Male stress urinary incontinence: Considerations for evaluation and treatment

PSA <0.01, PPD = 3

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January 2017
Jean L. Fourcroy MD, PhD, MPH
June 16, 1930 - October 12, 2016
Disclosures

- Boston Scientific Inc.
- Cook Myosite Inc.
Disclosures
Superstitions in medicine

• Patients
  • Saturday discharge, air to tumor

• Surgeons
  • Rituals, black clouds, full moons, VIPs

• Medical literature
  • Silicon implants, HRT
  • 2% rate of severe incontinence requiring surgery s/p RRP
Superstitions

- Joan Quigley

"Everything in life is luck"
PPI incidence and risk factors

- Dependent on definition
  - Questionnaire vs. chart review
  - Single surgeon vs. multi-institutional
  - Time dependent (3 m to 2 yrs)
- Risk factors
  - Salvage
  - Membranous urethral length preop
- Technical
  - Nerve sparing
  - Posterior rhabdosphincter reconstruction
National use of AUS

- AMS database: national average 6 per 100 RP

Predicting PPI

• More than just ISD?
  • Preop AUASI

• Preoperative variables
  • Age
  • Prostate size (CaPSURE data)
  • Bladder function
  • Capacity and compliance
  • Prior TURP
  • Salvage procedures
Postoperative variables

• Bladder neck contracture
• Urethral stricture
• Cancer recurrence
• Medical comorbidities
Timing of evaluation

Artificial Urinary Sphincter: Report of the 2015 Consensus Conference

X. Biardeau, S. Aharony, the AUS Consensus Group,* L. Campeau, and J. Corcos**
Department of Urology, Jewish General Hospital, McGill University, Montreal, Québec, Canada

• As of the 2015 ICS meeting, there were no existing guidelines on timing of SUI surgical treatment

• ICS released consensus statement recommending:
  • Surgical therapy with AUS should be offered to individuals with SUI who have failed conservative management 6 months after prostatectomy
  • Patients must have sufficient dexterity and cognitive function

• Practice Guidelines Committee convening panel
Timing of evaluation

- Traditional - 12 months to 2 yrs
- Current - 6 - 12 months if no improvement for at least 3 months
- Earlier after TURP
- Initiate conservative treatments
SUI evaluation

- History and physical
- UA
- Cystoscopy
  - BNC – staged approach
  - atrophy
- Voiding diary (dry at night?)
- PPD
- Uroflow/PVR
- UDS?
- AUASI?/ICIQ-UI/standardized questionnaires
Utility of urodynamics

• Bladder and/or sphincter dysfunction
• Relative contribution
• Defining ALPP
Utility of urodynamics
Utility of urodynamics
Utility of urodynamics
Utility of urodynamics
Utility of urodynamics
Conservative treatments

• Lifestyle adjustments
• Pelvic floor muscle training
• External compression devices
• Electrical stimulation
• Magnetic chair

Surgical options

• Historical devices
• Bulking agents
• Bulbar sling
  • Bone anchored
  • Transobturator
  • Quadratic
• Artificial urinary sphincter (AUS)
Bulking agents

- Ideal candidate < 3 PPD, ALPP > 60 cm H2O
- Durasphere, fat, collagen, Coaptite, PTFE, Tegress, Macroplastique
- No preop radiation, cryotherapy or TURBNC
- Compliance with several injections
- Expect 80% of select patients will improve, but less than 50% will be dry

Surgical options

- Bulbar male slings
- Artificial urinary sphincter
- Which procedure for which patient?
  - Defining level of incontinence
  - Pads per day?
  - Mild (1-2), Moderate (3-4), Severe (5+)
  - ALPP?
  - Expectations

Post prostatectomy Incontinence

- BNC
- TURBNC

- 6 months Cystoscopy
- UDS
- DO/OAB mgt

ALPP > 60 - 70
PPD < 3

Bulking/CT? Bulbar sling

ALPP < 60 - 70
PPD > 3

AUS

Behavioral
PFE
VD
Bulbar urethral sling indications

- Lower volume incontinence
  - Dry at night
  - Some sphincteric contractility
- Can not manipulate AUS
- Do not want a mechanical device
- Intermittent catheterization needed?

