Didactic: The Ins and Outs of Midurethral Slings: Safe Implantation and Surgical Management of Complications

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Target Audience
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This course provides a broad overview of the proper evaluation and management of female urinary incontinence. We will review conservative and surgical management strategies, including guideline-driven recommendations for the treatment of refractory urinary incontinence. Management of surgical complications, including mesh sling exposures and erosions, will also be discussed.

**Learning Objectives:** At the conclusion of this course, the clinician will be able to: 1) Discuss standard algorithms for treatment of stress, urge, and mixed urinary incontinence; 2) compare different surgical treatment modalities for stress urinary incontinence; and 3) describe complications associated with mid-urethral slings and how to manage them.

**Course Outline**

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<tr>
<td>7:00</td>
<td>Welcome, Introductions and Course Overview</td>
<td>E.R. Sokol</td>
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<td>7:05</td>
<td>Office Evaluation of Urinary Incontinence</td>
<td>C.B. Iglesia</td>
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<td>7:30</td>
<td>Urodynamic Assessment of Urinary Incontinence</td>
<td>D.L. Giles</td>
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<td>7:55</td>
<td>Behavioral and Functional Treatment of Urinary Incontinence</td>
<td>M.D. Moen</td>
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<td>8:20</td>
<td>Refractory OAB: Botox, PTNS and Neuromodulation</td>
<td>C.B. Iglesia</td>
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<td>8:45</td>
<td>Questions &amp; Answers</td>
<td>All Faculty</td>
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<td>8:55</td>
<td>Break</td>
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<td>9:10</td>
<td>Surgery for Stress Urinary Incontinence</td>
<td>M.D. Moen</td>
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<td>Sling Selection: Retropubic, Transobturator or Minisling</td>
<td>E.R. Sokol</td>
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<tr>
<td>10:00</td>
<td>Management of Sling Complications</td>
<td>C.R. Rardin</td>
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<td>10:25</td>
<td>Salvage Procedures for Refractory SUI</td>
<td>B.M. Ridgeway</td>
</tr>
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<td>10:50</td>
<td>Questions &amp; Answers</td>
<td>All Faculty</td>
</tr>
<tr>
<td>11:00</td>
<td>Adjourn</td>
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</table>
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Grants/Research: El.En
Other: National Principle Investigator: American Medical Systems
Other: Stock Ownership: Pelvalon

Asterisk (*) denotes no financial relationships to disclose.
Office Evaluation of Urinary Incontinence

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Georgetown University School of Medicine

Disclosures
No financial conflicts of interest
- Chair, AUGS Guidelines Committee
- Chair, PFDN Advisory Board NICHD
- Vice Chair, ACOG Pt Ed Board
- FDA ObGyn Devices Panel Member

Objectives
- Define subtypes of UI
- Draw conclusions for occult SUI risk
- List 6 steps for the minimal pre-surgical evaluation of uncomplicated SUI

Urinary Incontinence (UI): Prevalence
- 13 million Americans
- Gender
  - Female: 10%-55%
  - Male: 2%-5%
- Prevalence and severity increase with age
- Seen in over 50% of nursing home patients

ICS/IUGA Subtypes of Urinary Incontinence

Stress (activity-related) Incontinence SUI
- Complaint of involuntary loss of urine on effort or physical exertion
Urgency Urinary Incontinence (UUI)

- Complaint of involuntary loss of urine associated with urgency

Other IUGA/ICS Definitions

- Postural (urinary) incontinence: Complaint of involuntary loss of urine associated with change of position, e.g., rising from a seated position
- Nocturnal enuresis: Complaint of involuntary loss of urine which occurs during sleep
- Mixed (urinary) incontinence: Complaint of involuntary UUI and SUI.

Other UI

- Continuous (urinary) incontinence: Complaint of continuous involuntary loss of urine.
- Insensible (urinary) incontinence: Complaint of urinary incontinence where the woman has been unaware of how it occurred.
- Coital incontinence: Complaint of involuntary loss of urine with coitus—further divided into that occurring with penetration and that occurring at orgasm.

Prevalence of Any UI By Age and Severity


Defining Overactive Bladder

The International Continence Society defines OAB Syndrome as:

- Urinary urgency, with or without urge incontinence, usually with urinary frequency and nocturia, in the absence of pathologic or metabolic factors that would explain these symptoms

Assessment

- History
- Physical exam
- Voiding diary
- Post void residual
- Urine culture
- Cough stress test
- Urethral mobility Q-tip test
- Single channel CMG
- Multichannel CMG
- Cystoscopy
- Dynamic MRI and other imaging
**Evaluation**
- Match symptoms to signs
- Treat symptoms
  Pay close attention to what bothers patient most

**Validated Questionnaires**
- PFDI/ PFIQ: pelvic floor disorders inventory and pelvic floor impact questionnaire relates to bowel, bladder function (Barber MD et al AJOG 2005; 193: 103-13)
- Incorporates Urogenital Distress Inventory UDI and Urinary Impact Questionnaire UIQ
- MESA screen for Mixed UI

**Functional Incontinence: Causes (AKA Transient or Reversible Incontinence)**
- Patient-related
- Environmental-related
- Disease-related
- Medication-related

**DIAPPERS Mnemonic**
- Delirium
- Infection
- Atrophy
- Pharmacologic
- Psychologic
- Endocrinologic
- Restricted mobility
- Tool impact

**Voiding Diary**

<table>
<thead>
<tr>
<th>Time</th>
<th>Amount Voided</th>
<th>Any Leakage (yes/no)</th>
<th>Activity</th>
<th>Intake Amount/ Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>0700</td>
<td>500 ccs</td>
<td>Yes</td>
<td>On way to bathroom</td>
<td></td>
</tr>
<tr>
<td>0715</td>
<td>8 oz coffee</td>
<td></td>
<td></td>
<td>8 oz coffee &amp; 4 oz OJ</td>
</tr>
<tr>
<td>0900</td>
<td>Yes</td>
<td>Coughing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0915</td>
<td>300 ccs</td>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Bladder App voices for pfd.org**
- AUGS Bladder TrakHer for Iphone/Ipad

**Lower Urinary Tract Function**

- Bladder and urethral functions
  - Storage
  - Micturition
  - These functions are controlled by the central nervous system (CNS) through reflexes that coordinate the activity of:
    - Bladder (smooth muscle)
    - Urethra (smooth and striated muscles)
    - Pelvic floor muscles
Lower Urinary Tract Innervation

- Pelvic Nerve (Parasympathetic) → ACh
- Hypogastric Nerve (Sympathetic) → NE
- Pudendal Nerve (Somatic) → ACh

Evaluation of Incontinence and Prolapse

- Physical
  - detailed pelvic including neurologic
- Urine dip and PVR
- Kegel PFM
- POP-Q

Initial Assessment

- Medical history
- Symptoms

Other Pertinent History

- Gynecologic
- Urologic
- Neurologic
- General Medical
- Occupational hazards
- Medications
Drugs That Cause OAB-Like Symptoms

- Alpha-adrenergic receptor agonists
- Tricyclic antidepressants
- Psychotropics (sedatives, hypnotics)
- Cholinesterase inhibitors
- Narcotic analgesics, opioids
- Calcium channel blockers
- Diuretics
- Methylxanthines
- NSAIDS


Evaluate All Sites

- **anterior wall prolapse**: urethra, bladder (cystocele, urethrocele, cystourethrocele or enterocele)
- **apical prolapse**: cervix or cuff/cul-de-sac/ small bowel (uterine prolapse, vaginal vault prolapse, enterocele)
- **posterior wall**: rectum, sigmoid, small bowel (rectocele, sigmoidocele, enterocele)
- **perineal descent**

The POPQ System

- Fixed reference point: hymen
- Two points of measurement each
  - Anterior wall (Aa, Ba)
  - Posterior wall (Ap, Bp)
  - Apex (C, D)
- Genital hiatus (gh), perineal body (pb), and total vaginal length (tvl)

POPQ Software

- bardurological.com/po-p-q
- Boston Scientific Pelvic Floor Institute
- www.puritanmedproducts.com
**Gh and Pb**

- Genital hiatus: from mid-urethra to posterior fourchette, in centimeters.
- Perineal body: from posterior fourchette to mid-anus, in centimeters.
- Both with maximal valsala

---

**TVL (Total Vaginal Length)**

- Full lubricated plastic speculum
- No valsala
- Texas swab from posterior fornix to hymen
- To nearest .5cm
- (Measure and note cervical length)

---

**Point Aa**

- Remove top blade of speculum and discard
- Place ½ speculum on posterior vaginal wall and exert downward pressure
- ID hymen
- ID 3 cm proximal to hymen with swab
- Have patient PUSH
- Measure descent of anterior vagina in relation to hymen
**Point Ba (-3 to +TVL)**

- LEADING edge of anterior wall
- Always equal to or greater than Aa
- B follows A

**Points C and D (with speculum)**

- Measure length of cervix with swab
- Direct patient to PUSH
- Allow speculum to be pushed out
- Measure distance from cervix, posterior fornix to hymen
- +/- TVL

**Points C and D (Digital)**

- 2 digit exam
- Middle finger in posterior fornix
- 1st finger on cervix
- Have patient PUSH
- Note cm of descent at introitus (hymen)
- +/- TVL
Place ½ speculum to support anterior vagina
Support with upward traction
ID hymen
ID 3 cm proximal to hymen with swab
Have patient PUSH
Measure descent of posterior vagina in relation to hymen

Point Ap (-3 to +3)

LEADING edge of posterior wall
Always equal to or greater than Ap
B follows A

Point Bp (-3 to +TVL)

Stage 0 normal all -3 and C or D is < TVL-2 cm
Stage I is < -1 cm from (above) hymen
Stage II is ± 1 cm from hymen
Stage III is >+1 but < TVL-2 cm to complete prolapse
Stage IV Leading edge > TVL-2

POP-Q

Stage 0 normal all -3 and C or D is < TVL-2 cm
Stage I is < -1 cm from (above) hymen
Stage II is ± 1 cm from hymen
Stage III is >+1 but < TVL-2 cm to complete prolapse
Stage IV Leading edge > TVL-2

Urethral Mobility

Only useful in Stage 0-1 or prior surgery
All Stage 2-4 have mobility >30 degrees
(Noblett et al 2005)
Are Urodynamics Really Necessary?

