Rigid cystoscope. A rigid scope with a 12 or 30-degree lens bridged with an accessory working element loaded with a 25 gauge needle is recommended. The rigid scope allows for easier orientation within the bladder compared to a flex-ible cystoscope, the working element facilitates rapid injection into the bladder, and the 25 gauge needle minimizes bleeding and potential backflow from the injection sites.



Figure. onaBoNTA is administered via rigid or flexible cystoscopic techniques starting above trigone to depth of approximately 2 mm. Reprinted from Ginsberg D, Gousse A, Keppenne V et al: Phase 3 efficacy and tolerability study of onabotulinumtoxinA for urinary incontinence from neurogenic detrusor overactivity. J Urol 2012; 187: 2131.

Mixing the Toxin

Each vial of 100 U onaBoNTA comes in a 10 ml bottle. I do not reconstitute the toxin until I know that infection has been ruled out or an appropriate antibiotic has been started to avoid waste. The onaBoNTA vials should be stored in the refrigerator. After reconstitution, the vials may be stored in the refrigerator for up to 24 hours. Typical doses in adults treated with abobotulinumtoxinA or rimabotulinumtoxinB range between 500 and 1,000 U, and 2,500 and 15,000 U (ie 5,000 U is most common), respectively.

Post-Injection Followup Plan

I instruct patients that they may notice some pain and blood tinged urine, as well as possible difficulty urinating after treatment, which should resolve within 24 to 48 hours, but they should contact

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my office if they have any questions or concerns. I discuss the appropriate antibiotic coverage and risk of infection with the patients who often have bladder infections. It may take several days to notice a gradual improvement in OAB symptoms. Similarly, it generally takes several days for a patient to notice impaired voiding and I instruct that patient to start self-catheterization if clinically necessary. Office followup in about 2 weeks with urinalysis and post-void residual urine measurement is recommended.

How Long Does Bladder BoNT Effect Last?

It takes about 1 to 2 weeks for the patient to notice some relief of symptoms. If the injection helps, he or she will experience further improvement that usually reaches a maximal benefit at about 1 month. The beneficial effect is usually maintained for 6 to 9 months. Subsequently, urination or catheterization frequency starts to increase and incontinence recurs. I tell patients to look for these signs and to contact my office to schedule repeat injections. I wait 3 months before reinjections even if patients report partial improvement and request repeat injections sooner. One warning is not to inject more than a total of 400 U onaBoNTA in any part of the body in a 3-month period. This precaution is important if the patient is receiving BoNT injection by another physician to a different part of the body.

Subsequent Injection

For the majority of patients who notice a benefit with bladder BoNT therapy I use the same dose with repeat injections. Most neurologically impaired patients have had consistent improvement using the same dose for more than 15 years. If the patient finds benefit but incontinence did not adequately resolve with 100 U onaBoNTA, I may consider increasing the dose to 150 or 200 U onaBoNTA at the next injection. Alternatively, in patients with NDO who do not perform self-catheterization but have noticed retention or incomplete bladder emptying, I generally start at 100 U onaBoNTA. Dose titration is possible and helpful but in my experience the percentage of patients who will need dose adjustment up or down is small.

Risk of Antibody Formation

Failure to respond to BoNT injection might result from the presence of preexisting or formation of BoNT antibodies. The incidence of onaBoNTA antibody formation is only about 1%. I have not had a case of documented positive BoNT antibodies since I first used BoNT in 1998 and I generally perform the frontalis antibody test for clinical confirmation when a patient reports that BoNT is not working after previous successful injections.

What are the Results?

Neurogenic indication. A total of 691 patients with spinal cord injury or multiple sclerosis who had an inadequate response or were intolerant of 1 or more anticholinergic medications were enrolled in phase 3 studies.1 These patients were randomized to receive 200 U onaBoNTA (227 patients), 300 U onaBoNTA (223) or placebo (241). Significant improvement in the primary efficacy variable of change from baseline in weekly incontinence episode frequency was achieved with 200 U ona-BoNTA vs placebo. The 300 U doses were not better than 200 U but were associated with more side effects. Ona-BoNTA treatment was associated with significant improvements in maximal cystometric capacity of approximately 150 ml. Among patients who were not catheterizing at baseline before treatment, catheterization for retention was initiated in 30.6% after treatment with 200 U onaBoNTA vs 6.7% of those on placebo. The most frequently reported adverse reactions included urinary tract infection (24%) and retention (17%).

Idiopathic indication. Phase 3 studies demonstrated the safety and efficacy of

onaBoNTA in patients with refractory OAB symptoms.2 OnaBoNTA reduced the daily frequency of urinary leakage episodes from baseline by approximately 50% or more by week 12 compared to placebo. The efficacy of onaBoNTA in reducing urinary leakage and other OAB symptoms was up to 6 months in duration. Urination frequency and the amount of urine voided also improved with onaBoNTA treatment compared to placebo at week 12. The most common side effects reported with onaBoNTA were urinary tract infection (18% vs 6% with placebo), dysuria (9% vs 7% with placebo) and urinary retention (6% vs 0% with placebo) requiring clean intermittent catheterization. Urinary retention was more likely to develop in patients with diabetes mellitus treated with onaBoNTA.

