Adventures in UroGyne: Updates in Urinary Incontinence

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DISCLOSURES

- Juniper BioMedical Medical Advisory Board
- Aqua Therapeutics Scientific Advisory Board
- Origyn Solutions Clinical Advisory Board
- Esch Holdings, LLC Consultant
- FemTherapeutics Consultant
- ABOG General Gyn and Urogynecology board examiner; travel honoraria
- Defense Expert Witness for Medical Malpractice (General Gyn and Urogyne)



OBJECTIVES

- 1. Definition (SUI and OAB)
- 2. Etiology and Pathophysiology
- 3. Evaluation and Diagnosis
- 4. Treatment Options
 - a. Conservative Management
 - a. Pharmacologic Treatments
 - b. Efficacy and side effects
 - b. Surgical Therapies



Normal Micturition

Continence

• Intact micturition physiology and an intact functional ability to toilet oneself

• Sources of Control

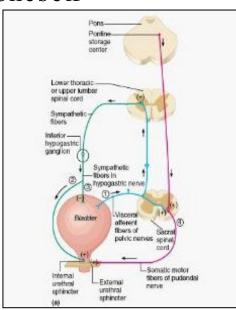
- Higher cortex of the brain, pons, spinal cord
- Peripheral autonomic, somatic, sensory afferent innervation
- Anatomical components of the lower urinary tract.

• Bladder is a "compliant balloon"

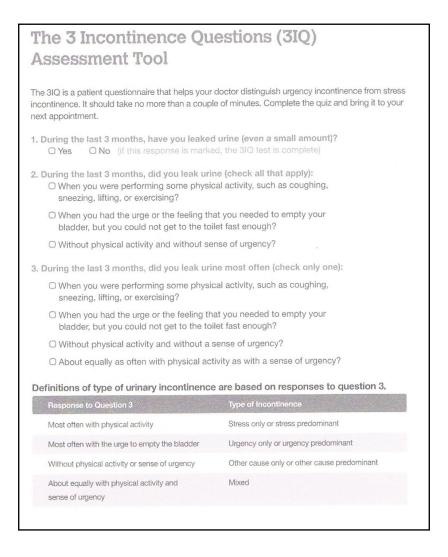
• As it fills, the pressure remains lower than urethral resistance.

Normal urination

• Urethral resistance decreases and a phasic contraction of the detrusor muscle empties the bladder



Urinary Incontinence



Differential Diagnosis - Urinary Incontinence

Genitourinary etiology

- Filling and storage disorders
 - Urodynamic stress incontinence
 - Detrusor overactivity (idiopathic)
 - Detrusor overactivity (neurogenic)
 - Mixed types
- Fistula
 - Vesical
 - Ureteral
 - Urethral
- Congenital
 - Ectopic ureter
 - (Epispadias)

Non-genitourinary etiology

- Functional
 - Neurologic
 - Cognitive
 - Psychologic
 - Physical impairment
- Environmental
 - Behavioral
- Pharmacologic
- Metabolic

Risk Factors

- Age
- White
- Post-menopausal status
- Obesity
- Smoking
- Medical comorbidities
 - Diabetes
 - Sleep apnea

- Cognitive impairment
- Nerve damage
 - Spinal cord injury
 - Cerebrovascular accident
 - Multiple sclerosis

Factors to consider and rule out

- Infection / Inflammation
 - Recurrent Urinary Tract Infection
 - "Interstitial Cystitis" / Painful Bladder Syndrome
- Bladder outlet obstruction
 - Urethral Stricture

- Bladder pathology
 - Bladder cancer
 - Bladder stones
- Behavior / Iatrogenic
 - Diures is due to excessive fluid intake
 - Impaired urine concentration
 - Medications

Other Considerations

Medications that affect lower urinary tract (LUT) function

Type of Medication	LUTEffects
Diuretics	Polyuria, frequency, urgency
Caffeine	Frequency, urgency
Alcohol	Sedation, impaired mobility, diures is
Narcotic analgesics	Urinary retention, fecal impaction, sedation, delirium
Anticholinergic agents	Urinary retention, voiding difficulty
Antihistamines	Anticholinergic actions, sedation
Psychotropic agents Antidepressants Antipsychotics Sedatives and hypnotics	Anticholinergic actions, sedation Anticholinergic actions, sedation Sedation, muscle relaxation, confusion
Alpha-adrenergic blockers	Stress incontinence
Alpha-adrenergic agonists	Urinary retention, voiding difficulty
Calcium-channel blockers	Urinary retention, voiding difficulty