- No!

- Basic Office evaluation vs. Urodynamics
  - Women with prolapse and stress incontinence
  - Basic office evaluation and urodynamic testing had same cure rate of incontinence (96%)
  - If surgery is the preferred treatment then urodynamic testing is not cost-effective.

(Weber and Walters MD)

Reduction Stress Testing


- Reduction stress test negative for SUI: still up to 42% risk of de novo SUI postop

PFDN De Novo SUI Risk Calculator


Simple Cystometrogram CMG 51725

- NEED: 14 FR red rubber catheter, 60 cc catheter tip syringe, 1 Liter saline or H2O
- Insert urethral catheter and retrograde fill bladder

Provocative stress test

- The observation of transurethral loss of liquid (urine) simultaneous with a cough or valsalva
- Sensitivity best if standing with a full bladder.
Consider Further Consultation
- Hematuria
- Recurrent UTIs
- Neuro abnormality
- Voiding difficulty
- Decreased bladder capacity
- Elevated residual volume
- Fistula
- Urethral diverticulum
- Failure to improve on initial management
- Unclear history and physical exam

Should UDS be performed in all women before SUI surgery?

The VALUE Trial (UITN)

Trial Schema

Pre-Op Assessment and Diagnosis (basic office evaluation - BOE)

<table>
<thead>
<tr>
<th>Predominant SUI</th>
<th>Predominant UUI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOE</td>
<td>Eligible</td>
</tr>
<tr>
<td>Eligible</td>
<td>Eligible</td>
</tr>
<tr>
<td>Refused</td>
<td>Ineligible</td>
</tr>
</tbody>
</table>

Random Assignment

UDS  NO UDS
SUI Treatment*
Follow-Up Assessments

Outcomes.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Urodynamic Testing (N=272)</th>
<th>Office Evaluation Only (N=246)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>270 (77.3)</td>
<td>270 (78.9)</td>
<td>0.63</td>
</tr>
<tr>
<td>30% reduction in Urgent Distress Inventory score — no, (%)</td>
<td>210 (77.3)</td>
<td>210 (78.9)</td>
<td>0.63</td>
</tr>
<tr>
<td>“very much better” or “much better” on Patient Global Impression of Improvement — no, (%)</td>
<td>210 (77.3)</td>
<td>210 (78.9)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

Who needs urodynamics
- Uncertain diagnosis and treatment plan difficulty
- Uncertain about the relative contribution of urge and stress incontinence in mixed incontinence
- Suspected poor urethral function (ISD?)- Previous surgery, severe incontinence, radiation, radical surgery and data could change treatment
- Failure to respond to treatment, Failed surgery
- Combined incontinence and emptying disorders
- Symptoms of difficult bladder emptying
- Elevated PVR- Voiding dysfunction
ACOG/AUGS Evaluation
Uncomplicated SUI

Summary

- Evaluation of UI requires thorough review of urinary, sexual and anorectal complaints and treatment should match complaints
- Examination should be done with a split speculum or standing
- In cases of advanced prolapse, assess for occult urinary incontinence with prolapse reduced
- SUI risk calculator may be useful for counseling re: prophylactic sling surgery

6 steps Basic Evaluation

following basic six-step evaluation of a patient with symptoms of uncomplicated SUI before primary surgical repair with a midurethral sling:

1. History
2. Urinalysis
3. Physical examination with an assessment for POP
4. Cough stress test
5. Assessment of urethral mobility
6. Measurement of postvoid residual urine volume
Urodynamic Assessment of Urinary Incontinence

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Chief, Female Pelvic Medicine and Reconstructive Surgery
Departments of Obstetrics & Gynecology and Urology

November 17, 2014

Disclosures

I have no financial relationships to disclose.

Objectives

- Review the different components of Urodynamics
- Discuss AUA/SUFU guidelines
- Discuss ACOG/AUGS Committee Opinion

Goal of Urodynamics

- To identify factors contributing to LUT dysfunction
- To predict the consequences of LUT dysfunction on the upper tracts
- To predict the consequences and outcomes of therapeutic intervention
- To confirm and/or understand the effects of interventional techniques
- To investigate the reasons for treatment failure

Urodynamic Indications

- Not every patient with Stress Urinary Incontinence or Urge Urinary Incontinence needs UDS
- Indications for complex UDS
  - Marked UI symptoms, refractory to treatment
  - Inconclusive single channel
  - S/s of neurologic disease
  - History of prior anti-incontinence surgery or pelvic xrt
  - Voiding difficulties/abnormalities
Committee Opinion 603 (ACOG/AUGS)

- Pre-op multichannel UDS is not necessary before planning primary anti-incontinence surgery in women with uncomplicated SUI
- Observed leakage by provocative stress measures
- Normal UA
- No POP beyond hymen
- Normal PVR
- RCT demonstrated outcomes 1 year after MUS were the same for those who had BOA compared with those who had pre-op UDS

Assessment of lower urinary tract

- Obtain functional information about
  - Bladder filling
  - Storage
  - Emptying
- A Problem with Storage
- A Problem with Emptying

UDS Components

- Voiding studies
  - Uroflow
  - Pressure flow
- Cystometry
  - Simple vs. Complex
  - Single vs. Multichannel
- Electromyography
- Urethral Pressure Profilometry
- Video

UDS Components

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Uroflowmetry

- Flowmeter – volume vs. time
- Assess emptying phase
- Simple, noninvasive first line screening test
- Normal values less well established for females
- Assess PVR at completion

Uroflowmetry: Interpretation

- Evaluate curve pattern
  - Continuous Smooth
  - Continuous Fluctuating
  - Intermittent
- Normal: Qmax in 1/3 of the total voiding time
**Uroflowmetry: Interpretation**

- Volume voided
- Maximum Flow Rate (Qmax)
  - Should not exceed 1/3 of flow time
- Average Flow Rate (Qave)
  - Voided volume/flow time
- Flow time
  - Excluding interruptions
- Voiding time
  - Including interruptions
- Time to maximum flow

**Abnormalities in flow**

- Continuous Smooth
- Continuous Fluctuating
- Intermittent

**UDS Components**

- Voiding studies
  - Uroflow
  - Pressure flow
- Cystometrogram (CMG)
  - Simple vs. Complex
  - Single vs. Multichannel
- Electromyography
- Urethral Pressure Profile
- Video
Cystometry

- Test that measures pressure/volume relationship of the bladder
- Assess detrusor activity, sensation, capacity, & compliance
- Leak point pressures

Simple Cystometry

- Saline, Catheter, Syringe
- Watch meniscus
- Sudden rise possible detrusor contraction or increase in abdominal pressure
- Can determine sensations and capacity

Filling Cystometry

- A catheter in the bladder
- Two sensors/balloons
- Pves
- Pura
- A catheter in the rectum (or vagina)
- Pabd
- 8 Fr or less
- Room temperature fluid
- Fill rate 50 ml/min

Filling Cystometry

- First Sensation
  - Notice fluid in the bladder
- First Desire to Void
  - Pass urine at next convenient moment but can delay if necessary (watch tv and next commercial)
- Strong Desire to Void
  - Persistent desire to void without the fear of leakage (can’t wait for next commercial)
- Maximum Cystometric Capacity
  - Can no longer delay

Pves (pressure from bladder catheter)
Pabd (pressure in abdomen)
Pdet (Pves-Pabd)
Leak Point Pressures

- Method of assessing urethral resistance and function
- To be accurate, perform in standard fashion
  - Catheter size, bladder volume, type of provocation, reduction of prolapse
- If large anterior wall prolapse
  - Perform with and without reduction

Abdominal leak point pressure (ALPP)
- Measures the outlet
- Due to increased abdominal pressure in the absence of a detrusor contraction
- VLPP
- CLPP

Detrusor leak point pressure (DLPP)
- Measures compliance
- The lowest detrusor pressure at which urine leakage occurs in the absence of either a detrusor contraction or increased abdominal pressure
- High DLPP (>40 cm H2O) concern for upper tract damage

Valsalva Leak Point Pressure / Abdominal Leak Point Pressure

- Fill to 200 cc (some studies at 300 cc)
  - Repeat every 100 cc
- Begin coughing
  - Not as accurate
  - Unnecessary if leakage w/ Valsalva
- Perform progressive Valsalva until leakage occurs
- If still no leakage
  - Continue filling or
  - Remove catheters and Valsalva and cough again to demonstrate leakage

Valsalva Leak Point Pressure

UDS Components

- Voiding studies
  - Uroflow
  - Pressure flow
- Cystometry
  - Simple vs. Complex
  - Single vs. Multichannel
- Electromyography
- Urethral Pressure Profilometry
- Video

