Evidence Based Approach to Urinary Incontinence

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- AMS – Research Committee 522
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- UptoDate Royalties
Surgery for SUI: Burch, Slings, Bulking, deNovo SUI

Learning Objectives

• Perform a variety of evidenced-based surgical procedures for stress incontinence.
• Perform and describe the indications, intra and postoperative complications, and success of continence procedures.
• Describe the indications, intra and postoperative complications and success of continence procedures.
• Cite published success and complication rates for each continence procedure, quality of studies, and level of evidence.
• Discuss differences in success rates of primary and secondary continence procedures.
• Discuss differences in continence procedure success rates in women with and without urethral hypermobility.

• Identify, evaluate, and manage complications associated with continence surgery.

• Discuss role of urodynamic testing when planning continence surgery.

• Discuss alternatives, advantages, disadvantages, and evidence for prophylactic continence procedures at the time of vaginal and abdominal prolapse surgery in stress continent women.

• Discuss impact of concomitant prolapse surgery on continence procedure success rates.
Several Conditions Must be Met Before a Patient with SUI Should Undergo Surgery

- Correct diagnosis
- Trial of conservative therapy
- Acceptable surgical candidate
- Does not desire fertility (+/-)
Discuss Role Of Urodynamic Testing When Planning Continence Surgery

• CMG helps to identify DO or mixed incontinence. TVT and TOT have similar cure rates for mixed incontinence (Jain 2011)

• Lower VLPP (<86 cm H2O) or MUCP (<45 cm H2O) had a 2-fold increased odds of failure after TO or RP MUS (TOMUS: Nager 2011)

• For uncomplicated SUI, preoperative office evaluation alone (H&P, UA, PVR, CST) was not inferior to evaluation with urodynamic testing for outcomes at 1 year after surgery (VALUE: Nager 2012)

• Preoperative voiding dysfunction or high PVR may be associated with longer catheter times or postoperative voiding dysfunction
Discuss Differences in Success Rates of Primary and Secondary Continence Procedures

- Systematic review (Pradham 2011) of MUS for recurrent SUI suggested cure rates for RP TVT were significantly greater than for TOT.

- In RCTs by Rechberger (2009) and Schierlitz (2012), the long-term cure rates for RP TVT were significantly greater than for TOT in women with USUI and ISD.

- Data have suggested that Burch procedures and MUS have lower cure rates in women with non-mobile bladder neck.
## Rates of Surgical Cure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Success Rate</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior Colporrhaphy</td>
<td>34-100%</td>
<td>60%</td>
</tr>
<tr>
<td>Retropubic Colposuspension</td>
<td>68-97%</td>
<td>84%</td>
</tr>
<tr>
<td>Needle Urethropexy</td>
<td>61-97%</td>
<td>88%</td>
</tr>
<tr>
<td>TVT, TOT</td>
<td>81-100%</td>
<td>88%</td>
</tr>
<tr>
<td>Pubovaginal Sling Procedure</td>
<td>66-89%</td>
<td>81%</td>
</tr>
</tbody>
</table>
AHCP R Review of Anterior Vaginal Repair

- 9 studies were reviewed – 1,449 patients
- Overall cure rate was 62%
- Average complication rate was 14%
- Substantial variation among techniques, related to vaginal and bladder neck dissection
Comparison of Postoperative Cure Rates in Randomized Clinical Study for Anterior Colporrhaphy, Burch Retropubic Urethropexy and Pereyra Procedure

Burch Colposuspension

- 2 sutures on each side of the bladder neck is better than 1
- Burch cure rate is similar to TVT, but less effective than fascial sling
- Burch (and MMK) are more effective for SUI than paravaginal defect repair, Kelly plication, needle urethropexy
- Adding a hysterectomy does not alter the effectiveness of Burch
- Laparoscopic route is equal or slightly less effective than open route
When Might I Use Laparoscopic or Open Burch Now?