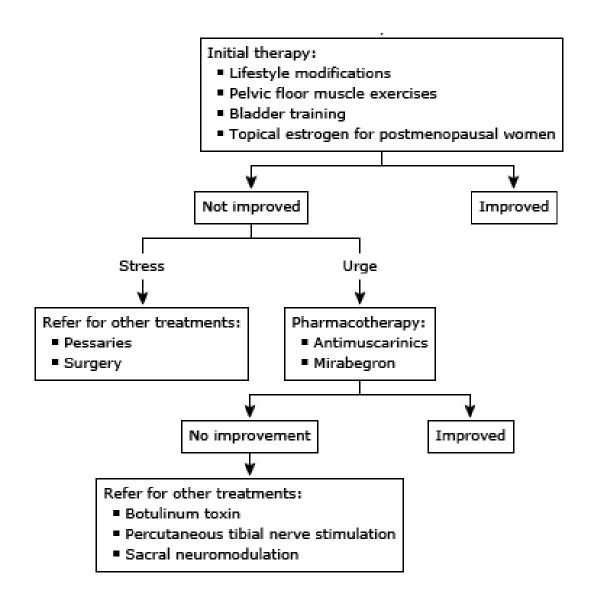
History & Physical

- Check Urine Dipstick (or UA with UCx)
 - rule out infection
- Uroflow and Post void residual
 - rule out obstructive voiding, retention
- Abdominal and Pelvic exam
 - fibroids
 - urethral diverticulum
 - HSV
 - cough stress test
 - urethral hypermobility
 - prolapse
- Neurologic exam S2, S3, S4
- Cystoscopy
 - lesions, stones
- BLADDER DIARY





Treatment Algorithm



Stress Urinary Incontinence Definition

• Involuntary, sudden loss of urine secondary to increased intraabdominal pressure that is bothersome or affecting the patient's quality of life.

• Physical activities precipitating SUI include laughing, sneezing, straining,

coughing, or exercising.







PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS

NUMBER 155, NOVEMBER 2015 (Reaffirmed 2018)

(Replaces Practice Bulletin Number 63, June 2005)

Urinary Incontinence in Women

Urinary incontinence, the involuntary leakage of urine, is caused by a variety of factors and may result in a wide range of urinary symptoms that can affect women's physical, psychological, and social well-being and sometimes can impose significant lifestyle restrictions. Identifying the etiology of each woman's urinary incontinence symptoms and developing an individualized treatment plan is essential for improving her quality of life. The purpose of this joint document of the American College of Obstetricians and Gynecologists and the American Urogynecologic Society is to review information on the current understanding of urinary incontinence in women and to outline guidelines for diagnosis and management that are consistent with the best available scientific evidence.

Background

Urinary incontinence is a common condition in women. Approximately 25% of young women (1), 44–57% of middle-aged and postmenopausal women (2), and 75% of older women experience some involuntary urine loss (3, 4). The estimated direct cost of urinary incontinence care in the United States is \$19.5 billion (5). Approximately 6% of nursing home admissions of older women can be

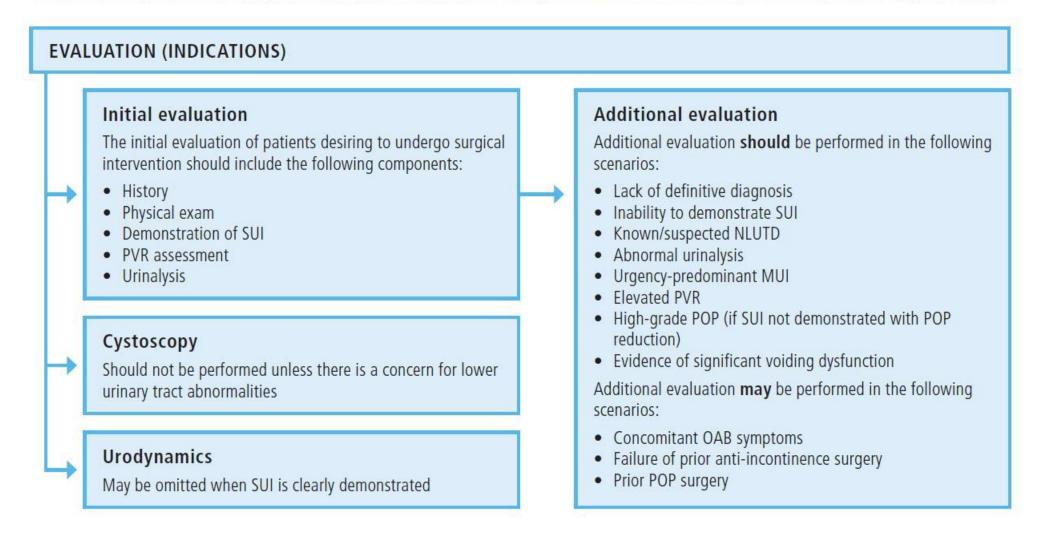
Etiology

Urinary incontinence can be caused by a variety of factors. The differential diagnosis includes genitourinary and nongenitourinary conditions (see Box 1). Some conditions that cause or contribute to urinary incontinence are potentially reversible.

Types

There are three main types of urinary incontinence in

Female Stress Urinary Incontinence: AUA/SUFU Evaluation and Treatment Algorithm



TREATMENT

Non-Surgical

- Continence pessary
- Vaginal inserts
- Pelvic floor muscle exercises

Surgical

- Bulking agents
- Midurethral sling (synthetic)
- Autologous fascia pubovaginal sling
- Burch colposuspension

If a midurethral sling surgery is selected, either the retropubic or transobturator midurethral sling may be offered. A single-incision sling may be offered to index patients if they are informed as to the immaturity of evidence regarding their efficacy and safety. Physicians must discuss the specific risks and benefits of mesh as well as alternatives to a mesh sling.