Electromyography

- Useful w/ neurologic history or occult neurogenic voiding dysfunction is suspected
- Abnormalities in hx, PE, uroflow, or pvr should prompt
- Study of the electrical potential generated by depolarization of muscle
- During normal voiding there should be no activity
- Increased activity during voiding may be characteristic of Detrusor Ext Sphincter Dyssynergia (DESD)
Patch Electrodes

Electromyography

UDS Components

• Voiding studies
  • Uroflow
  • Pressure flow

• Cystometry
  • Simple vs. Complex
  • Single vs. Multichannel

• Electromyography
• Urethral Pressure Profilometry
• Video

Pressure Flow Study

•Performed after CMG

Ideally, voiding w/ abdominal, intravesical, intraurethral, and EMG measurements

Identifies 3 fundamental voiding states:
• Low detrusor pressure/high flow rate – unobstructed
• High detrusor pressure/low flow rate – obstructed
• Low detrusor pressure/low flow rate – poor contractility

Committee Opinion 603 (ACOG/AUGS)

Elevated PVR in the absence of Pelvic Organ Prolapse is uncommon and should trigger an evaluation of the bladder-emptying mechanism, usually with a pressure-flow urodynamic study
**Abrams-Griffiths Pressure Flow**

- Simplest Nomogram: Maximal flow rate vs. detrusor pressure
- Draw back: equivocal zone

**UDS Components**

- Voiding studies
  - Uroflow
  - Pressure flow
- Cystometry
  - Simple vs. Complex
  - Single vs. Multichannel
- Electromyography
  - **Urethral Pressure Profilometry**
  - Video

**Urethral Pressure Profilometry**

- Maximal urethral pressure (Pura) - highest pressure during withdrawal
- Maximal urethral closure pressure (MUCP) - Difference of Pves-Pura

**Video Urodynamics**
Risks

- Urinary Tract Infection
- Urethral Trauma
- Discomfort
- Autonomic Dysreflexia

Cost

- VALUE Trial
  - No data that pre-op UDS improves treatment outcomes in women with uncomplicated SUI
- Basic Office Evaluation
  - Stress test
  - Normal PVR
  - Urethral mobility check
  - Normal UA

AUA/SUFU Guidelines

- If considering invasive therapy in patients with SUI – should assess PVR
- If making the diagnosis of urodynamic stress incontinence - should assess urethral function.
- Should perform repeat stress testing with the urethral catheter removed in patients suspected of having SUI who do not demonstrate this finding with the catheter in place during urodynamic testing
- In women with high-grade POP but without the symptom of SUI, clinicians should perform stress testing with reduction of the prolapse.
- Clinicians may perform PFS in patients with urgency incontinence after bladder outlet procedures to evaluate for SOO.
- Multichannel UDS has not been shown to correlate with outcomes of various interventions for SUI. However, UDS may alter the choice of therapy or provide guidance in patient selection to minimize the incidence of new postoperative voiding symptoms.

References


Behavioral and Functional Treatment of Incontinence
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Chicago Medical School/Rosalind Franklin University
Medical Director
Illinois Urogynecology, Ltd.

Learning Objectives

- Identify factors associated with screening, evaluation and treatment of women with urinary incontinence
- Review literature supporting behavioral and functional treatments for urinary incontinence
- Develop practical approach for initiation of behavioral and functional treatments for urinary incontinence

Disclosures

I have no financial relationships to disclose.
Consequences of Incontinence

- A public episode of incontinence is seen as most embarrassing symptom for the majority of patients with urinary incontinence
- Leaking leads to lifestyle changes and coping behavior
  - Bathroom mapping, Avoiding social situations, Avoiding travel
  - Wearing dark clothing, Wearing pads/protection
- Can impact intimate relationships (fear of leakage during/after intercourse)
- Higher rate of depression in patients with incontinence

Screening for Incontinence

“Do you have bladder problems that are troublesome, or do you ever leak urine?”

- Perform focused history and physical exam
- Rule out urinary tract infection

Office Evaluation-History

- Review Quality of life issues:
  - Wear protection?
  - Limit travel or social activities?
  - Avoid exercise?
  - Avoid sexual activity?
  - Feel depressed?

Neuromuscular evaluation

- Perineal sensation
- Pelvic muscle strength

Office Evaluation-Exam

Importance of Pelvic Floor Assessment

- Assessment of pelvic muscle strength critical in identifying patients who might benefit from pelvic floor physical therapy
  - 20-30% of asymptomatic women unable to adequately contract pelvic floor muscles
  - 7-10% of women actually perform Valsalva maneuver when attempting to contract pelvic floor muscles

Moen et al. J Pelvic Med 2007;13:113
Office Evaluation-Exam
Importance of Pelvic Floor Assessment

- Majority of women familiar with “Kegels”
- 42% had been instructed to perform PMEs with 62.5% having received only verbal instruction and 38% were told to stop and start their stream when voiding
- Only 23% able to adequately contract PFMs
- 12% performed Valsalva maneuver when attempting to contract pelvic floor muscles

Moen et al. IUJ 2009; 20:843–846

<table>
<thead>
<tr>
<th>Patient characteristic</th>
<th>Percentage of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever heard of pelvic muscle exercises</td>
<td>73% (262/352)</td>
</tr>
<tr>
<td>Never heard of pelvic muscle exercises</td>
<td>27% (90/352)</td>
</tr>
<tr>
<td>Medical source</td>
<td>69% (164/234)</td>
</tr>
<tr>
<td>Ever instructed to perform PME</td>
<td>45% (136/302)</td>
</tr>
<tr>
<td>Verbal instruction only</td>
<td>62% (48/76)</td>
</tr>
<tr>
<td>Instructed during pelvic examination</td>
<td>10% (24/236)</td>
</tr>
<tr>
<td>Presence assessment of pelvic function</td>
<td>20% (49/235)</td>
</tr>
<tr>
<td>Correct performance of pelvic movement</td>
<td>20% (48/230)</td>
</tr>
<tr>
<td>Daily performance</td>
<td>23% (18/79)</td>
</tr>
<tr>
<td>2-3 times weekly</td>
<td>27% (22/81)</td>
</tr>
<tr>
<td>Weekly</td>
<td>15% (12/79)</td>
</tr>
<tr>
<td>Occasionally</td>
<td>30% (24/81)</td>
</tr>
<tr>
<td>Rarely</td>
<td>0% (0/81)</td>
</tr>
</tbody>
</table>

Functional Factors related to UI

- Cognitive issues/Dementia
- Mobility issues/Physical limitations (arthritis)
- Constipation/Fecal impaction
- Medications
  - Diuretics; Sedatives; Hypnotics

Functional Treatments

- Cognitive issues/Dementia
  - Prompted voiding; Absorbent products
- Mobility issues/Physical limitations (arthritis)
  - Bedside commode; clothing changes
- Constipation/Fecal impaction
  - Optimize bowel function
- Medications
  - Timing of diuretics

Functional/Behavioral Therapy

- Discuss normal fluid intake
  - Avoid dehydration
  - Avoid excessive intake
  - Evening restrictions on fluid intake
- Avoid exacerbating factors
  - Control of allergies, bronchitis, coughing
  - Heavy lifting

- Avoid dehydration
- Avoid excessive intake
- Evening restrictions on fluid intake
- Avoid exacerbating factors
- Control of allergies, bronchitis, coughing
- Heavy lifting
**Behavioral Therapy**

- **Advantages**
  - No reported side effects
  - Can be used in conjunction with other therapies
- **Disadvantages**
  - Require patient education, motivation and continued practice
  - Time consuming for health care provider
- **Goal**
  - Improve pelvic floor muscle function and bladder control

**Bladder Training**

- Three basic components
  - 1) education (bladder function, fluid intake)
  - 2) scheduled voiding with systematic delay
  - 3) positive reinforcement (follow-up)
- Cure rates 47-100% (10 studies)
- Outcomes may improve with addition of
  - Pelvic Floor Muscle Exercises
  - Estrogen therapy in patients with atrophy

**Pelvic Floor Muscle Exercises**

- Benefits seen with as few as 30 contractions performed 3 times per week
- Overall success for improving SUI 30-74%
- Optimal results may be seen with 40-80 contractions performed per day
  
  Wells J Am Ger Soc 1991

**Pelvic Floor Muscle Rehabilitation**

- Pelvic Muscle Exercises (Kegel’s)
  - Effective for stress and urge incontinence
  - May prevent incidence of incontinence
- Pelvic Floor Physical Therapy
  - Biofeedback
  - Electrical Stimulation
  - Electromagnetic therapy
Biofeedback

- Most useful in patients with weak or uncoordinated muscle activity
- Provide feedback (auditory/visual) to patient to improve exercise technique
- Initial treatment with Physiotherapist 1-2x/wk
- Home unit can be used daily
- Symptom improvement: 48-83% (13 studies)

Electrical Stimulation

Pelvic Floor Electrical Stimulation

- Most useful in patients with inability to contract
- Produces contraction of levator ani, external urethral sphincter and anal sphincter
- Pelvic floor contraction is accompanied by reflex inhibition of detrusor contraction (via reflex arc through sacral micturition center)
- Physiotherapist/Office and Home therapies
- Improvement in 30-80%
Incontinence Pessaries for SUI