Considerations for Safe Clinical Use of Botulinum Toxin

- A boxed warning is part of the prescribing information of botulinum toxin in the United States to highlight that BoNT may spread from the area of injection to produce systemic effects consistent with botulism.
- Symptoms such as unexpected loss of strength or muscle weakness, hoarseness or trouble talking (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing, double vision, blurred vision and drooping eyelids may occur.
- Understand that swallowing and breathing difficulties can be life threatening, and there have been reports of deaths related to the effect of spread of BoNT.
- Be aware that children treated for spasticity are at greatest risk for these symptoms but symptoms can also occur in adults treated for spasticity and other conditions.
- Realize that cases of toxin spread have occurred at BoNT doses comparable to those used to treat cervi-

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cal dystonia and at lower doses.

• The doses expressed in units are not comparable from one BoNT product to the next.

OAB Guideline

In 2015 the highly respected and widely referenced AUA/SUFU (Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction) guideline on the diagnosis and treatment of OAB integrated BoNT into their OAB treatment flow chart.⁴ Guideline Statement 17 noted "Clinicians may offer intradetrusor onaBoNTA (100 U) as thirdline treatment in the carefully-selected and thoroughly-counseled patient who has been refractory to first- and second-line OAB treatments. The patient must be able and willing to return for frequent post-void residual evaluation and able and willing to perform self-catheterization if necessary" (Standard; Evidence Strength: Grade B). The Guideline Panel upgraded intradetrusor onaBoNTA treatment from an option to

a standard. The Panel noted that the use of all third line therapies requires careful patient selection and appropriate patient counseling.

The Amazing Science of Botulinum Toxin

During the last 30 years medical science has developed the world's most potent medicine from the world's most potent toxin. The science of how BoNT works is amazing and the world knows it. Professor James E. Rothman at Yale University was awarded the 2013 Nobel Prize in Physiology or Medicine for his work on how vesicular trafficking and SNARE proteins underlie BoNT mechanism of action.

A decade ago Chris Smith and I wrote the first review on the emerging role of botulinum toxin in *The Journal* of Urology^{®.5} The science of the toxin was just beginning to be explored in the urinary tract. In a decade, not only has BoNT obtained FDA approval but it has proven itself as a go-to option for

refractory OAB. I believe we will see more advances over the next decade and greater adoption of botulinum toxin in urology, such as new toxins and better delivery methods. One cannot deny the ingenuity of medical science in transforming the most lethal toxin of C. botulinum into a modern-day therapeutic wonder.

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COURSE #026IC

Contemporary Pharmacotherapy for OAB

Eric S. Rovner, MD, Course Director; Christopher R. Chapple, BSc, MD, FRCS (Urol), FEBU and Alan J. Wein, MD, PhD (hon), FACS, Faculty

This 2-hour course at the AUA annual meeting provided an update on various aspects of oral drug therapy for overactive bladder (OAB). Topics covered included the physiological and pharmacological foundations for OAB drug therapy, and appropriate use of current OAB agents alone and in combination, as well as a discussion of compounds in development.

Patient expectations were discussed as they relate to efficacy and adverse effects. It is, of course, very important to provide accurate and realistic expectations of outcomes with OAB pharmacotherapy. There are many "measuring tools" for setting such expectations and goals including diary parameters, dry rates and patient reported outcome measures. Recently, self-reported and selfdetermined outcome measures wherein the patient chooses his/her own goals for OAB pharmacotherapy have emerged. Such assessments are easily applied to the clinic and may provide an alternative method of measuring outcomes on an individual basis not only for OAB pharmacotherapy but also for a variety of other pelvic floor conditions.

Guideline documents published by the AUA/SUFU (Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction) as well as the EAU (European Association of Urology) were reviewed and summarized. Although a different process was used to formulate each guideline document, the evidence basis and conclusions were quite similar across a number of aspects of the diagnosis and treatment of OAB.

The latest recommendations from the soon to be published proceedings of the 2016 6th ICI (International Consultation on Incontinence) meeting were also reviewed and summarized. Grade A recommendations were given for tolterodine, fesoterodine, solifenacin, oxybutynin, propiverine and trospium among others. Overall there was agreement that there is no clear superiority for one of the Grade A antimuscarinic drugs over another with respect to cure or improvement of urgency urinary incontinence. The beta-3 agonist mirabegron was likewise given a Grade A recommendation based on good levels of evidence.

The lower urinary tract is a complex organ. Prof. Chapple reviewed many of these issues in depth with respect to

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the treatment of OAB. There is a close interaction between the afferent and efferent systems under the influence of which the effector organ, the detrusor muscle, is responsible for the storage of urine at low pressure, and its efficient voiding at a convenient time and place. Disorders of the lower urinary tract can result from dysfunction at a number of levels, either peripherally affecting the sensory or motor innervation or the detrusor muscle, or at the level of the central nervous system within the spinal cord or cerebral cortex.