- Combined with other laparoscopic or open repairs (BTL, LH, sacral colpopexy)
- Young women who desire fertility potential
- History of mesh complications, erosions, allergy. A good use for Burch is for TVT erosion, infection, or pain, with recurrent SUI
- Patient doesn’t want a foreign material
Autologous Fascia Slings

- Large body of experience and many cohort studies
- Success for SUI: 66%-85% depending on definition
- RCT by Albo et al (2007) showed it to be superior to Burch but with higher rate of complications (UTIs, voiding, urge)

- Multicenter NIH-funded RCT with 655 women
- At 24 months, success rates for SUI were:
  - 66% for sling
  - 49% for Burch; P < 0.001
- More women who had a sling had UTIs, difficulty voiding, post-op urge incontinence
- Serious adverse events were similar between groups
- Treatment satisfaction at 24 months was 86% for sling and 78% for Burch (P = .02)
“Tension-Free" Midurethral Slings (MUS)
Advantages of TVT, compared to Burch and Fascial Slings

- May be performed under local anesthesia
- Short operating time
- Outpatient procedure
- Tape is loosely placed, minimizing anatomic distortion
- Decreased incidence in post-op voiding dysfunction
Outcome of 50 Women with TVT Over Time

Ward and Hilton, 2002: Prospective Randomized Trial of Open Burch vs. TVT for SUI

- 344 patients randomized from 14 centers in U.K.

- No significant differences in cure rates after 6 months: TVT – 66%; Burch – 57%

- Bladder injury more common with TVT; longer voiding and recovery times with Burch
TVT Complications in 1455 Patients in 38 Hospitals in Finland in 1999

Bladder perforation 3.8%
Minor voiding difficulties 7.6%
Retention 2.3%
Retropubic hematoma 1.9%
Major vessel injury 0.07%
Need for post-op laparotomy for a complication 0.3%

Kuuva and Nilsson, 2002
Reasons to Consider Trans Obturator Slings

• Reproduces a more natural suspension mechanism (Hammock)
  – Less risk for overcorrection/ urgency/ dysuria
  – Less voiding dysfunction
  – Fewer bladder perforations

• Safe passage
  – Less risk for vascular, bowel, bladder injury
  – May be no need for cystoscopy?

• Easy to learn and to teach
The gynecologist is doing an outside-in transobturator sling for a 50 year-old woman with stress urinary incontinence. The helical trocar passes around the ischiopubic ramus but will NOT pass through which anatomic structure:

A. Obturator canal  
B. Obturator internus muscle  
C. Peri-urethral endopelvic fascia  
D. Obturator foramen  
E. Gracilis muscle

The gynecologist is doing an outside-in transobturator sling for a 50 year-old woman with stress urinary incontinence.

The helical trocar passes around the ischiopubic ramus but will **NOT** pass through which anatomic structure:

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C. Peri-urethral endopelvic fascia  
D. Obturator foramen  
E. Gracilis muscle

Needle insertion starts along the lateral edge of the ischiopubic ramus just below the insertion of the adductor longus tendon. The path is around the ischiopubic ramus. Needle penetrates gracilis, adductor brevis, obturator externus muscles, obturator membrane, obturator internus muscle, periurethral endopelvic fascia and exits through the vaginal incision.
Transobturator Approach

OUTSIDE – to – IN

VS.

INSIDE – to - OUT
Needle entry & path
TOT & TVT-O Sling Angles

TVT-O

Monarc TOT
Transobturator Approach: Systematic Review by Madhuvrata 2012

- The outside-in and inside-out versions of TOT slings have similar cure rates
- Inside-out slings may result in a little more thigh pain if the surgeon passes the needle too far lateral in the thigh muscle
- Outside-in slings result in more vaginal perforations or ‘button holes’ in the fornices
RCT of TVT vs TOT: Survival Time for Any Urinary Incontinence.
Risk of Subjective Failure After Transobturator vs. Retropubic Midurethral Slings

Success Rate

<table>
<thead>
<tr>
<th>Method</th>
<th>Unadjusted</th>
<th>With control for site</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective success</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retropubic sling %</td>
<td>80.8</td>
<td>82.4</td>
</tr>
<tr>
<td>Transobturator sling %</td>
<td>77.7</td>
<td>79.6</td>
</tr>
<tr>
<td>Difference in Rates of Treatment Success with 95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transobturator Better</td>
<td>-3.6, 3.0, 9.6</td>
<td></td>
</tr>
<tr>
<td>Retropubic Better</td>
<td>-3.9, 2.8, 9.4</td>
<td></td>
</tr>
</tbody>
</table>

**Subjective success**

<table>
<thead>
<tr>
<th>Method</th>
<th>Unadjusted</th>
<th>With control for site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retropubic sling %</td>
<td>62.2</td>
<td>62.4</td>
</tr>
<tr>
<td>Transobturator sling %</td>
<td>55.8</td>
<td>56.0</td>
</tr>
<tr>
<td>Difference in Rates of Treatment Success with 95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transobturator Better</td>
<td>-1.6, 6.4, 14.3</td>
<td></td>
</tr>
<tr>
<td>Retropubic Better</td>
<td>-1.7, 6.4, 14.5</td>
<td></td>
</tr>
</tbody>
</table>