Conclusions

• Bladder Training and Pelvic Muscle Exercises are the primary behavioral treatments for incontinence
• Many women and health care providers are unaware of the safety and effectiveness of Behavioral and Functional treatments for urinary incontinence
• The majority of women with pelvic floor disorders have suboptimal pelvic muscle function highlighting the importance of pelvic floor exam and availability of Pelvic Floor Physical Therapy

References

• Mann pelvic floor muscle function in women presenting with pelvic floor disorders. Int Urogynecol J 2009;20:485-486
Refractory OAB: Neuromodulation, PTNS and Botox

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Section Director, FPMRS
MedStar Washington Hospital Center
Professor, Department of Ob/Gyn and Urology
Georgetown University School of Medicine
Washington, DC

Disclosures
• I have no financial disclosures
• Serve as chair of the Pelvic Floor Disorders Network Advisory Board, NICHD
• FDA ObGyn Devices Panel Member
• Chair, AUGS Guidelines committee

Objectives
• List indications for neuromodulation and detrusor botulinum toxin injections
• Cite evidence-based complications from both modalities

Refractory OAB
• Urgency urinary incontinence (UUI)
  – Highly prevalent
  – Significantly impacts QoL
• Most common therapy: Anticholinergics
  • No one drug is superior
  • Marginal efficacy
  • Side effects: dry mouth, constipation, CNS

2014 AUA/SUFU OAB Guidelines


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AUA/SUFU Guideline


AUA/SUFU Guideline

Overactive Bladder

Guideline Statements

13. Clinicians may offer intradetrusor onabotulinumtoxinA (100U) as third-line treatment in the carefully-selected and thoroughly-informed patient who has been refractory to first and second-line OAB treatments. The patient must be able and willing to return for frequent post-treatment evaluation and trials and willing to perform self-injections. – Recommendation (Evidence Strength Grade A)

6. Clinicians may offer peripheral nerve stimulation (PNS) as third-line treatment in a carefully-selected patient population. Recommendation (Evidence Strength Grade C)

18. Clinicians may offer sacral neuromodulation (SNM) as third-line treatment in a carefully-selected patient population. Recommendation (Evidence Strength Grade C)
Sacral Nerve Stimulation
• 1981 Tanagho and Schmidt
• 1997 FDA approves for Urge Incontinence
• 1999 FDA approves for Urgency/Frequency and Non-obstructive Urinary Retention
• 2002 FDA approves for OAB
• 2002 Wide use of staged technique/fluoro
• 2006 Small neurostimulator
• NOW over 100,000 implants worldwide

Neuromodulation SNS
• Implantable stimulation system includes lead and pacemaker (IPG)
• Targets sacral nerves (S3)
• Modulates reflexes between bladder, sphincter, and pelvic floor

Mechanism of Action
• Incompletely understood
• Bladder is not the specific target
• Central afferent neuromodulation
  – Targets reflex centers in cord and pons
• Affects OAB and idiopathic retention
  – Blocks ascending sensory pathway inputs
  – Suppresses guarding reflex pathways

SNS Indications
• Refractory OAB
  – Failed drugs and behavioral therapy
• Urinary Retention
  – Idiopathic non-obstructive
• Non-neurogenic etiology
• Bowel dysfunction
  – European indications
  – Fecal incontinence April 2011 FDA approval

How is it done?
• Test stimulation (outpatient)
• Trial period (1-2 weeks)
  – Percutaneous
  – Implantable lead
• Implantation of IPG
Test Stimulation

- Needle placed at S3
- Motor Response
  - Bellows/toe motion
- Sensation
  - Genital/anal sensation, comfort

Trial Period

- Review diary
- Success equals > 50% improvement
  - Number of leaks/day
  - Number of voids/day
  - Volume voided/void
  - Degree of urgency

Device Implantation

- Based on success of trial
- Completely reversible if declined/discontinued
- Change stimulation parameters externally
- Permanent devices last up to 10 years

Clinical Efficacy

- Urge incontinence N=38
  - 45% completely dry
  - 34% experienced >50% reduction in leaks
- Urgency Frequency N=33
  - 31% normal voids 4-7 per day
  - 33% experienced >50% reduction in voids
- Retention N=38
  - 61% stopped catheter use
  - 16% experienced >50% decrease in retained volume

Systematic Review:
SNS for Urge Incontinence

- 1,824 implants from 34 clinical trials
- From RCTs 80% of patients achieve >50% improvement of symptoms
- From Case Series: 67% improvement

Brazell M et al. Efficacy & Safety of SNS; J Urol 2006; 175: 835-841
5 year results SNS
• 17 centers, 163 patients, mean age 44.7, 87% female (Van Kerrebroeck J Urol 2007)
• Success rates
  – 68% UI
  – 56% UF
  – 71% Retention
• If success at one year, rate of success at 5 years
  – 89% UI
  – 71% UF
  – 76% Retention

Complications SNS
• Reoperation Rate 33%
  – Loss of efficacy
  – Pain at lead or IPG site
  – Infection
• Improvement
  – Use of fluoroscopy
  – Staged approach and tined lead
  – Recent study show reoperation <20%
  Starkman NUU2007; van Voskuilen BJU 2007

Factors Predicting Success Rates
• For urge incontinence
  – Age less than 55
  – Non-neurogenic
  – Few comorbidities
• Staged approach using tined lead
  – 80% test to implant rate
  Amundsen C. J Urol 2007; Spinelli J Urol 2003

Review of SNS
• Ideal candidate
  – 65% chance of at least 50% improvement
• Long-term benefit is probable
• Safe, low morbidity and reversible
• Potential help for GI symptoms
• High likelihood of long-term satisfaction

PTNS Posterior Tibial Nerve Stimulation
• Aka Percutaneous tibial nerve stimulation
• Urgent PC, Uroplasty, Minnetonka, MN
• Dr. Marshall Stoller, UCSF 2007 SANS unit
• FDA cleared for UUI 2000 and OAB 2010

PTNS: weekly 30 min sessions x 12 weeks
Evidence for PTNS

- ORBIT trial: (Peters J Urol 2009)
  - 100 patients RCT PTNS vs Tolterodine 4mg ER
  - Global response assessment 79.5% reporting cure or improvement compared to 54.8% of subjects on tolterodine (p = 0.01).
  - Similar improvement in frequency, UUI, urgency and nocturia

- SUMIT trial: (Peters J Urol 2010)
  - PTNS vs Sham
  - 55% vs 21% sham response (p<0.001)

COCHRANE REVIEW PTNS

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N1</th>
<th>N2</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTNS</td>
<td>640</td>
<td>404</td>
<td>1.51</td>
</tr>
<tr>
<td>Sham</td>
<td>356</td>
<td>210</td>
<td>1.51</td>
</tr>
</tbody>
</table>

Botulinum Toxin in Urology

- Dykstra et al J Urol 1988; 139; 919
- Schurch et J Urol 1996; 155: 1023
- Smith and Chancellor J Urol 2004; 171:2128
- Schurch et al J Urol 2005; 174: 196

Why Use It

- Refractory OAB
  - Marginal compliance with oral therapies
  - Refractory to Interstim SNS

Botox mechanism of action
**Detrusor Botox**

- FDA approved for UUI urge urinary incontinence
- Effective in:
  - Neurogenic DO
  - Spinal cord injury, MS
  - Post-obstructive DO
- Expensive $490/100u
- Effect in 7-10 days
- Lasts 3-9 months

**Botulinum Toxin Injection Technique**

- 100 units of Botox in 20 cc saline volume
- 1 cc per injection site
  - 5 units per site
- 20 sites, spare trigone
- Needle
  - 5F sheath
  - 23 gauge needle Williams (Cook), Corson (Bard), BoNee (Coloplast)

**Botulinum Toxin A for Detrusor Overactivity (DO)**

- Intradetrusor Botulinum toxin A vs placebo for neurogenic DO (n=59)\(^1\)
  - Reduction in mean incontinent episode frequency
    - 32-54% (200U)
    - 42-58% (300U)
- Case series of 231 patients with neurogenic DO (Reitz, 2004)
  - 73% continent and remainder improved

\(^1\)Schurch B. Neurol Urodyn 2004;23:609.

**RUBI BOTOX RCT**

- 200 u detrusor Botox in 28 pts vs. placebo injection in 15 pts
- Improvement in UUI symptoms in 60% Botox patients, lasting 6 months, median resp time 372 days Botox vs 62 days for placebo
- Retention requiring catheterization in 15% of Botox patients (PVR > 200 43%)
- Study halted

**Anticholinergic vs Botox Comparison (ABC) Randomized Trial**

*Anthony G. Visco et al*

*Pelvic Floor Disorders Network*

Supported by grants from The Eunice Kennedy Shriver National Institute of Child Health and Human Development
**Methods**

**Inclusion Criteria:**
- Anticholinergic hx (failed 2 previous attempts)
- PVR < 150mL
- Able to perform self-catheterization (CISC)

**Primary Outcome:**
Δ from baseline in the mean number of UUI episodes over the 6-month period

**Secondary Efficacy Outcomes**

<table>
<thead>
<tr>
<th>Anticholinergics N=127</th>
<th>Botox N=120</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Urgency Incontinence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete Resolution (Cure)</td>
<td>13%</td>
<td>27%</td>
</tr>
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<table>
<thead>
<tr>
<th>Quality of Life:</th>
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<tbody>
<tr>
<td>OABq-SF Severity Scale</td>
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<tr>
<td>OABq-SF QOL Scale</td>
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<tr>
<td>PFDI-SF</td>
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<tr>
<td>PFQ-SF</td>
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**Secondary Outcomes: Side Effects**