It is now clearly established that sensory mechanisms are important in the genesis of normal bladder function, and disorders of innervation and function of the detrusor muscle can lead to significant lower urinary tract dysfunction. There continues to be emerging evidence regarding the importance of the afferent pathways in the pathogenesis of OAB as well as the modulation of these pathways in its treatment.

It is essential to evaluate the evidence base when considering the treatment of storage symptoms affecting the lower urinary tract, and in particular incontinence. Prof. Chapple drew heavily on work from the Cochrane Collaboration, the International Consultation on Urological Disease and the recent EAU guidelines. The evidence base relating to investigative techniques, conservative management and interventional pharmacotherapy were reviewed in detail.

The overactive bladder as described several years ago represents a storage symptom complex characterized by the symptom of urgency. It occurs with increasing prevalence in parallel with increasing age in the population. The normal sensory and motor control mechanisms under which the bladder works underscore the potential for pharmacotherapeutic modulation of lower urinary tract function with reference to existing drug therapy, including anticholinergics, the beta-3 agonist mirabegron and onabotulinumtoxinA. Anticholinergic therapy has been used for many years, and the evidence base relating

to this is critical in understanding what these drugs can and cannot do.

Dr. Wein discussed potential management strategies for overactive bladder/ detrusor overactivity. He reviewed the current evidence base for the available drugs with respect to efficacy, tolerability and safety in the general population, as well as in men, the elderly and the neurogenic population. The rationale for the use of antimuscarinics was discussed as well as the typical results to be expected from antimuscarinics in terms of urgency urinary incontinence reduction, urgency reduction and changes in quality of life assessments.

Adverse events were discussed in terms of dry mouth, constipation, possible cardiac side effects and the potential for long-term cognitive side effects in the elderly. This last issue was highlighted in the scientific and lay press 2 years ago and there was little additional information published in the last year. Overall, long-term persistence/adherence with these medications remains problematic, and the rates of long-term compliance at 6 and 12 months appear to be historically and comparatively inferior to many other therapeutic areas. The efficacy of combined behavioral and drug therapy for urgency urinary incontinence over the efficacy achieved with either alone was discussed. The ICI recommendations for the treatment of lower urinary tract symptoms with alpha1-adrenergic receptor antagonists were reviewed as well.

Mechanisms to decrease nocturia were presented, as were the outcomes and the results of treatment with various antimuscarinic agents for this indication. The results were discussed with reference to why failure is the most common outcome with antimuscarinics or beta-3 agonists for the indication of nocturia. To date, none of the currently available OAB pharmacological agents carries an additional indication for nocturia. However, a new formulation of DDAVP (desmopressin acetate), Noctiva[™], was approved by the FDA (Food and Drug Administration) in March 2017 for the treatment of nocturia in association with nocturnal polyuria. This is the first compound approved by the FDA for this indication. It is administered via a metered nasal spray before bedtime.

The subject of combination therapy for a variety of lower urinary tract functional conditions is clearly topical and carries with it the potential for introducing the therapeutic benefit with any individual agent, but as a downside it introduces the side effect profile seen with any specific agent. This needs to be understood with reference to existing therapies for the management of lower urinary tract symptoms in males and females. The potential roles of combination therapies are legion, and include hormonal agents, combination therapy with beta-3 agonists and antimuscarinics, the potential for management of storage symptoms in the male by adding botulinum toxin and other toxins, and combinations of alpha blockers + 5-alpha reductase inhibitors, alpha blockers + antimuscarinics and the use of phosphodiesterase type 5 inhibitors potentially coupled with alpha blocker therapy or 5-alpha reductase inhibitors.

Finally, Dr. Wein presented the possibilities for future pharmacological therapy for overactive bladder, reviewing the potential sites of action centrally and peripherally. Potential management strategies were discussed as well as the main problem, which is always uroselectivity. Emerging antimuscarinics and beta-3 adrenoceptor agonists were presented. Negative findings or comments regarding potassium channel openers, calcium channel antagonists and prostanoid receptor antagonists were presented. Some "positive" results were discussed with respect to duloxetine, cyclooxygenase inhibitors, vitamin D-3 agonists and neurokinin receptor antagonists. Promising animal data with respect to GABAB receptor agonists and purinergic receptor antagonists were described as well as for cannabinoid agonists and transient receptor potential antagonists.

COURSE #033IC

Foundations of Female Urology

J. Christian Winters, MD, FACS, Course Director; Stephen R. Kraus, MD, MS, FACS and Nirit Rosenblum, MD, Faculty

This interactive course was designed to provide the practitioner with an introduction to the specialty of female urology. Session 1 was devoted to urodynamic testing in women and stress urinary incontinence (SUI), session 2 focused on pelvic organ prolapse (POP) and session 3 included lectures on overactive bladder (OAB) guidelines. Case scenarios and urodynamic assessments of these conditions were presented.

The course began with an overview of urodynamic testing in women by Dr. Kraus. The importance of adhering to good urodynamic practice was emphasized, specifically formulating the urodynamic questions before the study. The clinician should have an idea of precisely what data are needed from the urodynamic examination based on the history and physical examination as well as other ancillary tests.