Bulbar urethral slings

- Relative and absolute contraindications
  - Bone deformation or severe osteoporosis
  - Compromised immune system
  - Coagulopathy
  - Renal insufficiency, upper tract obstruction
  - Urinary tract infections
  - Previous or active osteomyelitis
  - Unstable BNC, urethral stricture
  - Severe incontinence, prior AUS, radiation?

Bulbar urethral slings types

A. Bone anchor
B. Transobturator
C. Quadratic

Wessells, H and A Peterson 2016 Campbell-Walsh Urology, 91, 2169-2183
Bulbar urethral sling: bone anchored
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- Why are these off the market?
- Presumed lack of durable efficacy
- Unique complication profile
  - Wound infection in groin
  - Retention
  - Perineal pain
  - Osteomyelitis
Bulbar urethral sling: transobturator

- Inventors – Christian Gozzi, MD and Peter Rehder, MD, Innsbruck, Austria
- Difficult case led to new concept
  - Soldier with shattered pelvis s/p augmentation cystoplasty
- Proven TOT technology for female SUI
Mechanism of action

- Sling is placed on the proximal urethral bulb
- Tensioning the sling elevates the dorsal aspect of the sphincteric urethra and supporting structures
- Repositioning causes circumferential coaptation
- Force is applied parallel to the urethral lumen
Mechanism of action

- Relocates proximal urethra into the pelvic outlet
- Folding of spongiosium over urethra

Mechanism of action

• Thick spongiosum between sling and urethra
• Generally non-obstructive with unchanged flow rates

AdVance transobturator sling
AdVance transobturator sling
Patient positioning

- Dorsal lithotomy position, with legs bent at $\leq 90^\circ$
- 14 Fr. Foley catheter
Identify landmarks

- Turn of bulbar urethra
- Medial aspect of obturator foramen
- Adductor longus insertion
Dissection to bulbar musculature

- Perineal incision
- Lone Star retractor
Division of bulbar musculature

- Divide muscle in midline and deflect laterally
- Identify central tendon
- Place marking suture at origin of central tendon
- Partially release the central tendon sharply
Helical needle insertion site

- Helical needle insertion site is one finger breadth below each adductor longus tendon in the groin crease lateral to the ischial pubic ramus.

- Identify the insertion site with either a spinal needle or via palpation using above mentioned landmarks.
Helical needle passage

- 45° angle to the midline incision
- Place finger of the opposite hand into the apex of the triangle - bulbar urethra medially and the ischial pubic ramus laterally
- Insert and advance the needle tip along the lateral edge of the pubic ramus
- Once two “pops” are felt, stop advancing the needle and drop the needle handle toward the midline prior to rotating into your finger (placed at the apex of the triangle)
Helical needle passage

- POP
- POP
- STOP
- DROP
- ROTATE
Sling positioning

- Connect sling to needle tip, make sure sutures are facing away from the corpus spongiosum.

- Rotate the needle back along the same insertion pathway to pull sling through obturator foramen and out the stab incision.
Suture sling to bulb at central tendon

- Ensure that the mesh is flat against the corpus spongiosum
- The edge of the proximal flap of the sling should be located at the origin of the central tendon (previously marked)
- Anchor with biodegradable sutures both proximal and distal in that location
Tension sling

- Apply tension by firmly pulling both ends of the sling to achieve 2-4 cm proximal movement of the bulb

- Flexible cystoscopy may be used to confirm proper sling positioning as evidenced by circular sphincteric coaptation
Final steps

- Cut sling ends below blue markings and remove plastic protective barriers (sheaths)

- Optional: tunnel sling arms back toward the perineal incision to decrease the risk of sling migration?