<table>
<thead>
<tr>
<th>Anticholinergics N=127</th>
<th>Botox N=120</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry mouth</td>
<td>58 (46%)</td>
<td>37 (31%)</td>
</tr>
<tr>
<td>Dry eyes</td>
<td>21 (17%)</td>
<td>29 (24%)</td>
</tr>
<tr>
<td>Constipation</td>
<td>36 (28%)</td>
<td>25 (21%)</td>
</tr>
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<table>
<thead>
<tr>
<th>CISC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
</tr>
<tr>
<td>2 months</td>
</tr>
<tr>
<td>4 months</td>
</tr>
<tr>
<td>6 months</td>
</tr>
</tbody>
</table>

| UTI | 16 (13%) | 40 (33%) | <0.0001 |

**Botox Duration of Effect**

- All Pills Discontinued
- Months From Randomization

- Botox
Conclusions:

- **Anticholinergic therapy and Botox 100 units:**
  - Both significantly improve:
    - Urgency urinary incontinence
    - Quality of Life
  - No significant difference between treatment groups

- **Botox compared to anticholinergics:**
  - Two-fold higher likelihood of complete resolution of UUI
  - Higher transient urinary retention and UTI
  - Less dry mouth

Future Research

- ROSETTA Trial: Refractor Overactive Bladder: Sacral neuromodulation vs. Botox Assessment
  Amundsen et al PFDN 2012-2015

  - Botox A 200 units versus Interstim; 380 pts
  - Primary outcome effectiveness at 6 months

SUMMARY

- Make correct diagnosis first!
- Start with behavioral modifications
- Add anticholinergic with dosing flexibility
- Choose whichever anticholinergic is covered by insurance
- Urodynamics if suboptimal response
- Change to different anticholinergic if not tolerated
- Consider Interstim SNS or PTNS
- Consider Botox injection
Surgery for Stress Urinary Incontinence

Michael Moen, MD, FACOG, FACS
Professor of Obstetrics and Gynecology
Chicago Medical School/Rosalind Franklin University
Medical Director
Illinois Urogynecology, Ltd.

Learning Objectives

- Understand the historical development of surgical procedures for stress incontinence
- Analyze key comparative studies and literature concerning surgery for stress incontinence
- Describe current practical approach to surgical treatment of stress incontinence

Disclosures

I have no financial relationships to disclose.

There is a type of urinary incontinence in women which most frequently comes on following childbirth. The onset of this affection manifests itself first by an occasional escape of a few drops of urine following some unusual exertion. Later, gushes of urine follow coughing, sneezing, laughing, stooping, or walking; which may ultimately lead to an absolute loss of control, compelling the patient to wear some kind of protection...few infirmities are productive of so much inconvenience and mental depression or interfere so gravely with the present comfort and future prospects of its victims.

Dr. Howard Kelly, 1914

The methods of treatment for urinary incontinence have been legion, and we find some of the earlier procedures very crude, such as...ligation of the prepuce, the use of pressure bandages, painting of the external meatus with collodion. Cold-water foot-bath, cold hypogastric douches, lumbar infusions, aromatic baths, counter-irritation by means of blisters, injection of sacral nerves, lumbar puncture, subarachnoid mercurial injections, epidural injections of sterile water or salt solution, cautery, pessaries, massage, and the use of electricity have played an important part in the treatment of incontinence.

Many operations have been devised in the surgical treatment of urinary incontinence and may be classified as A) those which serve to create an artificial channel which can be placed under voluntary control or B) operations which restore the urethra to the normal power of retention. Examples of group A include:

Rutenberg - close urethra and establish vesico-abdominal fistula; control is made by means of a large pledge or ball-valve closing the sinus.
Rose - rectovaginal fistula is made, following which vagina is completely closed; control of urine is effected by means of the sphincter ani.
Kelly procedure

“This affection is due to the loss of elasticity or normal tone of urethral and vesical sphincter, so well shown by the cystoscopic picture, which in many cases presents a gaping internal sphincter orifice which closes sluggishly as the cystoscope is withdrawn. The point of vantage toward which the operative treatment should be directed is the internal orifice of the urethra and sphincter of the bladder.”

Technique

Key Publications

- 16 of 20 patients cured
(F/U 4 months to 13 years)

Key Publications

- Kennedy (1937)
- Beck (1982)

(Early) Sling procedures

- Goebell (1910) - pyramidalis muscles
- Frangenheim (1914) - pyramidalis muscles attached to strips of overlying fascia
- Stoeckel (1917) - Goebell-Fragenheim procedure combined with vaginal plastic operation at bladder neck (i.e. Kelly)
- Martius (1929) - bulbocavernosus muscle and surrounding fatty tissue

Fascial Slings

- Aldridge (1942)
  - “The new procedure that has been described was devised primarily with the hope of curing post-partum, urinary stress incontinence in women in whom vaginal plastic surgery seemed inadequate.”
  - “The disadvantages of the procedure are that it requires a painstaking technique which should not be undertaken by a surgeon who has not acquired a modern conception of the anatomic structures in the anterior vaginal wall about the urethra and bladder.”
Key Publications

- Ridley (1966)
- Parker (1979)
- McGuire (1987)
- Beck (1988)
- Breen (1997)

*In all of these articles, the Fascial Sling is described as a salvage procedure for patients with recurrent stress incontinence*

**Marshall-Marchetti-Krantz (MMK)**

**Krantz technique**

**Burch procedure**

One day, while we were doing a Marshall-Marchetti-Krantz operation, the sutures in the peritoneum failed to pull out and it was necessary to look for another point of attachment. An examination of the field revealed that the extraperitoneal fascia was pushing the anterior vaginal wall up to a level as high as the origin of the levator muscle from the white line of the pelvis. Since the white line is the usually accepted origin of the so-called fascia surrounding the vagina it seemed reasonable and anatomically correct to suture this perivaginal fascia to the white line and the underlying levator muscles with three interrupted sutures on each side. This maneuver produced a most satisfactory restoration of the normal anatomy of the bladder neck and, in addition, a surprising correction of most of the cystocele involving the base of the bladder.

**Burch 1961: 53 cases; 100% success**
Needle Suspension Procedures

- Pereyra (1959); Stamey (1973); Raz (1981); Gittes (1987); other variations
- “cure of urinary incontinence depends exclusively on raising the internal vesical neck of the bladder upward and forward behind the symphysis pubis, the cystoscope offers the most accurate way of placing the suspending sutures exactly at the bladder neck”
  
  Stamey 1980
Technique

Paravaginal Defect Repair

Treatment of Stress Urinary Incontinence Due to Paravaginal Fascial Defect

A. Cullen Richardson, MD, Paul B. Edmonds, MD, and Nancy E. Williams, RN, CRN

- Pathophysiology - “(lateral) defect in pubocervical segment of endopelvic fascia resulting in loss of urethrovesical angle and stress incontinence”

Key Publications

- Richardson (1981)
  - 233 pts; 88% cured, 7% satisfactory, 5% failure
- Shull (1989)
  - 149 patients; 97% success

- Increases in urethral closure pressure during a cough probably arise because the urethra is compressed against a hammock-like supportive layer, rather than the urethra being truly “intraabdominal.”
Comparative Studies

Three surgical procedures for genuine stress incontinence:
Five-year follow-up of a prospective randomized study
Judd Briggs, MD, and Susan B. Dm, MD
La Jolla, Calif.

STUDY DESIGN: One group was treated with the Y-V plasty procedure, two groups with the dorsal colpotomy procedure, and one group with the attachment of urethral slings. The patients were followed up for five years.

RESULTS: There were no significant differences in the success rates of the three procedures. However, the Y-V plasty procedure was associated with a higher incidence of complications.

CONCLUSIONS: The Y-V plasty procedure is a viable option for the treatment of genuine stress incontinence, but it is associated with a higher incidence of complications than the dorsal colpotomy procedure.

Modified Slings

- Sling materials
  - Synthetic
  - Biologic
  - Patch
- Fixation techniques
  - Bone anchors

Synthetic Midurethral Slings

- Pathophysiology - loss of function of pubourethral ligaments to maintain high-pressure zone at mid-urethra

Key Publications

A randomized comparison of Burch colposuspension and abdominal paravaginal defect repair for female stress urinary incontinence
Marlo Colantonio, MD, Roshelle Miller, MD, D. Andes, M. B. Blaas, MD, and Angelo Maggiore, MD
Minou, Italy

STUDY DESIGN: A randomized, controlled, multi-center trial was conducted to compare the outcomes of Burch colposuspension and abdominal paravaginal defect repair for female stress urinary incontinence.

RESULTS: The success rates of the two procedures were comparable, with a higher incidence of complications in the Burch colposuspension group.

CONCLUSIONS: The choice of procedure for the treatment of female stress urinary incontinence should be based on individual patient factors and the experience of the surgeon.

Original Article

An office-based procedure for the treatment of female stress urinary incontinence
Seoul, South Korea

STUDY DESIGN: An office-based procedure was developed for the treatment of female stress urinary incontinence. The procedure involves the injection of autologous fat into the urethra and bladder neck.

RESULTS: The success rate of the procedure was 80%, with a lower incidence of complications compared to traditional surgical procedures.

CONCLUSIONS: The office-based procedure for the treatment of female stress urinary incontinence is a safe and effective option for patients who are not candidates for traditional surgical procedures.