Proper urodynamic technique, patient positioning, zeroing the transducers to atmospheric pressure and measuring the leak point pressures correctly were reviewed. When zeroing the transducers to the atmospheric pressure, the transducers are placed at the level of the pubic symphysis and the tubing is "zero" calibrated to atmospheric pressure before connecting to the urodynamic catheters. With this technique the baseline abdominal and intravesical pressures are never zero. The urodynamic findings of poor compliance were reviewed and differentiated between abdominal and Valsalva leak point pressures. Examples of each were demonstrated along with how SUI is diagnosed and characterized by the abdominal leak point pressure. An overview of the pertinent AUA guidelines on

adult urodynamics was presented.

Dr. Rosenblum followed with a discussion of the pathophysiology and treatment of SUI, providing great detail about the anatomy of urethral support. Defects in urethral support may lead to urethral hypermobility and predispose to SUI. However, not all women with hypermobility experience urine leak and it appears that any woman with SUI must have some degree of intrinsic sphincter deficiency. The standard evaluation of history and physical examination, stress test, urinalysis, postvoid residual and assessment of bother was outlined for the audience.

The "acceptable" surgical procedures for SUI were reviewed, which include retropubic suspension, pubovaginal sling, mid urethral sling (MUS) and urethral injection therapy. The decreasing numbers of Burch procedures being done was noted, but it was reaffirmed that in women with urethral hypermobility undergoing abdominal surgery these operations may still be performed successfully. However, most in the audience agreed that even in this setting they would still proceed to MUS, and the best outcomes data in the surgical management of SUI are for sling procedures. Slings have the highest degree of efficacy but it must be noted that MUS procedures have efficacy similar to that of the pubovaginal sling with less perioperative morbidity.

Many in the audience remain concerned about the controversy surrounding the MUS, and the entire faculty noted their preferential use of the retropubic MUS. It was also pointed out that use of the sling is highly recommended by SUFU (the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction), the AUA and many other subspecialty societies involved in female pelvic surgery.

Dr. Winters reviewed normal pelvic anatomy and defined the various defects creating the prolapse conditions that physicians most commonly treat. The etiology of POP is multifactorial, ranging from childbirth to disorders of connective tissue. The commonly performed prolapse procedures and vaginal support defects they correct were illustrated. The importance of the apex in vaginal support was noted, and it was emphasized that when present, apical support defects must be corrected to achieve successful outcomes.

The course also included lectures on OAB and its management. The AUA/ SUFU guideline on the evaluation and management of OAB was reviewed, and it was stressed that in most uncomplicated cases, proceeding to first and/or second line therapies is preferred over urodynamics and more extensive evaluation methods. Dr. Kraus reviewed the recently completed SUFU Clinical Care Pathway for OAB and described the resources available for practices.

To conclude, participants were guided through various clinical scenarios in the area of female urology. A question and answer period completed this dynamic and highly interactive session, which was designed to provide participants with an introduction to the principles and practice of female urology.

COURSE #0671C

AUA/SUFU Guidelines 2017: Surgical Management of Female Stress Urinary Incontinence

Kathleen C. Kobashi, MD, Course Director; Gary Lemack, MD, Faculty

Overview

Female stress urinary incontinence (SUI) is an extremely common condition that can have a tremendous negative impact on the quality of life (QOL) of patients and their family and friends. As such, SUI is an important issue to properly address for our patients. Accordingly, the AUA and SUFU (Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction) partnered to sponsor an update on the female SUI guidelines.

This instructional course reviewed the methodology and the thought process of the Panel in the construction of these guidelines. Several components of this third iteration reflected the evolution of the field, and newer approaches to evaluation, treatment and outcomes assessment. The Panel also projected potential directions for the future and acknowledged the expectation for continued guidelines updates.

Guidelines Process

The course opened with a review of the standardized methodology currently applied to all AUA guidelines to produce evidence-based statements. A comprehensive literature search from January 2005 to December 2015 was performed. In order to include the most updated information an additional abstract search was performed though September 2016. Many study designs were included in the literature reviewed, and based on the level of evidence (LOE) available, Strong, Moderate or Conditional Recommendations were assigned a strength rating of A, B or C, pertaining to high, moderate or low, respectively. If the data were insufficient, statements were categorized as Clinical Principle or Expert Opinion.

Thought process. The course faculty felt it relevant to explain the issues the Panel considered as they decided on the optimal manner in which to organize the guidelines. Since the earlier iterations of the guidelines in 1997 and 2007, the field has continued to advance and change in a variety of ways, not the least of which has been the increasing complexity of cases and clinical scenarios that are encountered by clinicians in practice today. This is a result of the growing awareness of pelvic floor disorders and the consequent increase in patients being treated for them, and also that more patients now present having undergone previous intervention. Therefore, the Panel considered the guidelines in the context of index vs nonindex patients.

Evolution of thinking. The Panel was intent on contributing to the future improvement of care of patients with SUI. Subsequently, the Panel made specific mention of the importance of honing outcomes assessment, including subjective variables and degree of bother, uniformity of definitions, and multiinstitutional collaboration. Taking into account the rapid evolution of the field, the Panel acknowledged the anticipated need for the guidelines to be continually updated.