- Close the bulbospongiosus muscle then the rest of the incision in several layers after irrigation and hemostasis
Virtue quadratic sling

- Relocates the proximal urethra via a transobturator component and compresses the bulbar urethra via a prepubic component
Transobturator Passage

Skin incision for transobturator arm

Virtue sling

Obturator foramen

Transobturator arms (clear sleeves) are passed 2 finger breadths below the junction of pubic symphysis and rami, in an "inside-out" technique, exiting just lateral to the groin crease.
External urethral sphincter injury post-prostatectomy

Prepubic arm fixation

Compression of bulbous urethra by sling reduces incontinence

Corpus cavernosum

Corpora spongiosa

Skin incisions for prepubic arms

Skin incision for transobturator arm

After tensioning, placement of sutures into the periosteum or fascia of ischiopubic rami will provide constant compression and stabilization of the Virtue male sling

Cystoscopy photos
Postoperative sling care

- Outpatient procedure
- Overnight catheter?
- Preoperative antibiotic prophylaxis only
- Voiding trial or catheter removal POD #1

Counsel patient to abstain from the following for 6 weeks:
- Heavy lifting
- Strenuous exercise
- Intercourse
Complications of male slings

- Efficacy
  - 32-80% success dependent on definitions/length of follow-up
- Displacement over time
- Chronic pain
- Osteomyelitis
- Urethral injury
- Infection

McCall, AN, Rivera ME, and DS Eliottt. 2016 Urology (93) 213-16
Comiter, C and A.D. Dobberfuhl. 2016 Investig Clin Urol (57) 3-13
Novel technologies

- Argus T adjustable TOT sling, RP sling
- Reemix adjustable sling
- proACT
- AMOMS
- ATOMS

Caremel, R and J. Corcos 2014 CUAJ (8) 202-12
Artificial urinary sphincter

- First implanted by Scott 1973
- Current model AMS-800
  - Pressure regulating balloon (61 – 70 cm H\textsubscript{2}O)
  - Deactivation button
  - Narrow backed cuff to decrease erosion
- 5 year revision free rate of 75%
- 89% success rate with 76% dry
- >90% patient satisfaction

AUS candidates

- Good manual dexterity and mental capacity
- Incontinent for at least 6 months (varies)
- Appropriate urodynamic results
  - Confirm factors contributing to incontinence and identify factors that may mitigate against a good outcome
- Appropriate cystoscopy results
  - Healthy placement site and exclusion of urethral strictures and anastomotic contracture
- Men (Women and children not approved in the USA)

AMS 800® Urinary Control System for Male Patients IFU 1004681
AUS contraindications

• Chronic urinary tract infections
• Irreversibly obstructed urinary tract
• Refractory DO?
• Altered compliance

Contraindications for AMS 800 with InhibiZone® coating

• Known allergy or sensitivity to rifampin or minocycline
• Systemic Lupus Erythematosus
AUS components

- Control pump
- Occlusive cuff
- Pressure regulating balloon
- Deactivation button
Control pump

- Controls the flow of fluid between cuff and PRB
Deactivation button

- Prevents fluid transfer between cuff and PRB
- Allows physicians to keep the cuff open:
  - During the postoperative healing period (6-8 weeks)
  - For transurethral procedures
Occlusive cuff

- Closes the urethra or bladder neck by applying pressure
- Available in multiple sizes:
  - 3.5-7.5 cm (0.5 cm increments)
  - 8.0-11.0 cm (1 cm increments)
Pressure regulating balloon

- Determines amount of pressure applied by cuff
- Pressures:
  - 51-60 cm H$_2$O
  - 61-70 cm H$_2$O
  - 71-80 cm H$_2$O
Quick connectors
AUS surgical procedure

• Dial soap and chlorhexadine wipes for day prior
• Shave and clean the abdominal and genital area (chlorhexadine)
• Preoperative antibiotics (vancomycin and gentamicin)
• Two surgical approaches for bulbous urethra:
  • Perineal (lithotomy)
  • Transverse scrotal (supine)
  • Retropubic for bladder neck
• Be meticulous!