From Richter HE et al, 2010
Transobturator Approach

Data generally suggest similar rates of continence, with less post-op voiding dysfunction and urgency, and fewer bladder perforations than retropubic TVT.
Risk of de Novo Irritative Voiding Symptoms After Transobturator vs. Retropubic Midurethral Slings

<table>
<thead>
<tr>
<th>Condition</th>
<th>TOT</th>
<th>TVT</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Bleeding</td>
<td>4%</td>
<td>2%</td>
<td>.16</td>
</tr>
<tr>
<td>Retropubic hematoma</td>
<td>2%</td>
<td>1%</td>
<td>.44</td>
</tr>
<tr>
<td>Bladder Injury</td>
<td>0%</td>
<td>5.1%</td>
<td>.004</td>
</tr>
<tr>
<td>Bowel Injury</td>
<td>0%</td>
<td>0%</td>
<td>1.00</td>
</tr>
<tr>
<td>Nerve Injury</td>
<td>2%</td>
<td>1%</td>
<td>.44</td>
</tr>
</tbody>
</table>

From Barber 2006
<table>
<thead>
<tr>
<th>Condition</th>
<th>TOT</th>
<th>TVT</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg Comp.</td>
<td>0.5%</td>
<td>0.5%</td>
<td>.89</td>
</tr>
<tr>
<td>Voiding Dys.</td>
<td>2.9%</td>
<td>8.9%</td>
<td>.01</td>
</tr>
<tr>
<td>Postop Anti-Cholinergics</td>
<td>6.3%</td>
<td>14%</td>
<td>.05</td>
</tr>
<tr>
<td>UTI</td>
<td>7.4%</td>
<td>12.7%</td>
<td>.08</td>
</tr>
<tr>
<td>Mesh erosion</td>
<td>0.5%</td>
<td>1%</td>
<td>.99</td>
</tr>
<tr>
<td>Reop. for SUI</td>
<td>1.5%</td>
<td>2.4%</td>
<td>.51</td>
</tr>
</tbody>
</table>
Conclusions of Barber et al, 2006

- Overall, complications from TOT and TVT are low.
- TOT has a significantly lower bladder injury rate than TVT.
- TOT results in lower rates of voiding dysfunction and postoperative anticholinergic use than TVT.
- Concurrent POP surgery at the time of TVT or TOT does not increase the risk of bladder injury or voiding dysfunction.
## Peri- and Postoperative Complications of Mid-Urethral Slings


<table>
<thead>
<tr>
<th></th>
<th>TVT n=4281</th>
<th>TVT-O n=731</th>
<th>TOT n=373</th>
<th>TVT vs. TVT-O</th>
<th>TVT vs. TOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation of the bladder</td>
<td>149 (3.5%)</td>
<td>6 (0.8%)</td>
<td>2 (0.5%)</td>
<td>&lt; 0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>Hematoma</td>
<td>50 (1.2%)</td>
<td>4 (0.5%)</td>
<td>0</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Urinary retention</td>
<td>69 (1.6%)</td>
<td>4 (0.5%)</td>
<td>6 (1.6%)</td>
<td>0.028</td>
<td>NS</td>
</tr>
<tr>
<td>Infection</td>
<td>28 (0.7%)</td>
<td>4 (0.5%)</td>
<td>3 (0.8%)</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>
Reoperations after Slings: Nguyen et al, Obstet Gynecol 2012

- 3,747 women underwent slings at Kaiser California and Hawaii 2008 – 2010
- 63% TVT, 21% TOT, 2% Mini-sling, 14% other (biologic)
- Overall intraoperatively, 1.4% had bladder perforations (2.0% for TVT only), 0.05% had urethral perforations
- Mesh-related reoperations: 1.3% sling loosening or transection for voiding dysfunction, 0.8% vaginal mesh erosion (30 in 3747), 0.06% urethral erosion, 0.03% pain, 0.03% drainage of RP hematoma (1 in 3747)
Reoperations after Slings:

• Population-based cohort of 188,454 women who had a sling between 2001 and 2010 (largest study to date)
• 9-year cumulative risk of sling revision/ removal was 3.7% (95% CI 3.5-3.9); this rate plateaued at about 4 years
• 2.5% had slings removed for mesh erosions vs. 1.3% had slings removed/ revised for urinary retention
• Younger age and concomitant anterior and apical prolapse procedure were risk factors for mesh revision or removal
Potential Disadvantages of TOT