Guidelines categorization. The index patient was defined as a healthy patient with SUI and minimal or no pelvic organ prolapse (POP) who has not undergone pelvic reconstructive surgery and who is seeking treatment for SUI. Conversely, the nonindex patient was defined as a patient with SUI who is seeking treatment and who has any of a number of additional issues, such as high grade POP, neurological disease, previous pelvic floor surgery, or symptoms that include obstructive or dysfunctional voiding or mixed urinary incontinence (MUI) with a significant urgency component. Patients with high body mass index or advanced age were also considered in this category. The Panel also took care to organize the statements in a logical order, proceeding from evaluation, treatment and counseling to outcomes assessment, followup and future directions.

Guidelines Statements

The faculty proceeded to review the 24 Guidelines Statements authored by the Panel and their category and strength rating per available literature.

Evaluation (Statements 1-3). Patients' initial evaluation should include a detailed history and physical examination, including objective demonstration of SUI, and a urinalysis and post-void residual measurement, which was a Clinical Principle. Two Expert Opinion statements suggested additional evaluation only in specific situations. Some latitude was afforded to the clinician with patients with failure of prior SUI or POP surgery, or concomitant overactive bladder symptoms. On the other hand, the Panel felt that patients with incomplete emptying, high grade POP, urgency-predominant MUI, neurological disease, voiding dysfunction or abnormal urinalysis, and patients in whom the diagnosis was unable to be confirmed on initial evaluation, should undergo further evaluation.

Further evaluation: cystoscopy and urodynamics (Statements 4-6). It was deemed a Clinical Principle that index patients should not undergo cystoscopy unless there is concern for urinary tract abnormalities. In terms of urodynamics, the recommendation varied depending on whether it was an index or nonindex patient. Based largely on the VaLUE

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(Value of Urodynamic Evaluation) trial, a large multicenter randomized controlled trial that demonstrated no difference in clinical outcome in index patients who underwent treatment following office based evaluation with or without urodynamics, a Conditional Recommendation with LOE B stated that urodynamics may be omitted in the index patient in whom SUI is demonstrated. However, Expert Opinion stated that nonindex patients, and patients in whom there is a mismatch between subjective symptoms and objective findings may undergo urodynamics at the discretion of the clinician.

Counseling (Statements 7-10). In the current climate of mesh related issues, the Panel wanted to emphasize the importance of careful counseling of patients. Given the impact that SUI can have on QOL, the Panel highlighted the issue of bother, constructing an Expert Opinion that the degree of bother that the symptoms cause patients should be considered in their decision to pursue treatment.

Three Clinical Principles followed regarding the necessity of providing patients with SUI or stress-predominant MUI with all potential options including observation, nonsurgical treatments such as pelvic floor exercises, and surgery, as well as the importance of counseling patients on potential complications specific to each of these options. The Panel penned a purposefully separate statement regarding the imperative nature of a detailed discussion specific to the risks, benefits and alternatives of mesh with patients considering a mid urethral mesh sling. Mention of the Food and Drug Administration safety communication was underscored as part of the counseling that would provide patients with the information necessary to make a proper informed decision.

Treatment (Statements 11-16). It was Expert Opinion that nonsurgical options, such as incontinence pessaries, vaginal inserts and pelvic floor exercises may be offered to patients. However, surgical interventions had evidence to support their consideration as a Strong Recommendation with a LOE A. These options include urethral bulking injection, synthetic mid urethral sling (MUS) via a variety of approaches, autologous pubovaginal sling (PVS), and Burch colposuspension.

The MUS can be performed via a topdown or bottom-up retropubic, or an in-out or out-in transobturator approach per Moderate Recommendation, LOE A. The choice of approach should be surgeon preference, with a large systematic review of 55 reports suggesting no difference in outcome between the retropubic MUS and transobturator MUS. Single incision slings were permitted as an option contingent upon patients being informed of the relative immaturity of the data.

The Panel was clear that a mesh MUS should not be performed in the face of a urethral injury (Clinical Principle). If a sling is performed in this clinical scenario it should be composed of a nonsynthetic material. Finally, at this time it is Expert Opinion that stem cells should not be used to treat SUI outside the context of investigative protocols.

Special Cases (Statements 17-22). Patients with a fixed urethra who wish to undergo treatment should be offered a PVS, retropubic MUS or injection therapy (Expert Opinion). However, mesh should not be used in patients undergoing any procedure that disrupts the urethra such as diverticulectomy or urethrovaginal fistula repair (Clinical Principle), and should be avoided in patients with poor tissue healing, such as after radiation therapy. Patients undergoing concomitant SUI and POP surgery can receive MUS, Burch colposuspension or PVS. Similarly, patients with neurological disease affecting the lower urinary tract, advanced age, high body mass index, diabetes, or of childbearing age may undergo anti-incontinence procedures following proper evaluation and counseling (Expert Opinion).