New pilots (surgeons) buckets

Luck

Experience
12 F catheter placement
Midline perineal incision
Dissection to bulbar urethra
Identify groove deep to urethra
Sharp dissection circumferentially
Pass right angle for cuff sizer
Sizing cuff
Back table preparation
PRB placement
Control pump placement
Control pump placement
Cuff placement
Cuff placement
Connections
Alternate techniques

- Penoscrotal
- Transcorporal
- Double cuff

Wessells, H and A Peterson 2016 Campbell-Walsh Urology, 91, 2169-2183
AUS outcomes

• Depends on definition
• In general, between 82-89% cured or improved
• 73-76% with 0-1 pad per day
• Revision rates approximately 26%
• Infection/erosion 8.5%
• Mechanical failure 6.2%
• Urethral atrophy 7.9%
• Still controversy regarding impact of radiation therapy

Wessells, H and A Peterson 2016 Campbell-Walsh Urology, 91, 2169-2183
Van der Aa, FV, M.J. Drake, G.R Kasyan et al. 2013 Eur Urol (63) 681
Managing AUS complications

• Realistic expectations
• Meticulous surgical technique
• Perioperative management
• Don’t rely on luck

Wessells, H and A Peterson 2016 Campbell-Walsh Urology, 91, 2169-2183
Van der Aa, FV, M.J. Drake, G.R Kasyan et al. 2013 Eur Urol (63) 681
Intraoperative: urethral injury

• Typically occurs during urethral mobilization
• Sharp dissection, avoid extensive peri-urethral tissue dissection during cuff placement
• Intra-operative indication:
  • Peri-catheter blood at time of urethral dissection
  • Irrigation through meatus shows extravasation
  • If noted intra-operatively abandon procedure and attempt to re-implant in 6-8 weeks
Postoperative: urethral injury

- Hematuria after catheter removal
  - Confirm with cystoscopy

- May lead to infection, erosion
  - May note early or persistent incontinence
Intraoperative: device injury

- Manifests as early failure after activation
- Care with hemostats, clamps, needles, pickups
**Postoperative: recurrent incontinence**

<table>
<thead>
<tr>
<th>Early and persistent urine leak</th>
<th>Delayed and recurrent urine leak</th>
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</thead>
<tbody>
<tr>
<td>Poor technique/deflation of control pump</td>
<td>Cuff atrophy</td>
</tr>
<tr>
<td>Overactive bladder</td>
<td>Mechanical malfunction/fluid leak</td>
</tr>
<tr>
<td>Early cuff erosion</td>
<td>Late cuff erosion</td>
</tr>
<tr>
<td>Incorrect AUS components</td>
<td></td>
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</tbody>
</table>
Postoperative: urethral erosion
Postoperative: urethral erosion

- Significant risk factors
  - Prior radiation therapy
  - Previous erosion and/or infection
  - History of urethral stent placement
  - Excessive cuff pressure:
    - Undersized cuff
    - Large catheter or catheterization while cuff remains inflated
- Erosion and infection are inter-related
  - Erosion leads to infection … infection may lead to erosion
Minimizing urethral cuff erosion

- Exercise care when mobilizing urethra for cuff placement
- Check for extravasation of irrigation fluid
- Measure carefully when determining correct cuff
- Deactivate cuff for six weeks
  - Allows healing of urethra and bladder neck
Appropriate cuff sizing
Managing urethral cuff erosion

- Explant
- Urethroplasty?
- Post-op catheter 3 weeks
- Wait 2-3 months prior to reimplant
- Reimplant at new site or consider transcorporal
Urethral atrophy

- Atrophy is a natural consequence of compression and occurs to some degree in all cases
- Potential risk factors for early atrophy
  - Undersized cuff (excessive cuff pressure)
  - History of pelvic radiation therapy
- Signs/Symptoms
  - Initial satisfactory continence with gradual increase in pad use over time
  - Number of cycles needed before pump stays collapsed increases
  - Pale urethral mucosa and poor coaptation visible during urethroscopy
Infection

• Infection is a devastating complication in male incontinence surgeries
• Risk factors may be patient related or surgical factors
• Key patient related factors:
  • Diabetes
  • Revision surgery
  • Immunocompromise
• Key surgical factors:
  • Alcohol-based intraoperative scrub over iodine-based scrub
  • Implant coatings capable of retarding infection (i.e., InhibiZone)
  • Preoperative antibiotics
Infection may necessitate removal

- May be indicated by a number of symptoms
  - Fever
  - Swelling
  - Erythema
  - Tenderness
  - Purulent drainage
  - Recurrent pain
  - Pump adhesion to scrotum

