STRESS URINARY INCONTINENCE IN WOMEN

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Disclosures

- Advisory Board, Analytica
- Author, UpToDate
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Overview

- Evaluation of stress urinary incontinence (SUI) in women
- Treatment options
- Surgical treatment
Trends in SUI surgery

- Health care claims data 2000-2009
- 27% increase in rate of SUI surgery due to increased sling procedures

Funk et al, Obstet Gynecol, 2012
Trends in SUI surgery

- State Ambulatory Surgery Database 2001-2009
- Age adjusted rates of midurethral slings
  - 2.36 $\rightarrow$ 9.45/10,000 population
- Submucosal injections
  - 1.75 $\rightarrow$ 1.41/10,000 population
  - Older patients, higher Charlson comorbidity index score

Suskind et al, Int Urogynecol J, 2013
Evaluation of SUI - History

- SUI vs UUI
- How urge-y is the patient?
- Voiding difficulties
- Pain symptoms, dyspareunia
- Prior treatment, pelvic surgery
- Prior radiation, current smoker
UUI and MUS

- Predictors of MUS failure:
  - Less urethral hypermobility
  - Increasing UUI at baseline
  - Prior UI surgery

Richter et al, Obstet Gynecol 2011
Paick et al, J Urol, 2007

- Decreased success rates in MUI vs SUI
  - 60% vs 80% success when defined as “very satisfied” and negative CST at 12 months
    Kulseng-Hanssen et al, Neurourol Urodynam, 2007
  - OR failure 2.4 (CI 1.6-3.6, p<.001)
    Stav et al, Int Urogynecol J, 2010
  - Subjective cure at 5 years 55% vs 81%
Post-operative UUI

- In patients with MUI, urgency component:
  - Resolves or improves 50-60%
  - Unchanged 30-40%
  - Worsens 5-15%

- De novo UUI symptoms in 10-15%

  Segal et al, Obstet Gynecol, 2004
  Botros et al, Neuourol and Urodynam, 2007
  Richter et al, NEJM, 2010
  Barber et al, Obstet Gynecol, 2008
Post-op voiding dysfunction

- AKA obstruction, change in flow, urgency, frequency
- Revision 1.5-3%
  - 70% unsatisfied, 56% would not recommend
    Abraham et al, Neurourol and Urodynam, 2015
- Possible to predict?
  - Pre-operative “voiding difficulty”
  - Concomitant surgery
  - Age
  - “valsalva voiding”
  - UDS parameters (flow rate, Pdet)
  - Prior UI procedure

Molden et al, Int Urogynecol J, 2010
Unger et al, Int Urogynecol J, 2015
Sokol et al, AJOG, 2005
Mesh exposure

• Occurs in 2-5% patients
• Current Smoking (3-5x)
• Diabetes (8-11x)
• Age

Withagen et al, Obstet Gynecol, 2010
Chen et al, Int Urogynecol J, 2008
Post-op pain

• Pain lasting more than 6 weeks (2-5%)
  • Pre-operative pain OR 3.21 (1.23-8.40)

• Dyspareunia (10%)
  • Pre-operative dyspareunia OR 4.66 (1.69-12.81)

Withagen et al, Obstet Gynecol, 2010
Abed et al, Int Urogynecol J, 2011

• Other risk factors
  • Age
  • Fibromyalgia

Geller et al, JMIG, 2017

• Pain more common in those patients seeking litigation vs not

Zoorob et al, FPMRS, 2016
Evaluation of SUI - PE

- Post-void residual
- Cough stress test
- Vaginal support
- Urethral hypermobility
- PFM strength
  - To determine home PFME vs office PT
- Myofascial tenderness
  - Predictor of post-op pain?
Role of UDS

• ValUE study
• 630 women with stress predominant UI and +CST randomized to UDS vs no UDS prior to sling surgery
• Success similar (77%) at 12 mos
  • ≥70% improvement on UDI
  • “much” or “very much” better on PGI-I
  • If -CST included, success still similar at 70%

Nager et al, NEJM, 2012
AUA Guidelines for Evaluation of SUI

• Standard: The evaluation of the index patient should include
  • Focused history
  • Focused physical examination
  • Objective demonstration of SUI
  • Assessment of post-void residual urine volume
  • Urinalysis and culture if indicated

• Recommendation: Additional diagnostic studies that can be performed to assess the integrity and function of the lower urinary tract include
  • Pad testing and/or voiding diary
  • Urodynamics
  • Cystoscopy
  • Imaging
Treatment of SUI