SPECIAL CASES

1. Fixed immobile urethra

- Pubovaginal sling
- Retropubic midurethral sling
- Urethral bulking agents

2. Concomitant surgery for POP repair and SUI

Any incontinence procedure

3. Concomitant NLUTD

Surgical treatment following appropriate evaluation and counseling

4. Child-bearing, diabetes, obesity, geriatric

Surgical treatment following appropriate evaluation and counseling

Treatment Options

- Absorbent products
- Artificial sphincter
- Behavioral therapy*
 - education, fluid mgmt, bladder training
 - pelvic floor muscle training (+/- biofeedback)
- Bladder outlet reconstruction
- Closure of bladder outlet
- Continuous catheterization
- Electrical stimulation
- External collecting device
- Intravaginal Supportive Device (pessary with knob)
- Occlusive devices
 - Miniguard®
 - FemAssist®
 - CapSure[™]
 - FemSoft®
 - Revive®
 - Impressa®
- Urinary diversion

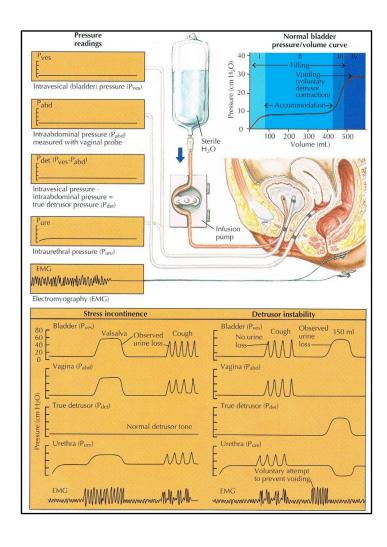
Surgery

- Colpourethropexy
- Needle Urethropexy
- Suburethral slings
- Peri-urethral bulking agents
- Mid-urethral Slings

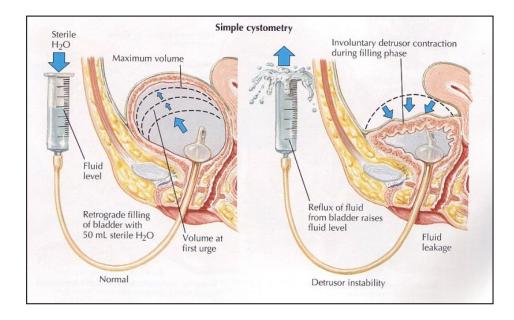
Pharmacologic therapy

- Estrogen
- α-Adrenergic agonists
- β-Adrenergic agonists
- β-Adrenergic antagonists
- SNRIs (serotonin-norepinephrine reuptake inhibitors)

Stress Urinary Incontinence



Simple Cystometrics



PESSARY



MILEX Products, Inc., Chicago, IL, USA

A. Ring J. Cube

B. Shaatz K. Hodge with knob

C. Gellhorn L. Hodge

D. Gellhorn M. Gehrung

E. Ring with support N. Incontinence dish with support

F. Gellhorn O. Donut

G. Risser P. Incontinence ring

H. Smith Q. Hodge with support

I. Tandem cube R. Inflatoball (latex)

Surgical Treatments

- (1907) Suburethal sling: Giordano described procedure in which gracilis muscle flaps were transplanted near the urethra
- (1914) Kelly plication
- (1917) Surgeons Goebell, Frankenheim, and Stoeckel developed a sling procedure using pyramidalis muscle w attached rectus fascia.
 - after the muscle bellies were dissected free to the level of the symphysis, the ends were passed behind the pubic bone and sutured below the urethra. The vesical neck was also plicated.
- (1930s) saw the decrease of musculofascial slings and the advent of slings composed only of fascia
- (1938) Periurethral bulking agents
- (1942) Aldridge dissected b/l strips of rectus fascia from the ant aspect of the muscle, leaving the medial portions attached to the muscle
 - the strips of fascia were then tunneled through the muscle, passed behind the symphysis, and sutured below the urethra. Ensuing years have brought the use of synthetic materials for slings and the use of suture bridges and patch slings
- (1949) Marshall-Marchetti-Krantz procedure
- Needle Urethropexy
 - Pereyra (1959), Stamey (1973), Raz (1981), Gittes (1987), Bone anchor needle suspension (1988)
- (1961) Burch Colposuspension
- (1972) Artificial sphincter
- (1996) Mid-urethral Sling



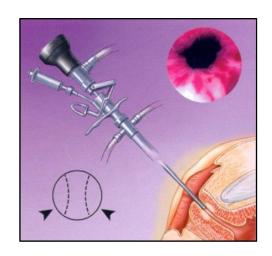
Treatment Options to date

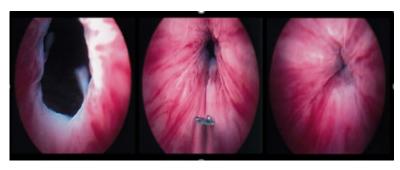
- Kelly Plication (1914)
- Peri-urethral bulking agents (1938)
- MMK: Marshall-Marchetti-Krantz procedure (1949)
- Burch Colposuspension (1961)
- Sub-Urethral Slings (1907)
 - Autologous Fascial Sling (Rectus, Fascia Lata), 1907 von Giordano
 - Needle Urethropexy
 - Pereyra (1959), Stamey (1973), Raz (1981), Gittes (1987), Bone anchor needle suspension (1988)
- Mid-urethral Sling Drs. Ulmsten and Petros (1996)