- Systemic antibiotics are generally not successful
  - Biofilm produced by infectious agent
  - Fibrous capsule forms around the device
  - Relatively poor blood supply
Urinary retention

• Presents as an early post-operative complication
• Typically occurs secondary to postoperative edema
• In the majority of cases will resolve spontaneously
• Persistent retention may indicate inappropriate cuff sizing
• Minimizing urinary retention:
  • Avoid implanting cuff that is too small
• Managing urinary retention:
  • Avoid long term indwelling catheter
  • Use a small (12F) straight catheter when required postoperatively to reduce the risk of catheter-related erosion
Additional curiosities
Additional curiosities
Additional curiosities
Additional curiosities
PPI

• Appropriate assessment
• Early evaluation
• Postoperative UDS, cystoscopy
• Mild incontinence, high ALPP
  • sling
• Severe incontinence, low ALPP
  • AUS
Post prostatectomy Incontinence

Behavioral
PFE
VD

6 months Cystoscopy

UDS

DO/OAB mgt

ALPP < 60 - 70
PPD > 3

AUS

ALPP > 60 - 70
PPD < 3

Bulking/CT
Bulbar sling

TURBNC

BNC
Future directions

Transurethral ultrasonography-guided injection of adult autologous stem cells versus transurethral endoscopic injection of collagen in treatment of urinary incontinence

H. Strasser · R. Marksteiner · E. Margreiter · M. Mitterberger · G. M. Pinggera · F. Frauscher · M. Fussenegger · K. Koller · G. Bartsch
Future directions

Autologous Muscle Derived Cells for Treatment of Stress Urinary Incontinence in Women

Kenneth M. Peters,* Roger R. Dmochowski,† Lesley K. Carr,‡ Magali Robert,‡ Melissa R. Kaufman,§ Larry T. Sirls,|| Sender Herschorn,¶ Colin Birch, Patricia L. Kultgen and Michael B. Chancellor**

2007 Society of Women in Urology Christina Manthos Mentoring Award Recipient
New paradigm

- Novel treatment strategies
- Regenerative vs. symptom management
- Target and reverse disease progression
- No foreign body
- Autologous cells
- Background data combined with powerful clinical plan
- Significant obstacles remain in understanding MOA
• Biopsy harvested from skeletal muscle
• Delivered back to clinical site following *ex vivo* expansion
• Injected into targeted muscle layer
• Mechanisms of potential therapeutic benefit
  - Direct - New muscle formation
  - Direct - Augmentation of existing muscle
  - Indirect - Secretion of growth factors/host tissue remodeling
Sterile tissue procurement

- Minimally invasive
- In-office
- Local anesthesia
- Usually <15 minutes
- ~150 mg of tissue obtained
Urethral injection procedure

- Minimally invasive
- In-office
- Local anesthesia
- Multi-Injection Needle, which allows for 3 simultaneous injections at controlled depth
Phase I/II Studies: Pad tests/leaks

Legend:
- Blue: Negative pad test (<1.3 g)
- Red: ≥50% improvement in pad test
- Gray: Zero stress leaks over 3 days
- Black: ≥50% reduction in stress leaks

Percentage of patients at 12 months

<table>
<thead>
<tr>
<th>AMDC-USR dose</th>
<th>10 x 10^6</th>
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Current initiatives

• Phase III of the clinical development program for female SUI

  • Randomized, double-blind, placebo-controlled trials assessing the safety and efficacy of $150 \times 10^6$ AMDC-USR for treatment of SUI in women is ongoing in United States and Europe
Additional initiatives

• Phase II pilot study for male post-prostatectomy incontinence
  • Assessing the safety and efficacy of $150 \times 10^6$ AMDC-USR for treatment of post-prostatectomy SUI at 2 clinical sites: Vanderbilt and Beaumont

• Underactive bladder
  • Compassionate use patient
  • Current development of Phase II trial in Japan

• Fecal incontinence

• Tongue dysphasia

• Additional urologic initiatives?
Inaugural SWIU Mentoring Conference: 2012
We are lucky!

Luck favors the mind that is prepared.

~ Louis Pasteur