• Behavioral modification
• PFME vs office pelvic floor PT
• Pessary
• Surgical treatment
  • Peri-urethral bulking
  • Burch urethropexy
  • Suburethral slings
Stress urinary incontinence treatment

• Behavioral
  • Weight loss of 5-10% resulted in 60% decrease in incontinence episodes (vs 15% decrease in controls)
    Subak et al, J Urol, 2005

• Pelvic floor muscle exercises
  • Cochrane review in 2007 supported that PFM training be included in first-line conservative management for women with UI
  • RCT 460 women randomized to PFMT vs midurethral sling
    • 50% women in PFMT group crossed over to surgery group
    • Overall, greater objective and subjective cure in surgery group
    • BUT, 30% of PFMT only group reported improvement (“much better” or “very much better”)
    Labrie et al, NEJM 2013
Pessaries

- 190 women with SUI or MUI, 63% chose pessary trial
- 89% with successful fitting
- 50% still using at 6 mos

Donnelly et al, Int Urogyn J, 2004
PFM exercise vs pessary

- NIH/NICHD study, n=446
  - 50% with ≥14 UI episodes/week
- Randomized to pessary, PFME, or both
- 8 weeks of in office treatment
- 12 months:
  - “much better” or “very much better” in 53% PFME vs 58% pessary
  - No bothersome SUI symptoms in 62% both grps
  - >75% reduction in weekly UI episodes in 57% in both grps

Richter et al, Obstet & Gynecol 2010
Surgical treatment of SUI

- Peri-urethral bulking
- Burch urethropexy
- Suburethral slings
  - Autologous fascial sling
  - Mid-urethral sling
    - Retropubic MUS
    - Transobturator MUS
    - Single incision MUS
Periurethral bulking

- 30-40% dry, 50% improved at 1 year
  - 67% responders “dry” at 24 months
- Approximately 50-60% patients require >1 injection
- Temporary retention 40%

Mayer et al, Urology, 2007
Ghoniem et al, J Urol, 2010

www.oxfordgynaecology.com
Fascial sling vs Burch urethropexy

- 655 women randomized to PVS or Burch
- Outcomes
  - Success rate higher for sling (66% vs 49%, p=.001) at 24 mos
  - Treatment satisfaction 86% vs 78%, p=.02
- Sling revision in 6% PVS vs 0% Burch
- De novo UUI requiring treatment 3% in both groups
  
  Albo et al, NEJM, 2007

- E-SISTEr – 74% subjects enrolled
  - 5 year continence – 31% vs 24%
  - Satisfaction – 83% vs 73% (p=.04)
  - Retreatment in 2% vs 12% (p<.0001)

  Brubaker et al, J Urol, 2012
RMUS (TVT)

- Ward, Hilton data, BJOG 2008
  - 175 women underwent TVT
    - 98 with 5 year follow-up
    - 72 with full data
  - 58/72 (81%) with neg. pad test
    - 75% if last result carried forward
  - 63% reported cure of leakage on questionnaire
  - 91% satisfied or very satisfied with results
  - 2.3% underwent re-operation for USI
  - 3 vaginal tape erosions (2 detected at 5 years)
  - De novo urgency in 2%, UUI in 1%
RMUS vs TMUS

- NIH sponsored RCT of 597 women
  - At 12 months, similar satisfaction (86% vs 90%, p=0.14)
    - 79% vs 85% at 5 years (p=0.15)
  - Persistent urgency incontinence in 13-14%

- Adverse events over 24 months
  - Mesh erosion in 2.7% subjects
    - 7 additional erosions at 5 years – 3.8%
  - Pain >6wks 2.3%
  - Voiding dysfunction 3.4% RMUS vs 2% TMUS
  - Neurologic symptoms 5% RMUS vs 9.7% TMUS (p=.04)

  Richter et al, NEJM, 2010
  Brubaker et al, AJOG, 2011
  Kenton, AJOG 2011
RMUS vs TMUS

• RCT of 170 women, mean f/u 18.6 mos.
• Outcomes
  • ~ 60% “dry”, 25% improved, 15% no change
  • 80% reported bladder symptoms “much better” or “very much better”
  • Re-treatment for SUI 4.7% TVT vs 1.3% TOT
• Complications
  • Bladder perforation in 7% TVT vs 0% TOT
  • Erosions in 5.6% TVT vs 1.2% TOT
  • Leg pain or difficulty ambulating in 2.4% TVT vs 4% TOT (NS)
• New bladder symptoms
  • New or worsened UUI in 4-10%
  • 3-6% required catheterization > 6 weeks after surgery or had surgery for obstructed voiding