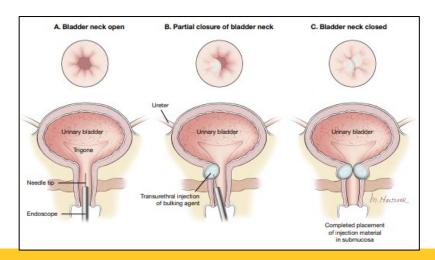
Bulking Agents

Periurethral bulking agents

- 1938, Murless (sclerosing agent)
- 1970's, Teflon
- Autologous fat
- 1989, first reported use of GAX-collagen (Glutaraldehyde cross-linked)
- 1993, FDA approves GAX-collagen for incontinence
- Durasphere[®]
 - Pyrolytic carbon-coated beads
- Coaptite[®]
 - Calcium hydroxyapatite particles
- Macroplastique ®
 - Cross-linked polydimethysiloxane
- Bulkamid ®
 - Polyacrylamid hydrogel



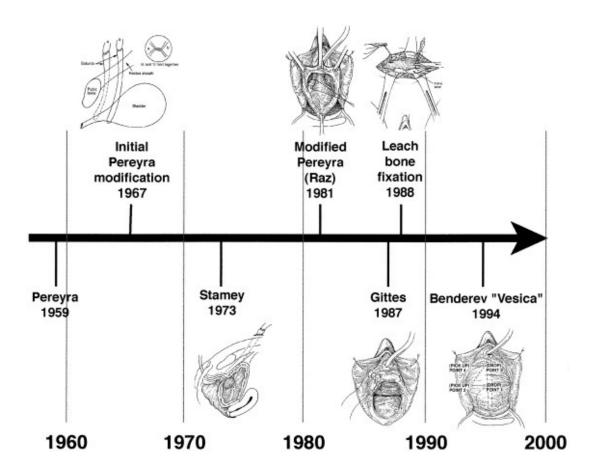




Marshall-Marchetti-Krantz & Burch

- 1949: MMK-a single suture (No. 1 chromic) placed on both sides of the urethrovesical junction
 - Each suture is then fixed to the periosteum or fibrocartilage of the pubic bone in such a way that the vesical neck is barely brought in contact with the pubic symphysis.
- 1962: 'Burch' was a modification due to difficulty in finding adequate periosteum in an elderly patient for MMK
 - Coopers ligament
 - Modification to LSC and RAprocedures

Needle Urethropexy



- Pereyra (1959)
- Stamey(1973)
- Raz (1981) "modified Pereyra"
- Gittes (1987)
- Bone anchorneedle suspension (1988)

Midurethral Sling – Gold Standard



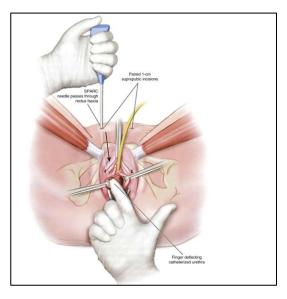
- 1990: Ulmsten and Petros described the Integral Theory
- 1996: Ulmsten described the "TVT" retropubic operation
- 1999: Palma (preamble to 'mini-sling' using bovine)
- 2001: Delorme advanced modality to the transobturator tape
- 2006: TVT Secur (Gynecare)
 - → Era of mini-slings?
- 2012: Postmarket surveillance studies
- Single incision slings

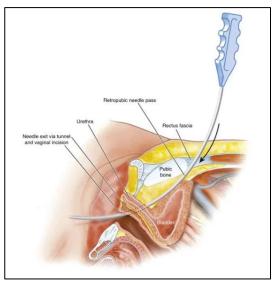




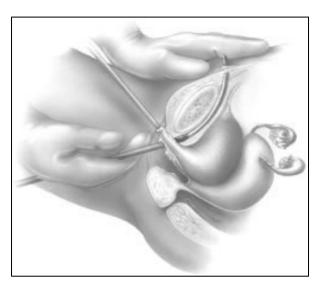
Preop Counseling

- Benefits "cure rates"
 - Long term data
- AE's:
 - Failure
 - Retention
 - Mesh erosion
 - Mesh exposure