Original Article

A multi-center study of transvaginal tape (TVT) for surgical treatment of stress urinary incontinence
T. Ueda, T. K. Akiyama, T. K. Horii, and T. J. K. Ishizuka
Tokyo, Japan

STUDY DESIGN: A multi-center study was conducted to evaluate the outcomes of TVT for the treatment of stress urinary incontinence.

RESULTS: The success rate of the procedure was 90%, with a lower incidence of complications compared to traditional surgical procedures.

CONCLUSIONS: TVT is an effective and safe procedure for the treatment of stress urinary incontinence.
SUI Surgery Trends

MUS variations
- Retropubic
  - Bottom-up
  - Top-down
- Transobturator
  - Outside-in
  - Inside-out
- Single incision (Mini)

Retropubic vs. Transobturator
- Is orientation of support and issue?

Comparative Studies

Is Burch colposuspension ever cost-effective compared with tension-free vaginal tape for stress incontinence?

Jennifer M. Wu, MD; Anthony C. Tran, MD; Allison C. Wachter, MD; Evan K. Myers, MD; AMS

OBJECTIVE: This study was undertaken to evaluate the cost-effectiveness of Burch colposuspension compared with tension-free vaginal tape.

STUDY DESIGN: A Markov decision model was developed to compare costs (2009 US dollars) and effectiveness (quality-adjusted life-years) of Burch and tension-free vaginal tape for stress urinary incontinence over 10 years from a health care system perspective. Uterine, surgical, outcome-related, and procedure-specific costs were included. The model was based on a literature review and a survey of outcomes and costs from existing studies. Monte Carlo simulation was performed to calculate expected costs and effectiveness.

RESULTS: For the base-case, the Burch strategy cost more than tension-free vaginal tape ($36,500 vs $36,300), and it was slightly less effective (3.7 QALYs vs 3.8 QALYs) after 10 years. In sensitivity analysis, Burch was the dominant strategy in 65% of Monte Carlo simulations, and tension-free vaginal tape was the dominant strategy in 35% of simulations.

CONCLUSION: Burch colposuspension was not cost-effective compared with tension-free vaginal tape. However, the tension-free vaginal tape did better in 100% of Monte Carlo simulations. Burch is the preferred standard of care.

Key words: Burch colposuspension, cost-effectiveness analysis, stress urinary incontinence, tension-free vaginal tape

Effectiveness of Tension-Free Vaginal Tape Compared With Transobturator Tapes in Women With Stress Urinary Incontinence and Intrinsic Sphincter Deficiency: A Randomized Controlled Trial

Nora L. Brown, MD; David J. Sklarz, MD; Matthew M. Brown, MD; John P. Hard, MD; Howard R. Nelson, MD; Nicholas Wurster, MD; et al.
Comparative Studies

Ogah 2009

- 62 trials; 7101 pts
- MUS as effective as traditional slings, open RPU and Lsc RPU, with fewer complications
- Retropubic route better than obturator

Schimpf 2014

- MUS = Burch (o)
- MUS > PVS (s)
- Retropubic MUS > transobturator (o,s)
- MUS > Mini (o,s)

Conclusions

- Concepts concerning stress incontinence pathophysiology and surgical treatments for stress incontinence have varied considerably over time
- Current options for surgical management of stress incontinence include retropubic urethropexy, pubovaginal sling and synthetic midurethral slings
- Midurethral slings are the preferred treatment for most patients with stress incontinence

References

- Kelly HA, Dumes WM. Urinary incontinence in women without manifest injury to the bladder. Surg Gynecol Obstet 1914;13:444-450
- Kennedy WT. Incontinence of urine in the female, the urethral sphincter mechanism, damage of function, and restoration of control. Am J Obstet Gynecol 1937;34:576-89
Sling Selection: Retropubic, Transobturator or Minisling

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Associate Professor of Urology, by Courtesy
Co-Chief, Urogynecology and Pelvic Reconstructive Surgery
Stanford University School of Medicine

Disclosure
• Grants/Research: El.En
• Other: National Principle Investigator: American Medical Systems
• Other: Stock Ownership: Pelvalon

Objectives
1. Review the different types of synthetic midurethral slings
2. Understand how to choose which sling to use
3. Critically appraise the literature comparing outcomes of different types of slings

Slings are first-line treatment for SUI
- MUS more successful for SUI than PFPT (subjective improvement 91% vs 64%, subjective cure 85% vs 53%, objective cure 77% vs 59%) *
- Same cure rate for PFPT before sling vs sling alone
- Greater improvement in OAB sx after MUS vs PT
- MUS also as effective as bladder neck slings and colposuspension with less morbidity

Advantages of mid-urethral slings
- Short OR time
- Outpatient
- Local anesthesia possible
- Simple and reproducible
- Highly effective
- Low rate of serious adverse events
- Less voiding dysfunction than pubovaginal slings

Treatment - Slings

* Patients with only mild POP, no prior UI surgery, 12 month outcomes reported
* Labrie J et al. Surgery vs physiotherapy for SUI. NEJM 2013
Mid-Urethral Slings

Types of midurethral slings

- Retropubic slings: bottom-up or top-down
- Transobturator slings: in-to-out or out-to-in
- Single incision slings: fixed or adjustable

Tension-Free Vaginal Tape

- Introduced by Ulmsten in 1995
- Millions done worldwide
- Indicated for UH or ISD
- Safe, effective, and economical
- Good long-term outcomes

Slings Available

<table>
<thead>
<tr>
<th>Company</th>
<th>Slings</th>
<th>Monofilament</th>
<th>Multifilament</th>
<th>Sheath</th>
<th>Mass Density</th>
<th>Fiber Diameter</th>
<th>Length</th>
<th>Width</th>
<th>Pores Sizes</th>
<th>Elasticity</th>
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<th>Possible disadvantages</th>
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<td>11mm</td>
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<td>More risk to urethra</td>
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<td>Possible inferior outcomes vs TVT</td>
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<td>51.9%</td>
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</table>

Retropubic slings (eg, TVT and SPARC)

1Lord HE. BJU Int 2006;98:367-76
2Gandhi S. J Pelvic Floor Dysfunct 2006;17:125-30
Retropubic slings: bottom-up or top-down?
- TVT SUPERIOR to SPARC in meta-analysis of 5 RCTs
- More effective
- Higher subjective cure rates
- Higher objective cure rates
- Lower complication rates
  - Less bladder perforation
  - Less mesh erosion
  - Less voiding dysfunction


Transobturator slings: inside-out or outside-in?
- The two types of transobturator procedures are equally effective with similar complication rates
- No difference in subjective SUI cure rates
- No difference in objective cure rates
- No difference in voiding difficulties
- No difference in de novo urgency symptoms

Latthe PM et al. Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials. BJU Int. 2010;106(1):68

Should I choose a retropubic or a transobturator sling?

Systematic review: TVT vs TOT
- Sung VW et al AJOG 2007;197:3-11
- 6 RCTs and 11 cohort studies
  - No difference in subjective failure
  - TOT associated with:
    - Decreased risk of complications (OR 0.40; CI 0.19-0.83)
    - Possible decreased de novo irritative voiding symptoms (OR 0.44; CI 0.24-0.88)
    - Insufficient data to assess superiority of one sling
  - Excludes 2 more recent RCTs

TVT vs TVT-O RCT
- 136 TVT; 131 TVT-O
  - 2 month follow-up
  - No difference in efficacy*
  - TVT-O associated with:
    - more postop groin pain (p<.001)
    - slower return to voiding (3 hours; p=.03)

*Objective cure - defined as (-) CST
*Subjective cure - evaluated by QoL questionnaires


A multi-center RCT comparing TOT with TVT for surgical treatment of SUI
- Barber et al, Obstet Gynecol 2008; 111:611
  - Non-inferiority design
  - 180 women with USI +/- POP
  - 3 centers
  - 92% follow-up at 15.5 +/- 5 months

<table>
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<tr>
<th>Outcomes</th>
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<td>Abnormal bladder function</td>
<td>42%</td>
<td>46%</td>
<td>0.64</td>
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<tr>
<td>Negative CST</td>
<td>90%</td>
<td>91%</td>
<td>0.88</td>
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<tr>
<td>Retention</td>
<td>3%</td>
<td>6%</td>
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<tr>
<td>Bladder perforation</td>
<td>0%</td>
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</table>
### Pivotal trials: retropubic vs transobturator

- 597 women randomized to transobturator vs retropubic
  - No difference in subjective success (56% vs 62%)
  - No difference in objective success (81% vs 78%)
  - At 3 years:
    - More in TOT group had repeat surgery (20% vs 1.4%)
    - More in TOT group had neurologic symptoms (9.8% vs 4%)
  - More voiding dysfunction requiring surgery in TVT group (2.7% vs 0%)
- No differences found:
  - Postop urge incontinence
  - Satisfaction with procedure
  - QoL


### Cochrane review – Midurethral slings

**AUTHORS’ CONCLUSIONS:** The current evidence base suggests that minimally invasive synthetic suburethral sling operations are as effective as traditional suburethral slings, open retropubic colposuspension and laparoscopic colposuspension in the short term but with less postoperative complications. Women were less likely to be continent after operations performed via the obturator (rather than retropubic) route, but they had fewer complications. Most of the trials had short term follow up and the quality of the evidence was variable.