Barber et al, AJOG March, 2008
Longer term outcomes

- 273 women randomized RMUS vs TMUS
- 95% had 5 year follow up
- 85% vs 86% with neg CST, neg pad test, no re-tx
- Satisfied: 85%
- Recommend to friend: 90%
- No new erosion/extrusion

Laurikainen et al, J Urol 2014
Other considerations…

• RCT of 164 women with ISD (slightly underpowered)
  • ISD defined as MUCP ≤20cm H2O or leak with ΔPves ≤60cm H$_2$O

• Outcomes
  • Primary endpoint = USI at 6 months (n=138)
    • USI in 21% TVT vs 45% TOT (p=0.004)
    • 0% TVT vs 13% TOT requested surgical re-treatment (p=.003)
  • Improved UUI ~40% both groups

Schierlitz et al, Obstet & Gynecol, Dec 2008
Fascial sling vs MUS

- 201 women who self-selected PVS vs MUS with minimum 12 mos f/u (2011-2012)
- 91 PVS; 110 MUS
  - MUS grp with more baseline UUI (86% vs 74%)
- Cure (no subj SUI, neg CST) similar (76% vs 81%)
  - 2.2% vs 3.6% w/persistent SUI symptoms
- UUI persistence, resolution, and de novo symptoms similar
- 1 mesh erosion, 1 hernia
- Sling release for retention in 1 MUS patient and 2 PVS patients
- VAS scale (10=very happy) similar: 8.4

Mock et al, J Urol, 2015
Single incision slings

- Systematic review (excluded TVT-Secur)
  - Similar subjective and objective cure rates in SIMS and TMUS
  - Lower post-op pain scores in SIMS
  - “trend” towards more repeat continence surgery in SIMS (RR 2.0, CI 0.93-4.31)

Mostafa et al, Eur Urol, 2013
SIMS vs MUS

- RT SIMS vs TMUS, n=224
  - Women with ISD excluded
  - Obj cure = neg CST
  - Subj cure = no SUI symptoms on ICIQ
  - Similar obj cure (96% vs 93%) and subj cure (94% and 97%) at 12 mos
  - 3 vs 2 subjects had repeat SUI surgery
  - Groin pain >6 mos in 0% v 6% (p=.014)
  
- Lee et al, AJOG, 2015

- RT RMUS vs SIMS, n=71
  - 3 years follow up
  - Failure if +SUI on KHQ or re-tx
    - 9% MUS vs 53% SIMS
    - Repeat surgery in 21% SIMS vs 0 RMUS

- Basu, Duckett, Int Urogynecol J 2013
<table>
<thead>
<tr>
<th>Procedure</th>
<th>12-23 mos (Range)</th>
<th>24-47 mos (Range)</th>
<th>48 mos + (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autologous fascial sling</td>
<td>90% (76-98)</td>
<td>81% (72-88)</td>
<td>82% (67-93)</td>
</tr>
<tr>
<td>Synthetic midurethral sling</td>
<td>84% (78-89)</td>
<td>81% (72-88)</td>
<td>84% (77-89)</td>
</tr>
<tr>
<td>Burch urethropexy</td>
<td>81% (73-87)</td>
<td>76% (68-83)</td>
<td>73% (65-80)</td>
</tr>
<tr>
<td>Collagen periurethral bulking</td>
<td>48% (41-55)</td>
<td>32% (24-42)</td>
<td>30% (18-45)</td>
</tr>
</tbody>
</table>
**Urgency incontinence outcomes at 12 to 23 months**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>De novo UUI (%)</th>
<th>Persistent UUI (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autologous fascial sling</td>
<td>9 (6-13)</td>
<td>33 (28-40)</td>
</tr>
<tr>
<td>Synthetic midurethral sling</td>
<td>6 (3-10)</td>
<td>44 (26-63)</td>
</tr>
<tr>
<td>Burch urethropexy</td>
<td>8 (5-11)</td>
<td>17 (4-40)</td>
</tr>
</tbody>
</table>
2014 AUGS/SUFU MUS statement

• Polypropylene material is safe and effective as a surgical implant
• The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history
• Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI
• The FDA has clearly stated that the polypropylene MUS is safe and effective in the treatment of SUI
Future?

- Autologous adult stem cells (muscle derived stem cells and adipose-derived stem cells)
- Prevention efforts – NIH/NIDDK PLUS Consortium
  - Develop the evidence base for normal or healthy bladder function and identify behavioral and other risk factors for conditions associated with LUTS
  - Establish the evidence base scientific basis for future primary and secondary prevention intervention studies
Summary

• Know your patient
• Remember non-surgical options

• Surgical treatment
  • Counseling is key
  • Set appropriate expectations
  • Be vigilant for complications/side effects