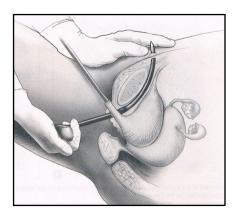


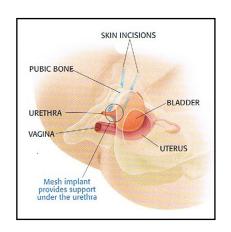


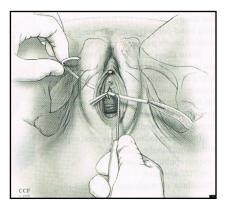


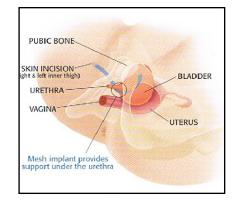


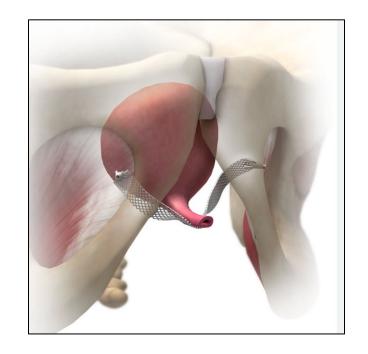


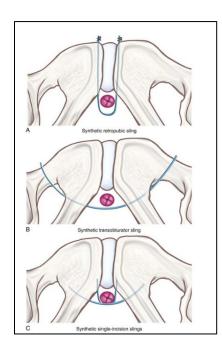












TOMUS Trial

Dangerous territory

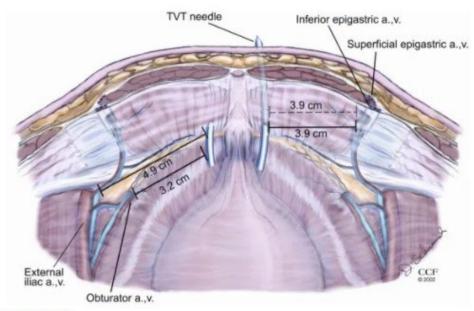
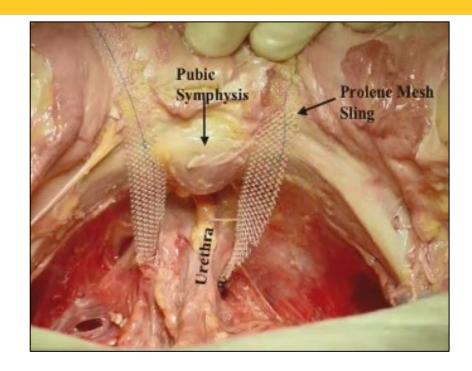


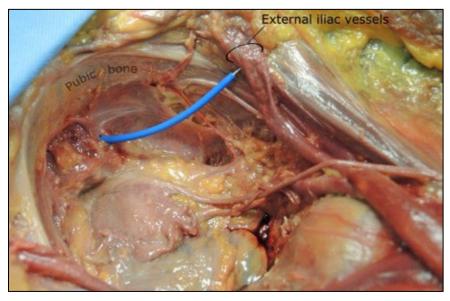
FIGURE 20.10

The relationship of the tension-free vaginal tape (TVT) needle to the vascular anatomy of the anterior abdominal wall and retropubic space.

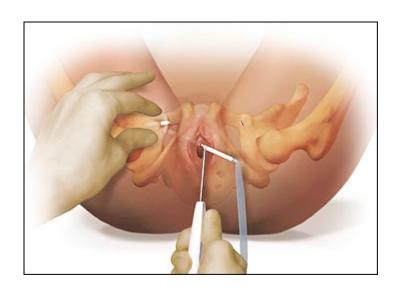
Numbers represent the mean distance from the lateral aspect of the TVT needle to the medial edge of the vessels. a, artery; v, vein.

(From Cleveland Clinic, with permission.)

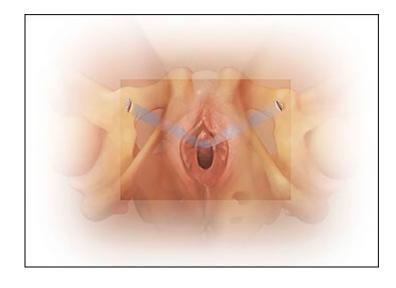


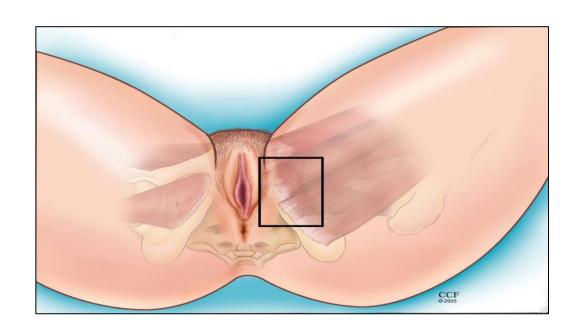


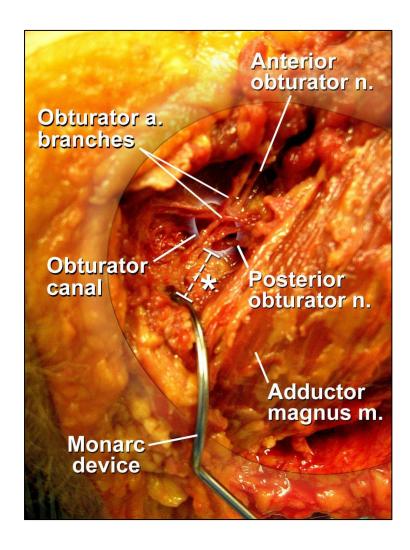




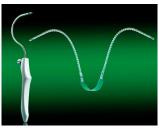








Single incision slings



Safyre



SolyxTM
Single-Incision Sling System







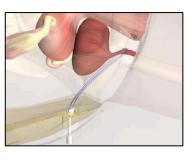


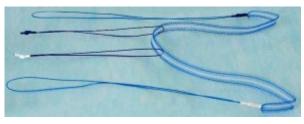
Altis®(Coloplast)

Remeex (Regulation Mechanical External™)









Transobturator adjustable tape





Adjust® (C.R. Bard)





Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence

The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.

Introduction

The purpose of this position statement by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) is to support the use of the midurethral sling in the surgical management of stress urinary incontinence, the type of urine leakage generally associated with coughing, laughing and sneezing.

Developed in the early 1990's, midurethral slings (MUS) treat stress urinary incontinence (SUI) in a minimally invasive, generally outpatient procedure. This technique utilizes a small mesh strip composed of monofilament polypropylene placed through the vagina under the mid-urethra exiting from 2 small sites in either the suprapubic or groin areas.