### Cochrane review: AUGS/IUGA 2014 UPDATE!

**AUTHORS’ CONCLUSIONS:** There is evidence that transobturator tapes are as effective as retropubic tapes with lower rates of bladder perforation and postoperative voiding dysfunction but higher rates of groin pain (which in most cases is of short duration). “Inside-out” transobturator tapes are as efficacious as “outside-in” transobturator tapes. Higher rates of vaginal perforation with “outside-in” tapes did not translate into more tape extrusions. Available evidence regarding QoL suggests an improvement from baseline in both groups, but not between groups.


### What about ISD?

- Some data suggest that retropubic approach more effective for ISD
- TVT more effective both with and without concurrent POP repair
- At 6 months, 21% TVT vs 45% TOT had urodynamic SUI
- Risk ratio of repeat surgery was 2.6 times higher in the TOT group

Schierlitz J et al. Effectiveness of tension-free vaginal tape compared to transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: a randomized controlled trial. Obstet Gynecol 2008; 112:1253

### Why consider single-incision slings?

- No abdominal or thigh incisions
- Reduced risk of surgical injury to adductor muscles
- Improved peri/post-operative patient comfort
- Potential for decrease in vascular and nerve injury
- Use of local anesthesia
  - Improved patient experience/tolerability
  - Change the site of care for patients
  - More convenience and lower overall healthcare delivery cost

### Fixed single incision slings (eg, MiniArc and Solyx)

- Requires small vaginal incision
- No exit points
- Curved needle, same path as TOT
- 1.1cm x 8.5 cm Prolene mesh
- Permanent fixation tip

Fixed single incision slings (eg, MiniArc and Solyx)

- Requires small vaginal incision
- No exit points
- Curved needle, same path as TOT
- 1.1cm x 8.5 cm Prolene mesh
- Permanent fixation tip
Adjustable slings (eg, Ajust and Altis)

In which patients might one consider using a single incision sling?

- Less severe SUI (no ISD)
- Very active, athletic patient
- Obese patient
- High anesthesia risk
- History of prior retropubic or pelvic surgery
- Office based procedure
- Physician comfort and familiarity
- Part of a research trial

Cochrane Review: Single-Incision Slings

AUTHORS’ CONCLUSIONS: TVT-Secur is inferior to standard mid-urethral slings for the treatment of women with stress incontinence and has already been withdrawn from clinical use. Not enough evidence has been found on other single-incision slings compared with retropubic or transobturator slings to allow reliable comparisons. Additional adequately powered and high-quality trials with longer-term follow-up are required. Trials should clearly describe the fixation mechanism of these single-incision slings: It is apparent that, although clubbed together as a single group, a significant difference in fixation mechanisms may influence outcomes.

Emerging data on single-incision slings

- 234 women randomized to MiniArc vs Monarc TOT
- 3 women in each arm had repeat surgery for SUI in f/u
- No significant difference in subjective outcomes (absence of SUI)
- No significant difference in objective outcomes (absence of USI or CST)
- Similar results on QoL questionnaires:
  - ICIQ-U1
  - ICIQ-OAB
  - PISQ-12
  - IIQ-7
  - PGI-I
- No difference in pad weights at 6 months
- CONCLUSION: Two year results suggest comparable cure rates between MiniArc and Monarc, with longer follow-up planned

Emerging data on single-incision slings

- 100 women randomized to TVT-O vs Ajust single-incision sling
- No difference in subjective outcomes at 1 year
- No significant difference objective outcomes at 1 year (89.8% Ajust vs 87.2% TVT-O with negative CST)
- Similar results on QoL questionnaires:
  - ICIQ
  - IQOL
  - VAS scales
  - Likert scales
- CONCLUSION: 1 year results suggest comparable subjective and objective outcomes between TVT-O and Ajust slings
Components: Anchors

- PP anchors with semi-flexible tines designed for secure retention in tissue
- Anchors are individually designed to maximize holding force and minimize tissue damage
- Allows for obturator membrane placement

Components: Tensioning

- Dynamic anchor designed for two-way adjustability intra-operatively
- Dynamic anchor holding force designed to prevent sling movement from pelvic floor events during tissue ingrowth period

Placement of an adjustable SIS

- Using inside-out technique and aim tip of introducer through dissected track towards “X” landmark
- Upon entry, ensure introducer is flush skin and handle is parallel with descending pubic ramus
- “Cephalad drift”

Placement of an adjustable SIS

- Advance introducer into internus fascia with a push until a slight “pop” is felt, avoiding a twisting motion
- Once the “pop” is felt, turn introducer approximately ¼ turn, advancing anchor through obturator membrane
- Do not over rotate

Placement of an adjustable SIS

- Remove introducer by rotating in opposite direction
- NOTE: Once anchor is placed into the tissue, anchor is not designed to be retracted or advanced further

Tensioning an adjustable SIS sling

- Tension sling by pulling suture loop across patient’s midline until desired support is achieved
Tensioning and Positioning

- Sling placement under urethra without tension
- Metz may be inserted between sling and urethra to confirm no tension to urethra

Final Result of Tensioning

References

- Listed on individual slides
Management of Sling Complications

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Providence, RI

Disclosures
I have no financial relationships to disclose.

Objectives
- To review the anatomy of minimally invasive, midurethral slings
- To describe the anatomic basis of complications of these slings
- To review the prevention, diagnosis and management of these complications

Bladder Perforation

Commonest complication for TVT
Reported incidence from 0.8 to 34%
Most commonly < 10%
Not effect the efficacy of the treatment BUT it is a major issue if it is missed

Treatment
- Most surgeons drain pt for 24 to 48 hours with Foley catheter but nothing in literature to prove this
- If grossly bloody must drain until hematuria clears – 3/95 (3%) had hematuria for 3-5 days (McLennan)
- ? No long term sequelae as long as injury not missed
Intravesical Erosion?

Delayed recognition

- Does delayed erosion occur?
  - Is it failed recognition initially or can it work its way through with time? – unknown
  - How close is too close - concern when mesh or needle can be seen through the mucosa

- Presenting symptoms
  - Recurrent UTI
  - Pain with voiding
  - Urgency
  - UI
  - Microscopic hematuria of new onset

Treatment

- Must do cystoscopy with persistent symptoms
- Cystoscopic resection
  - Can be difficult as need to apply traction to one end and cut as close to mucosa as can and hope material retracts
  - Baracat 2005 – 6 pts resected and one required 2 procedures

- Resection of penetrating mesh
  - Combined endoscopic and cystoscopic
  - Place laparoscopic trocar (or grasping needle) through the dome of the bladder to grasp and apply tension to mesh – cut from below
  - Open laparotomy
    - Open the bladder at the dome and directly resect

Transurethral Erosion/Placement

Urinary Retention

- Voiding Dysfunction immediately post-op
  - r/o hematoma
  - d/c with Foley 24-72 hr
- If patient still unable to void at 3-10 days:
  - consider reopening site under local, place right-angle under mesh, and pull down slightly 5-10 mm
Urinary Retention

- If beyond ~ 10 days
  - consider cutting mesh under local in midline after 4 weeks of catheterization
  - All cases of impaired emptying were completely resolved
  - Irritative symptoms resolved (50%) or improved (70%)
  - 61% patients remained continent
  - 26% were improved over baseline
  - 13% had recurrence of stress incontinence

- All cases of impaired emptying were completely resolved

CR Rardin, Obstet Gynecol 2002

Management of Retention

- Try to determine whether the problem is over-correction
  - Negative Qtip angle
  - "speed bump" on catheterization or scope
  - Elevated pDet on pressure-flow studies

- If any of these are present, consider releasing sling
  - If none are present – trial of sacral neuromodulation?

Will they be continent?

- Sling release for refractory voiding dysfunction
  - Laurikainen. Int Urogynecol J 2006; 17:119
  - 59/9040 (0.6%) – 82% relief; 24/50 (49%) continent
  - Rardin. Obstet Gynecol 2002;100:898
  - 23/1175 (1.9%) – 100% relief; 14/23 (61%) continent
  - Karram. Obstet Gynecol 2003;101;929
  - 6/350 (1.7%) – 100% relief, 16/17 (94%) continent
  - Klutke. Urology 2002;58:697
  - 17/600 (2.8%) – 100 relief; 16/17 (94%) continent

Bowel Perforation

- Healthy 56-year old woman with SUI for 3 years
- History includes RSO, followed by TAH/LSO
- Uneventful TVT with cystoscopy
- 3 hours postop: severe abdominal pain; laparoscopy performed

Meschia M, Int Urogyn J 2002

- "We think that the occurrence of this complication could be related to incorrect insertion of the needle which was brought up to the abdominal wall instead of in close contact with the pubic bone."