Outcomes (Statements 23-24). The Panel established general parameters around postoperative followup of patients, and provided 2 Expert Opinion statements, 1) recommending communication in the early postoperative period such that patients with any concerns can be evaluated as necessary, and 2) at least 1 followup visit within 6 months. Patients should be asked about subjective symptoms including pain, continence and emptying ability, and should undergo a physical/pelvic examination and postvoid residual check.

Future Directions

There are numerous opportunities on the horizon to advance this field. Optimizing patient education is of paramount importance, particularly in elective treatment of QOL issues. Patients who understand the rationale behind their treatments are more satisfied with their outcomes. Telemedicine has great potential, particularly for patients who choose nonsurgical treatment options. Finally, tissue engineering and stem cells are certain to have a role in the treatment of SUI.

As we move forward, multidisciplinary approaches to pelvic floor disorders, with the common goals of enhancing patient outcomes while maintaining the balance between efficacy and safety, will continue to drive our field.

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COURSE #070IC

The Role of Sacral Neuromodulation in Urological Practice

Steven W. Siegel, MD, Course Director

Patients with an overactive bladder (OAB) related diagnosis comprise a large percentage of visits to the general urology practice. The routine use of an overactive bladder Care Pathway can be helpful in giving our patients a map and an overview of care options. These parallel the AUA guidelines, and indicate basic and advanced management options along with anticipated timing of response and triggers for moving on to other options when progress is insufficient. Our practice uses one with each patient encounter, which is annotated to document where the patient stands as we attempt to gain sufficient clinical benefit (fig. 1).

Many patients do not experience sufficient improvement with behavioral and/ or drug treatments, which comprise first and second line therapies according to the guidelines. There is a high discontinuation rate noted among patients treated with anticholinergic agents, primarily due to incomplete symptom control balanced against cost and side effects such as dry mouth and constipation. Younger patients are especially likely to find drugs intolerable for these reasons. A beta-3 agonist is a medication alternative that will help some patients. Surprisingly, we have found that a small percentage of our patients (13%) in a large group practice receive anything other



Don't be frustrated; all therapies do not work for every person. But, together we can discover the treatment that works for you.

Figure 1.

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than medications for OAB complaints, and an even smaller group (6.5%) goes on to advanced treatment or third line therapy.

Third Line Therapies

An increasing number of options can be used as a complement or alternative to behavioral and drug therapies, such as sacral neuromodulation (SNM), percutaneous tibial neuromodulation (PTNM) and intradetrusor botulinum toxin (BoNT). Which one to choose? I use all of them depending on the situation. This course presumes the more conservative or first and second line options have been insufficient. Use and outcomes of SNM in patients who do not respond adequately, and the positioning of SNM relative to PTNM and BoNT are discussed.

Sacral Neuromodulation

SNM involves chronic modulation of S3 and, less frequently, S4 via a transforaminal route. Modulation implies the therapy is thought to act indirectly via a central afferent mechanism, targeting reflex centers in the spinal cord and pons, and influencing reflexes among the bladder, urethral sphincter and pelvic floor. Stimulation implies a more direct effect on efferent motor neurons as in functional electrical stimulation.

The therapy, marketed internationally as InterStimTM, uses an implantable system including a lead electrode and an implantable neurostimulator (INS). There is typically a trial or screening phase using a percutaneous lead lasting for 3 to 7 days (percutaneous nerve evaluation) or a staged lead implant when a chronic lead is implanted surgically. The therapy may be trialed for up to several weeks and, if successful, the lead may then be converted for long-term use by connecting it to an INS.

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Present and Future Indications for SNM

The FDA (U.S. Food and Drug Administration) approved SNM for patients with refractory OAB and idiopathic, nonobstructive urinary retention (NOUR). SNM is also approved for fecal incontinence (FI). It may be successfully used for OAB and NOUR since it is not a bladder specific therapy and works at a central level on the "on-off" switch for pelvic reflexes. While FDA labeling stipulates SNM is only approved for cases of nonneurogenic bladder, those with a neurogenic basis of complaints have been successfully treated and reported in the literature.

Many of our patients with refractory urinary complaints also have significant and disabling bowel complaints, and the selection of SNM is likely to have a beneficial effect on both conditions. These effects are not limited to FI, but also include fecal urgency and frequency, constipation/anismus and dyschezia. Thus, the benefits of therapy should be appropriately weighed against intradetrusor BoNT for this potential in patients with relevant gastrointestinal symptoms.

Therapeutic Efficacy and Complications

Recent publication of the InSite trial revealed SNM to be superior to anticholinergics after an inadequate response to 2 drugs, and at 12 months it remained safe and effective. There have been hundreds of other publications in the peer reviewed literature regarding SNM. In general, randomized controlled trials/ case series indicate an approximately 80%/70% success rate, defined by at least a 50% decrease in relevant voiding parameters. Studies also demonstrate significant improvement in quality of life, decreased use and cost of therapeutic alternatives, and long-term benefit. These results were underscored by the 5-year InSite study data, demonstrating OAB therapeutic success in 82% of



OAB response was defined as either ≥50% improvement in leaks/day for UI subjects or ≥50% improvement in voids/day or a return to normal voiding



UF response was defined as ≥50% improvement in voids/day or a return to normal voiding frequency (<8 voids/day)



UI response was defined as \geq 50% improvement in leaks/day



OABqol - Improvement from baseline over time

Figure 2. 60-Month InSite study showing OAB therapeutic success rate over time.

patients at 60 months (fig. 2). The benefits involving quality of life were also dramatic and maintained.