SUI is a highly prevalent condition of involuntary urine leakage resulting from faulty closure of the urethra typically associated with coughing, sneezing or exertion. SUI is often a debilitating and bothersome condition that can substantially reduce a woman's quality of life. Although non-surgical treatments such as pelvic floor exercises and behavioral modification are helpful in alleviating symptoms in some women [1], many proceed with surgery which is a more effective treatment [2].

In July 2011, the U.S. Food and Drug Administration (FDA) released a white paper [3] and safety communication [4] on the safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. In addition, lawyers have publicly advertised their services, targeting women with transvaginal mesh placed for both pelvic organ prolapse and stress urinary incontinence (SUI), and the media has reported on the pelvic organ prolapse mesh litigation. We are concerned that the multimedia attention has resulted in confusion, fear, and an unbalanced negative perception regarding the midurethral sling as a treatment for SUI. This negative perception of the MUS is not shared by the medical community and the overwhelming majority of women who have been satisfied with their MUS. Furthermore, the FDA website states that: "The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year."[5].



Transvaginal mesh implants

In recent years there has been some growing concerns about the use of transvaginal mesh implants, which are used for the treatment of <u>pelvic organ prolapse</u> (POP) or <u>stress urinary incontinence</u> (SUI).

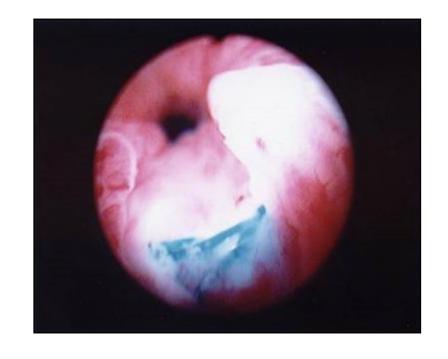
Following the public petition in Scottish Government about concerns raised with complications related to use of transvaginal mesh for both POP and SUI, the Scottish Government completed an <u>independent review</u> 2. This looked into the safety, use and efficacy (effectiveness) of transvaginal implants.

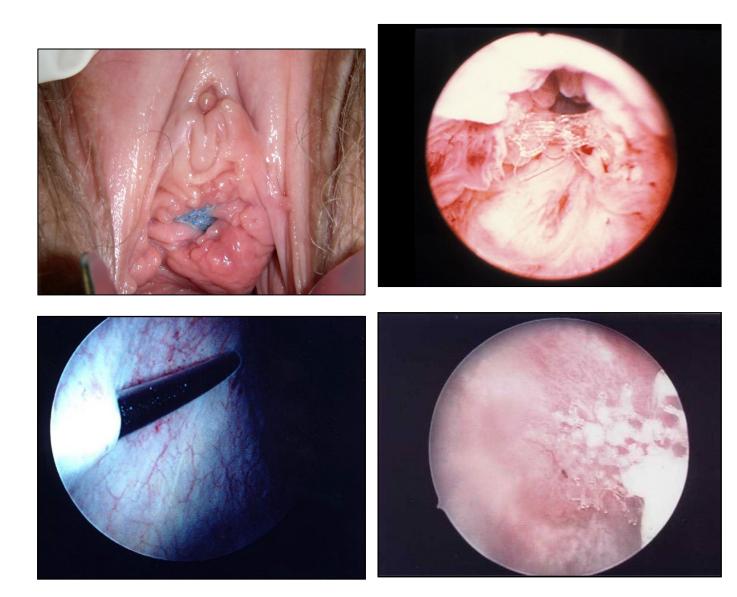
The report which was published in March 2017 made recommendations around managing patient who are considering surgery for SUi and POP and those suspected of having mesh related complications.

Some of the conclusions made by the independent review include:

- Shared decision making with health professionals and patient choice is essential when choosing treatments
- In the case of surgical treatment for stress urinary incontinence, individuals must be offered all
 appropriate treatments (mesh and non-mesh) as well as the information to make treatment
 option choices about their treatment
- In the surgical treatment of pelvic organ prolapse, current evidence does not show any extra benefit from the use of transvaginal implants (prolypropylene mesh or biological graft) over native tissue repair. Transvaginal mesh procedures must not be offered routinely

Complications

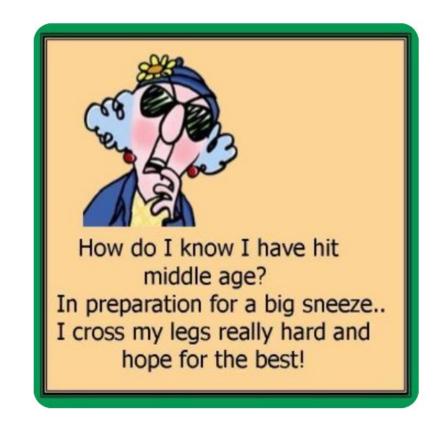




Images: Drs. Ferzandi and Kow

Take home points

- Bladder retraining
- Pelvic Floor Physical Therapy
- Pessary Devices
- Bulking Agents
- But...
 - The Gold Standard is MUS
 - Most studied device in medical literature