- Probably is less effective for recurrent USUI and for ISD patients

- Pain and infection in the genito-femoral folds and thigh; transient weakness in the upper leg

- There are rare cases of male sexual partners having penile pain and abrasions during intercourse from the woman’s TOT sling
The Mini-Slings

• Data are still too preliminary to comment on long-term continence rates
• Complications, post-operative voiding problems and pain are all uncommon with mini-slings
Urethral Bulking for SUI

- Durasphere EXP, Coaptite, Macroplastique currently available in North America; not shown to be more or less effective than Contigen
- Transurethral and periurethral methods have similar effectiveness
- Cure or improvement occurs in 70-80% of patients; total continence occurs in about 40%
- Repeat injections may be required; success after 2 or 3 injections is unlikely
- REF: Kirchin 2012 Cochrane
Identify, Evaluate, and Manage Complications of Surgery for SUI

- Cystotomy
- Fistula
- Persistent or recurrent UI symptoms
- Voiding dysfunction and retention
- Foreign body associated complications
- Urinary tract infections
Adverse Events after MUS Surgery for SUI
TOMUS: Brubaker, 2011

• 42% of patients had some adverse event; 20% were classified as serious

• Intraoperative bladder perforation occurred in 5.0% of RP slings and 0% of TO slings (P< .0001)

• Voiding dysfunction requiring surgery occurred in 3.0% of RP slings and 0% of TO slings (P= .002); UTIs more common after RP slings

• Neurologic symptoms occurred in 5.0% of RP slings and 9.7% of TO slings (P= .04)
• Concomitant surgery did not increase the overall occurrence of adverse events, but some individual events like UTIs were more common if other surgery was done

• Vaginal perforations were found with both types of slings (P = NS)

• 4% of all women experienced mesh complications by 24 months; not different between TO and RP slings
Question 2

Which statement is TRUE about treatment success after surgery for SUI?

A. Complication rates between retropubic and transobturator synthetic midurethral slings are statistically similar
B. Retropubic and transobturator slings have similar cure rates for recurrent SUI with ISD
C. In continent women having prolapse surgery vaginally, adding a retropubic TVT had no effect on post-operative rates of urinary incontinence
D. Open Burch procedures have lower cure rates for SUI than pubovaginal fascial slings


Question 2- Answer

Which statement is **TRUE** about treatment success after surgery for SUI?

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B. Retropubic and transobturator slings have similar cure rates for recurrent SUI with ISD
C. In continent women having prolapse surgery vaginally, adding a retropubic TVT had no effect on post-operative rates of urinary incontinence
D. **Open Burch procedures have lower cure rates for SUI than pubovaginal fascial slings**


Cochrane Review of Synthetic Slings (MUS)

- 62 trials; quality of evidence was moderate
- Synthetic MUS are as effective as fascial slings but with shorter OR time, less voiding dysfunction and de novo urge
- Synthetic MUS are as effective as Burch
- RP bottom-to-top route is more effective than top-to-bottom route
- Monofilament tapes have higher cure rates and fewer erosions than multifilament tapes
- TO route was less favorable than RP route in objective cure (84%; RR 0.96; 17 trials; N = 2434) although there was no difference in subjective cure rates.
- TO slings have less voiding dysfunction, blood loss, bladder perforations, and shorter operative times than RP slings

SUI Definitions

**Occult SUI**: SUI that is not symptomatic but becomes apparent only during clinical or urodynamic testing (i.e. cough stress test after prolapse reduced)

**De novo SUI**: SUI that is newly symptomatic, as when SUI develops after a prolapse repair in a woman who was continent before surgery
Occult SUI

- Diagnosed using pre-operative prolapse reduction testing in 31-80% of continent women with symptomatic and/or advanced prolapse who are planning to have surgery.

- When these women undergo prolapse repair without a concomitant continence procedure, the rate of post-operative de novo SUI is 13-65%.
Clues to Detecting Occult SUI

- Incontinence that improved or resolved as prolapse worsened
- The need to manually replace the prolapsed structures in the vagina to void
- Worsening or development of SUI with use of pessary
Diagnosis of Occult SUI

• Medical history

• Clinical or urodynamic testing with and without reduction of prolapsed structures

• Prolapse reduction can be by fingers, cotton swab, speculum blade, ring forceps, or pessary. One is probably not superior to another, except that the pessary is the least diagnostic.
POP with No Symptoms of SUI

• Most experts consider women with positive testing for occult SUI to be similar to women who have SUI symptoms, and advise combined surgery for prolapse and SUI

• However, it is controversial what to do to the bladder neck in women with symptomatic prolapse but no SUI on pre-operative testing with reduction, especially for POP surgery by the vaginal route
Risk of Developing Postoperative Stress Urinary Incontinence (SUI) In Women Undergoing Surgery For Pelvic Organ Prolapse (from UpToDate 2011)

Women Undergoing Surgery For Pelvic Organ Prolapse

- No clinical symptoms of SUI
- + clinical symptoms of SUI
Risk of Developing Postoperative Stress Urinary Incontinence (SUI) In Women Undergoing Surgery For Pelvic Organ Prolapse, cont.