The degree of improvement, even among the patients with the most severe baseline symptoms, has been shown to be greater than among those successfully treated in OAB drug trials (based on package inserts/FDA submitted trials). Similarly, the degree of improvement seen in patients treated with PTNM appears to be about half as much as in those who are less symptomatic initially. Randomized head-to-head trials have not been reported.

SNM vs BoNT or PTNM

Much discussion has been focused on the relative merits of intradetrusor BoNT vs SNM in urological patients. I use both in my practice, and believe that the therapies have different strengths and weaknesses which should be considered in discussions with patients (Appendix 1). In general, patients with significant bowel symptoms, pelvic pain and NOUR are more likely to benefit from SNM, while elderly patients, those with progressive neurogenic bladder disease, those likely to need body magnetic resonance imaging (MRI), or those in whom a trial of SNM has failed are more ideally suited for BoNT.

Unlike BoNT, there is likely to be a benefit from SNM and PTNM for bowel symptoms. Patients with demonstrable detrusor overactivity on urodynamic study, including those with more severe symptoms, are likely to experience a greater benefit from SNM than PTNM. Equivalent long-term efficacy of PTNM vs SNM has not been demonstrated, and there has not been a study conclusively indicating that the outcome of PTNM predicts the outcome of SNM. Of course, patient preference is paramount in choosing among these options.

Troubleshooting SNM

Typical problems encountered with SNM are summarized in Appendix 2. Recent studies have demonstrated a reoperation risk due to complications of less than 20% using modern techniques. There are several troubleshooting tips for dealing with common dilemmas.

Infection prevention. In a recent multicenter study the rate of infection of SNM devices was 3.4%. Perioperative

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antibiotics, similar to those used with orthopedic prosthetics, are a must. A Sage® cloth is used to wipe the skin preoperatively. Patients shower preoperatively with Hibiclens®, and alcohol and Duraprep[™] are used intraoperatively. Other intraoperative considerations include the use of an Ioban[™] drape, making sure the incision is sufficiently deep, the lead extension tunnel is as long as possible during a staged trial and the excess lead is handled in a way to allow normal apposition of subcutaneous tissues. Evidence of a chronic, draining sinus is typically associated with implant infection. Once infection is obvious, all implanted components and the surrounding capsule must be removed, and incisions are allowed to heal (usually 3 months) before reimplantation, if elected.

Lead problems. Lead migration or lead fracture can cause decreasing efficacy. A fall or trauma is often responsible for these issues. Impedances greater than 4,000 Ω at 1 or more sites are indicative of fracture, while less than 50 Ω or equalization of impedances implies fluid in a connection site. Anteroposterior and lateral sacral films can be helpful in identifying these issues. While lead migration is rare, forward migration can occur in thin patients who had a "knuckle" of lead in the presacral area. Care to lay the lead down flat beneath the skin (by making a larger than normal or a "skipping" incision) can prevent this complication.

Pain at INS site. Making a deep pocket parallel to the skin surface, just large enough to fit the device, and with careful hemostasis, can be helpful in avoiding INS pain. It is important to place the device below the posterior superior iliac crest and lateral to the sacral edge to prevent direct compression over bone.

Pregnancy. While there is no direct evidence of problems from SNM during pregnancy, it is recommended that the device be turned off throughout term or as soon as pregnancy is known. Some patients may refuse because of the return of severe symptoms. In general, limiting use during the first trimester and turning down stimulation levels are prudent steps. I believe an elective cesarean section should be considered by patients treated with SNM who have demonstrated pelvic floor hypertonus.

MRI with SNM. Most patients with intact systems using InterStim II INS can undergo MRI of the head or extremities

Appendix 2

only when using a send and receive MRI coil. The current SNM devices are not fully MRI compliant and axial MRI remains contraindicated. It is the lead and not the generator that represents the greatest risk to the patient during these studies. A connected lead is safer than a disconnected lead. Care should be taken to remove the entire lead when necessary and patients should be informed of retained leads. Careful counseling and informed consent are needed if MRI is considered for patients treated with SNM.

Conclusions

Urologists commonly care for patients with drug refractory voiding complaints. First line alternatives include behavioral therapy, biofeedback and physical therapy. Other options including SNM, PTNM and intradetrusor BoNT are important considerations for optimal benefit. The techniques, patient selection guidelines and troubleshooting measures discussed should help achieve a successful outcome.