Definition – Overactive Bladder



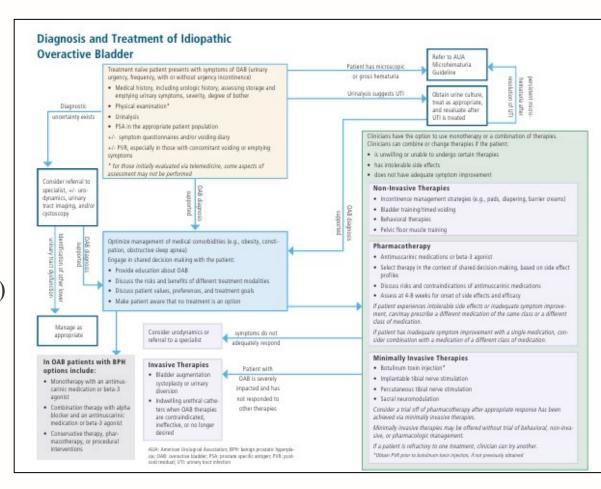
- International Continence Society Definition
 - "Urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UI), in the absence of urinary tract infection (UTI) or other obvious pathology."
- Urinary frequency
- Nocturia
- Urgency urinary incontinence

Symptoms / Complaints

- Diagnosis is made by clinical and subjective criteria
- Urinating eight or more times per day
- Waking up ≥ 1 time at night to urinate
- An overwhelming and sudden need to urinate, even if recently voided
 - "Idon't empty my bladder"
 - "I have urinary retention"
 - "Key in the door"
- Leakage of urine before she's able to make it to a bathroom

Overactive Bladder

- Bladder Diary
- UDS (?)
- First Tier
 - Bladder Retraining
 - timed voiding, fluid management
 - Caffeine and EtOH Reduction
 - Pelvic floor Physical Therapy (muscle relaxation)
- Second Tier
 - Medications (Anti-cholingerics, B3 agonists)
- Third Tier
 - Procedural





Dationt Mana	
	•
Patient Name	=

Intake and Voiding Diary

This chart is a record of your fluid intake, voiding and urine leakage. Please bring this diary to your next visit.

Instructions:

- 1. Choose 4 days (entire 24 hours) to complete this record they do not have to be in a row. Pick days in which will be convenient for you to measure every void.
- 2. Begin recording when you wake up in the morning-continue for a full 24 hours.
- 3. Make a separate record for each time you void, leak, or have anything to drink.
- 4. Measure voids (using cc measurements) using the hat.
- Measure fluid intake in ounces.
- When recording a leak please indicate the volume using a scale of 1-3 *(1=drops/damp, 2=wet-soaked, 3=bladder emptied), your activity during the leak, and if you had an urge ("yes" or "no").

DAY 1	Date:				
Time	Amount Voided (in ccs)	Leak Volume (scale of 1-3)	Activity during leak	Was there an urge	Fluid intake (Amount in ounces/type)
Example					
7:15a	325 cc				
7:45a		2	Watching TV	Yes	
8:15a					8 oz coffee, 8 oz orange juice
10:30a		1	Jogging	No	

Plan / Process and Treatment

- Rule out UTI (UA, Ucx)
- Check Post-void residual
- Review Voiding diary (+/- Urodynamics)
- Timed Voiding & Fluid Management
 - Caffeine
 - EtOH

Pharmacotherapy

- Antimus carinics
 - act on bladder M2/M3 receptors to inhibit involuntary detrusor contractions

- β-agonists
 - activates β -3 receptor in detrusor, causing detrusor relaxation and increased bladder capacity

	•				
OS	111	\mathbf{Q}	\mathbf{O}	†]	KX
- -					

Drug	Brand Name	Dose	Frequency
Antimus carinic - IR			
Oxybutynin IR	Ditropan	5mg	2-4x daily
Tolterodine IR	Detrol	1-2mg	bid
Trospium chloride	Sanctura	20mg	bid
Antimus carinic - ER			
Darifenacin ER	Enablex	7.5mg, 15mg	daily
Fesoterodine ER	Toviaz	4mg, 8mg	daily
Oxybutynin ER	Ditropan XL	5mg-30mg	daily
Oxybutynin TDS	Oxytrol	3.9mg = 1patch	twice weekly
Oxybutynin 10% ge1	Gelnique	100 mg = 1 g of ge1	daily
Solifenacin	Vesicare	5mg, 10mg	daily
Tolterodine ER	DetrolLA	2-4mg	daily
Trospium chloride	Sanctura XR	60mg	daily
β-3 Agonist			
Mirabegron	Myrbetriq	25mg, 50mg	daily
Vibegron	Gemtesa	75mg	daily

Pharmacotherapy-Side Effects

Anti-cholinergics

- Dry mouth
- Dry eyes
- Constipation
- Urinary retention
- GERD
- Blurry vision
- Cognitive side effects
- Contraindications: narrow angle glaucoma, gastroparesis, urinary retention

β3 Agonists

- High blood pressure*
- Contraindication: uncontrolled hypertension, ESRD, liver disease

*Mirabegron

Antimuscarinics

AUGS COMMUNICATION

AUGS Consensus Statement: Association of Anticholinergic Medication Use and Cognition in Women With Overactive Bladder

Author Information ⊗

Female Pelvic Medicine & Reconstructive Surgery 23(3):p 177-178, 5/6 2017. | DOI: 10.1097/SPV.0000000000000423

AUGS STATEMENT ON USE OF ANTI-CHOLINERGICS and the ELDERLY

- Patient selection for pharmacotherapy
 - Assess cost, dosing frequency, drug-drug interactions, potential side effects, and comorbid conditions that may increase adverse drug effects
 - Head-to-head comparison trials consistently show that extended-release agents have lower rates of adverse effects than immediate release agents
- Clinical strategies
 - Decreasing the starting dose of all antimus carinics is especially important in adults ≥60 years of age
 - Antimus carinics can take up to four weeks to reach their full efficacy
 - Avoid escalating the dose or declaring treatment failure prematurely.
 - The quick onset of action of the immediate release preparations makes them useful when continence is desired at specific times
 - Patients who fail treatment with one antimus carinic may respond to an alternate antimus carinic

What next?