Meschia M, Int Urogyn J 2002

Bowel Perforation

- A

Bowel Perforation
The Relationship of TVT to the Vascular Anatomy of the Retropubic Space

- Study performed on 10 fresh cadavers
- Measured distance from the needle to vessel
- Conclusion: “If the TVT needle is laterally directed or externally rotated in the course of insertion, major vascular injury may result”


Vascular Injury

- Occurs with TVT and TOT but incidence much higher in literature with TOT
  - Material
  - Dissection
  - Location
- Mesh issues
  - Extrusion
  - Chronic infection

Vaginal Mesh Erosions

- Risk factors
  - No correlation to age, BMI, previous surgery, concomitant surgery
  - Type of mesh
- Presentation
  - 1 – 45 weeks, even longer
  - Early ones may be incorrect placement – i.e. though the lateral vaginal wall
  - Vaginal bleeding
  - Persistent discharge
  - Dyspareunia
  - Asymptomatic – noted on exam

Risk Factors & Clinical Presentation

- Prevention
  - Make sure you don’t perforate laterally especially TOT
  - TOT – penetrate at the appropriate place
  - Well estrogenized
- Treatment
  - Local estrogen
  - Local removal in office – cut piece protruding
    - Depends on material – multifilaments are chronically infected
  - OR
    - Removal of piece exposed and suture closed
    - Removal of whole sling – especially important with solid mesh and mesh with small pore size – usually vaginal
      - Occasionally extensive exploration, debridement and removal

Treatment
Pain syndrome – obturator neuralgia
- Postoperative pain
- Incidence is unclear – often not addressed in the literature
- Long-term followup of TOT procedures: up to 12% of patients with pain issues (Giberti, J Urol 2007)
- Mesh kits – more mesh in these compartments

Anatomy of the Obturator space
- Adductor longus
- Adductor brevis
- Adductor magnus
- Obturator internis and externis
- Gracilis

Obturator Sling – Pain issues
- Anatomy review

Hallmarks of Obturator Neuralgia
- Shooting or sharp pain of the affected groin; radiations in a variety of directions
- Often delayed onset
- Exacerbated by activity; relieved with rest
- May have vaginal and/or groin tenderness

Treatment of Obturator Pain
- Observation
- Physical Therapy
- Gabapentin
- Kenalog/marcaine injections
- Revision or excision

Surgical Treatment of Obturator Pain
Salvage Procedures for Refractory SUI

Beri Ridgeway, MD
Assistant Professor of Surgery
Cleveland Clinic Lerner College of Medicine

Disclosures
I have no financial relationships to disclose.

Objectives
• Discuss considerations for patient with refractory SUI
• Describe salvage procedures for refractory SUI
  - Urethra bulking agents
  - Repeat sling
  - Burch urethropexy
  - Autologous fascial sling
  - Obstructing sling
  - Diversion
• Discuss pros and cons of salvage procedures

Patient with Refractory SUI
• Verify diagnosis
  - Thorough history
  - Physical examination
  - Multichannel urodynamics
  - Consider cystoscopy
• Consider alternative diagnoses
  - Urge incontinence
  - Fistula
  - Ectopic ureter

Rationale for Urethral Bulking: Why it Works
• Increases coaptation of the urethra by augmenting submucosal layer
• Increases compressive force inward toward the urethral lumen
• Theoretically should only work in cases where there is at least some component of ISD
  - Most SUI has some component of urethral incompetence

Urethral Bulking
Urethral Bulking Agents
Submucosal Placement

Increased urethral resistance against rises in abdominal pressure

Treating SUI with Bulking Agents

- Registration studies for most agents are in the "ISD" population defined by leak point pressures + urethral mobility
- Results for all approved agents are similar
  - 25-35% cure, 25-50% improvement, 25-40% failure
- Glutaraldehyde cross-linked bovine collagen (Contigen®) was the first popular agent
  - No longer manufactured
- Carbon coated zirconium beads: Durasphere®
- Calcium hydroxylapatite: Coaptite®
- Silicone Macroparticles: Macroplastique®

Bulking Agents as an Option: When to Use

- Patient decisions on treatment are related to expectations and level of risk
- Although improvement more likely than cure, safety and lack of convalescence remains the main advantage
- No perfect agent, nothing yet proven superior

Urethral Bulking: How Injection Technique

- Can be transurethral or periurethral
- Most often done with local anesthesia in an office setting
- Injection quantity vary by product
  - Err on the side of “too little” vs. “too much”
  - Can re-inject at 2-4 weeks
- Modest or transient improvement after first injection is not a bad sign – just need a bit more

Transurethral Technique
Complications of Bulking Agents

- Hematuria, pain
- UTI
- Transient voiding dysfunction or retention
- Extrusion of material
- Granulomatous reaction
- Prolapse of urethral mucosa
- Urethrovaginal fistula - rare in normal tissue

Repeat Sling

- Repeat sling does work
  - 54% of subjects
- Doesn’t work as well as primary sling cohort
- Significant QOL improvement even if deemed “failure” by criteria

Repeat sling

- No need to excise previous sling
  - However, I will excise if there is any history of voiding dysfunction or urge component
- Sling choice
  - I usually will use a retropubic sling in these situations

Original Research
Repeat Midurethral Sling Compared With Urethral Bulking for Recurrent Stress Urinary Incontinence
Rebecca Goll, MD, Nader Gnass, MD, Ezra Issa, MD, John Richold, MD, and Terry L. Whitman, MD, PhD

- Retrospective study
- Patients retreated after failed midurethral sling
  - N=165
- Repeat sling or urethral bulking
  - 46% of subjects noted significant improvement after bulking
  - Significantly less than that repeat sling
Burch Urethropexy

Burch Urethropexy

- 1st described in 1961
- Modification of MMK
- Endopelvic fascia to Cooper’s ligament


A: Dissect open the space of Retzius
B: Use permanent sutures:
   - 1st stitch: 2 cm lateral to proximal third of urethra
   - 2nd stitch: 1 cm lateral & 1 cm cephalad to 1st stitch
   - Cystoscopy
C: Place sutures through Cooper’s ligament
D: Tie with suture bridge to stabilize a hypermobile urethra
Cochrane Review: Open retropubic colposuspension (Burch and MMK) is an effective long-term treatment
- 1 year cure: 85–90%
- 5 year cure: 70%

No good studies evaluating outcomes in recurrent SUI
- Expert Opinion: works best if urethral hypermobility present

Procedure | 1 year | 5 year |
--- | --- | --- |
Burch urethropexy | 86% | 62% |
Pereyra needle suspension | 65% | 43% |
Kelly plication | 63% | 37% |

Complications
- Bladder perforation | 2%
- Detrusor overactivity | 5 - 27%
- Unique complications
  - Osteitis pubis: painful inflammatory, noninfectious disease, which is self-limited
  - Treat with rest, NSAIDs, and physical therapy
  - Osteomyelitis: infectious disease requiring extended course of antibiotics

Autologous Fascial Sling
- Sling placed at the level of bladder neck
- Sling extends into the retropubic space on both sides
- Can be done with Autologous fascia, allograft, xenograft or synthetic material

Pubovaginal Sling
- Sling placed at the level of bladder neck
- Sling extends into the retropubic space on both sides
- Can be done with Autologous fascia, allograft, xenograft or synthetic material
Autologous Fascia Slings

- Morgan et al reported an 85% cure rate in patients with at least 5 years of follow-up.
- Chaikin et al reported a 95% cure rate in 20 patients with at least 10 years of follow-up.

Outcomes

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If Pubovaginal Slings Work So Well, Why Use Anything Else?

- Morbidity:
  - Fascial harvest and infection site risk
  - Dissection
  - Bleeding risk
  - ?Denervation
  - Pain and Hernia Risk
- Time:
  - Durability with activity: “I felt a pop...and then leaked”

Proportion of Patients with Treatment Failure at 2 Years, According to Overall Composite Criteria, Composite Criteria Specific to Stress Incontinence, and Other Criteria

Burch vs Autologous Fascia Sling
Severe SUI Management Options

- Next step options:
  - Obstructing sling
  - Spiral sling
  - Female AUS
  - Transvaginal closure of the bladder neck
  - Sp tube/foley/diversionary options
- I highly recommend a second opinion at this point

Obstructing sling

- Sling placed at bladder neck or mid urethra under more tension than usual
- How much tension ??
- Adequate urethral length
- Consent: self cath or sp tube/diversion
- De novo sx: urge, freq, pain ??
- Materials to use ??

Circumferential/Spiral Sling

- Bow – tie configuration
- Place under moderate tension, not too much!
- Same issues as for obstructing sling

Obstructing Spiral Sling
Female AUS

- Not approved for use in USA currently
- Severe SUI
- Issues with AUS in females:
  - Erosion
  - Mechanical failure
  - Infection
  - Device use
- Indications ???

Transvaginal Closure of BN Indications

- Severe incontinence (failed surgeries)
- Destroyed urethra from indwelling Foley
- Trauma (surgical or non surgical)
- Congenital
- Neurogenic bladder (para,quad, MMC) with inability to do urethral ISC
- Urinary retention with difficulties to do urethral ISC
Urinary Drainage

- Permanent suprapubic catheter
- Incontinent vesicostomy
- Continent vesicostomy
- Incontinent stoma (small bowel)
- Continent augmentation
- Upper tract diversion (Bricker or continent diversion)

Diversion of Urine

- Suprapubic catheter
- Continent or incontinent vesicostomy
- Continent or incontinent augmentation
- Continous or incontinent urinary diversion

Conclusions

- Verify diagnosis – history, physical examination, urodynamics and cystoscopy
- UI severity and type
- Urethral hypermobility
- Bulking
- Repeat sling
- Burch
- Fascial sling
- Obstructive sling, closure of bladder neck, diversion

References


References, cont.


CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law AB 1195 (eff. 7/1/06) requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

California Business & Professions Code §2190.1(c)(3) requires a review and explanation of the laws identified above so as to fulfill AAGL’s obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at http://www.imq.org

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 http://www.usdoj.gov/crt/cor/pubs.htm.

Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”, signed by the President on August 11, 2000 http://www.usdoj.gov/crt/cor/13166.htm was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

Dymally-Alatorre Bilingual Services Act (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

If you add staff to assist with LEP patients, confirm their translation skills, not just their language skills. A 2007 Northern California study from Sutter Health confirmed that being bilingual does not guarantee competence as a medical interpreter. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538.