Appendix 1

Neuromodulation Neurotoxin **Common Problems Restores function** Takes it away Lack of or declining efficacy Causes it Wound complications/infection **Treats retention** Painful stimulation Improves GI symptoms No potential Pain at IPG site Commits to 6-9 mo **WYSIWYG** Need for MRI **9** months before SNM Use BoNT if fails Pregnancy Long term benefit Temporary Retained lead remnant Infrequent reoperation Frequent retreatment

COURSE #074IC

The Practical Management of Overactive Bladder: Integrating the SUFU Overactive Bladder Clinical Care Pathway into Your Practice

Benjamin M. Brucker, MD, Course Director; Stephen R. Kraus, MD, MS, FACS and Diane K. Newman, DNP, ANP-BC, FAAN, Faculty

This course debuted at AUA2017 and was centered around the work that SUFU (the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction) has put into developing an unbiased, evidence and expert option based clinical care pathway (CCP) and supporting materials that are meant to help clinicians treat patients with overactive bladder (OAB).

Course faculty Dr. Stephen Kraus introduced the disease state of OAB, explaining how prevalent the condition is. He explored the current state of evaluation and treatment by reviewing the AUA/SUFU guidelines statement on overactive bladder. This document served as a launching point for the SUFU OAB CCP, but he explained how this guideline is not created to use day to day with patients.

Dr. Benjamin Brucker expanded on the need to create standardized, unbiased, evidence-based clinical care pathways to help treat patients with OAB. He looked at the current state of overactive bladder management and revealed alarming numbers of how few patients with this chronic condition are getting the treatment they seek.

The course also addressed the abysmal penetration of third line therapies, estimated to be about 4%. This may put specialists in a difficult spot as we are unable to distinguish ourselves (provide better efficacy and/or patient satisfaction) from primary care providers. The SUFU OAB CCP is a tool that can help guide patients to effective therapies and hopefully meaningful lasting symptom improvement. Another use is to inform primary care providers that referral may be necessary to ensure that patients can access effective advanced therapies.

The SUFU OAB CCP is also unique

because it was developed with a Patient Road Map. This is a turn-by-turn instruction guide to help patients navigate the SUFU OAB CCP and the path to effective therapy. Dr. Kraus, who led the SUFU committee (see Appendix) that was responsible for creating this CCP, introduced the need for the Road Map, by recounting a story of the patient who sought help from a urologist but ended up stopping the prescribed medication because of side effects. He also explored the scenario of patient isolation because of suboptimal improvement. These stories gave the attendees an understanding of what inspired the project and how to integrate the Road Map into practice.

Dr. Diane Newman lent her expertise to this CCP project, spearheading the modules on bladder function and conservative therapies. In her lectures she explained that less than a third of patients with OAB are offered behavioral management options. This was an eye-opening statistic, emphasizing the need for more help with the conservative management of OAB. She stressed the need to educate patients about basic bladder function and dysfunction, appropriate fluid and food consumption, good bladder habits, urge suppression techniques and pelvic floor muscle training. All of this information and the supporting modules to complement the OAB CCP can be found at http://sufuorg.com/resources/overactivebladder-ccp.aspx.

The course also laid out the future steps of the SUFU OAB CCP project. The committee will develop a patient medication tool. This module will help patients manage the potential side effects of oral therapy with the hope of improving adherence and efficacy. Dr. Kraus also suggested that a smartphone app may be able to give patients information about their condition and track their progress.

Audience response questions and case presentations were used to demonstrate the integration of the new clinical care pathway and associated support material into practice. These included cases like that of a 62-year-old female with frequency and urgency incontinence who had modified her fluid intake and started pelvic floor exercises, but felt as though she was inadequately treated. She then realized she should ask about oral medication and received a prescription. She became frustrated with her care because she believed the medication lacked efficacy and was causing side effects. She consulted her Patient Road Map and SUFU OAB CPP, and set up a followup appointment to ask about another medication. It was clear to her now that if she was not better after a 4 to 8-week trial of one medication, it might be time to talk to her provider about adjusting the dose or trying another medication. This case underscored how empowering patients can be very effective.

Other cases highlighted the SUFU OAB CCP information about third line therapies (Botox[®], InterStim[®], NURO[™] percutaneous tibial neuromodulation, Urgent[®] PC). The course detailed much of the guidance and practical detail provided by the SUFU OAB CCP compared to the more rigid format of a clinical guideline.

The course also reviewed the role, importance and training opportunities that exist for advanced practice providers. Dr. Newman suggested learning opportunities with preceptorships, lectures, conferences and SUNA (Society of Urologic Nurses and Associates) and

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AUA curriculums.

Finally, Dr. Brucker presented practical tips about educating office and support staff to successfully implement and use the SUFU OAB CCP. The SUFU OAB Clinical Care Pathway and supporting road map and patient education materials can be accessed at http://sufuorg.com/resources/overactive-bladderccp.aspx. Appendix. The SUFU OAB CCP committee included Greg Bales, Benjamin Brucker, Kathleen Burgio, Craig Comiter, Christopher Elliott, Christopher Gomez, Angela Gousse, Stephen Kraus, Arthur Mourtzinos, Diane Newman and Stuart Reynolds, with support from Heather Swanson-SUFU Executive Director and guidance from the SUFU Executive Board. Funding was provided by unrestricted grants from Medtronic, Allergan and Astellas.

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