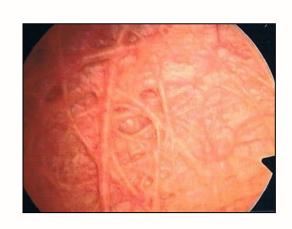
- Role of Pelvic Floor Physical Therapy
 - Say NO to Kegels!
- Revisit their voiding and fluid mgmt. and habits

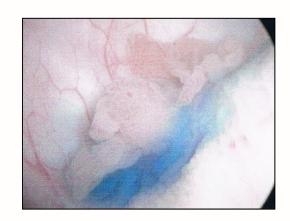
- ? Cystoscopy
- Move your patients to the next tier

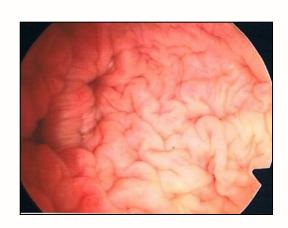
Cystoscopy











Posterior Tibial Nerve Stimulation

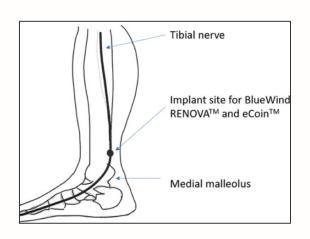


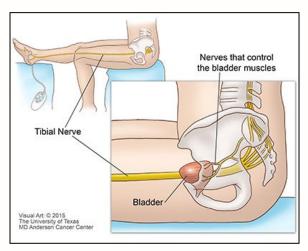










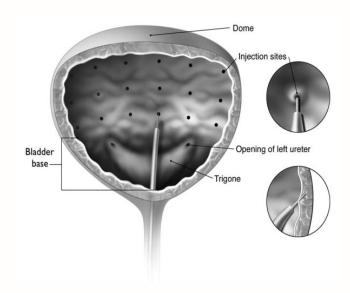


Percutaneous Tibial Nerve Stimulation

Intravesical Botox®

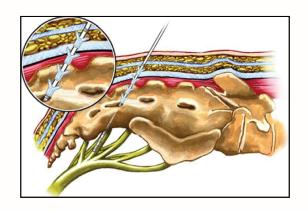
(onabotulinumtoxinA)

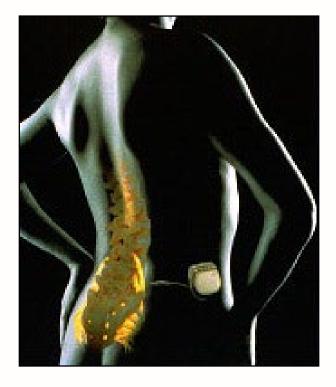
- Purified neurotoxin from Clostridium botulinum
- Blocks presynaptic release of acetylcholine at the neuromuscular junction resulting in permanent, flaccid paralysis
- Regrowth of new motor end plate units to reestablish the neuromuscular connection can take 3-24 months, at which point retreatment is required



Sacral neuromodulation (SNM)

- InterStim® Sacral neuromodulation, now add'l Axonics®
 - 1997 Approved by the FDA refractory urgency UI, refractory urgency-frequency, and idiopathic nonobstructive urinary retention
 - 2011 Approved for Fecal Incontinence
- The exact mechanism of action is uncertain; delivers mild electrical impulses
 - The electrodes are placed percutaneously adjacent to the S3 dorsal roots
 - Allows for communication with effector (bladder) organs and muscles (sphincter) innervated by the sacral nerves
 - If more than 50% improvement is seen, then patients will undergo permanent placement of the intermittent pulse generator
 - Adverse events: include lead migration, pain at the stimulator or lead site, infection, and transient electrical shock







Medtronic



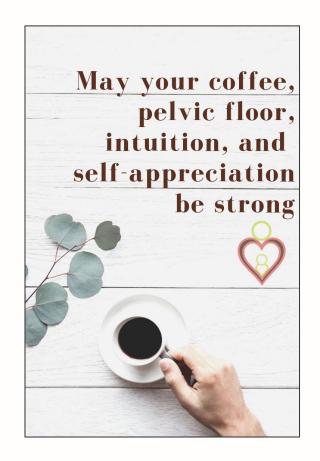






Conclusions

- OAB is a treatable chronic condition
- The social stigma is slowly lifting
- Expectations do need to be managed
- Adherence to algorithms is important for efficacy
- Referral to specialists should be offered early
- The public health burden is significant



THANK YOU

"The good physician treats the disease; the great physician treats the patient who has the disease."

William Osler



Courtesy, uber nurse Angela Barney!

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