+ clinical symptoms of SUI

No incontinence surgery

- Borstad 2006 65/90 (72%)
- Colombo 2000 19/33 (58%)*
- De Tayrac 2004 5/14 (36%)

Total: 89/137 (65%)

Incontinence surgery

- Colombo 1997 SUP 6/15 (40%)
- Colombo 1997 NS 6/21 (29%)
- Colombo 2000 RPU 5/35 (14%)*
- De Tayrac 2004 TVT 1/15 (6.7%)
- Partoll 2006 TVT 2/37 (5%)*
- Wille 2006 RPU 0/14 (0%)*

Total: 20/137 (15%)

* Denotes abdominal procedures, all other procedures were performed vaginally
Risk of Developing Postoperative Stress Urinary Incontinence (SUI) In Women Undergoing Surgery For Pelvic Organ Prolapse, cont.

- occult stress testing

**No clinical symptoms of SUI**

- occult stress testing

**No incontinence surgery**

- occult stress testing

**Incontinence surgery**

- occult stress testing

Total: 45/289 (mean 16%)

Total: 26/179 (15%)

* Denotes abdominal procedures, all other procedures were performed vaginally
Risk of Developing Postoperative Stress Urinary Incontinence (SUI) In Women Undergoing Surgery For Pelvic Organ Prolapse, cont.

- No clinical symptoms of SUI
- + occult stress testing
  - No incontinence surgery
  - Incontinence surgery

De Tayrac 2004 1/6 (13%)
Liang 2004 11/17 (65%)
Reener 2006 34/53 (0%)
Visco 2008 23/40 (50%)*

Total: 69/118 (59%)
Total: 69/118 (59%)
Total: 76/502 (15%)

* Denotes abdominal procedures, all other procedures were performed vaginally
In the 2006 CARE Trial, sacrocolpopexies were done with and without Burch

- In women with POP having ASC who were continent before surgery, Burch decreased the rate of post-operative SUI (32% for Burch vs 45% for no Burch)

- For women with occult SUI on pre-testing, 37% had SUI after Burch and 60% had SUI after no Burch

- For women with no occult SUI on pre-testing, 20% had SUI after Burch and 39% had SUI after no Burch

- However, it is still controversial what to do to the bladder neck in women with symptomatic prolapse having vaginal surgery who have no SUI on pre-operative testing with reduction
OPUS Trial

- In this multicenter RCT, 337 women without SUI but having vaginal surgery for POP were randomized to TVT or sham surgery
- The rate of UI at 12 months was 27.6% in the TVT group and 43.0% in the sham group (P=0.002)
- 6.3 slings were placed to prevent 1 case of UI at 12 months
- UTI’s, bleeding complications (3.1%), and voiding disorders (3.7%) were all higher in the TVT group

Prolapse and No SUI: Using Reduction Stress Testing (RST) to Decide Whether a Sling Should be Done

- Cohort study: 152 women had laparoscopic sacral colpopexy and followed 4 – 21 months
- Women with a (-) RST had sacral colpopexy only; women with a (+) RST had sacral colpopexy + sling
- At follow-up 18.6% of women in the (-) RST group had a later sling for de novo SUI
- In the (+) RST group 7.3% had voiding difficulties requiring sling revisions
- Overall, 88% of patients did not need a second surgery

For a patient with occult SUI having abdominal sacral colpopexy, I choose Burch if the case is open, and TVT or TOT if it is L/S or robotic.

For prolapse cases with occult SUI done vaginally, I choose a sling with the highest benefit and lowest risk. Patients are especially intolerant of urinary retention in this setting.

I usually choose a TOT over a RP TVT in women with occult SUI because there are comparable cure rates for SUI, but less risk of urge and retention. ISD is rare in this population.

For prolapse cases with no occult SUI on pre-op testing, I still do a small suburethral plication to try to prevent early de novo SUI (this is not supported by evidence).
References


• Nager CW, Tan-Kim J. Pelvic organ prolapse and stress urinary incontinence; combined surgical treatment. UpToDate 2011.


