Surgery for Stress Urinary Incontinence

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Scope of presentation

- Background
- Preoperative care:
  - Nonsurgical management
  - OAB
- RCT comparisons:
  - Burch vs. sling
  - Burch vs. TVT
  - TVT vs. TOT

Operations for Urinary Incontinence

- Suburethral Sling:
  - Traditional (1907)
  - Mid-urethral (1995)
- Colposuspension (1949/1968)

Preoperative evaluation:

- Urinalysis (r/o UTI)
- Post Void Residual
- Cotton-swab test or assessment of urethral mobility
- Cystometrogram
- Cough stress test
**Urodynamic Testing & Consultation:**

- Age > 50 years
- Non-mobile urethra
- Prior anti-incontinence surgery
- History of radiation therapy
- Uncertain diagnosis: symptoms do not correlate with objective findings
- Significant pelvic organ prolapse
- Neurologic disease

**Importance of “OAB”**

- Lower success rate for mixed UI than stress UI alone with surgical treatment:
  - 55% vs. 81% cure rate @ 5 years
- Poor durability of success with mixed UI:
  - 60% cure @ 4 years ⇒ 30% @ 4-8 years
- De novo and persistent urge UI is the most common cause of dissatisfaction after surgery.

**RCT Data: “Old Standard” Operations**

**RCT of Burch vs. Fascial Sling**

- Multicenter (~12 sites) US study
- 326 sling, 329 Burch


RCT of Burch vs. Fascial Sling

- Overall cure rate at 2 years:
  - Burch: 38%
  - Sling: 47% \( (P<.01) \)
- SUI specific cure rate at 2 years:
  - Burch: 49%
  - Sling: 66% \( (P<.001) \)


RCT of Burch vs. Fascial Sling

- Serious adverse events:
  - Burch: 10%
  - Sling: 13% \( (P=.2) \)
- Overall adverse events:
  - Burch: 47%
  - Sling: 63% \( (P<.001) \)
  - Difference due to UTI

**RCT of Burch vs. Fascial Sling**

- **Voiding Dysfunction:**
  - Burch: 2%
  - Sling: 14% (P<.001)

- **Postoperative treatment of urge UI:**
  - Burch: 20%
  - Sling: 27% (P=.04)
  - Difference due to persistence of urge (not de novo)


**The Tension-free Vaginal Tape System**

From TVT Lithograph.Ethicon
RCT of Burch vs. TVT

- 14 centers in UK
- 175 TVT, 169 Burch
- **Objective** cure rate at 2 years:
  - Burch 51%
  - TVT 63%
  - ~20% in each group lost to f/u: considered failures
  - OR= 1.7 (95%CI: 1.1-2.6)


RCT of Burch vs. TVT

- Only 20-25% of each group reported no incontinence under any circumstance
- @ 2 years:
  - More cystocele in TVT group (63 vs. 39%)
  - More cervical / apical prolapse in Burch group (60 vs. 29%)


RCT of Burch vs. TVT: results by center


RCT of Burch vs. TVT: results by surgical volume of center

**TVT: Long-term follow-up**

<table>
<thead>
<tr>
<th>N</th>
<th>Cure rate %</th>
<th>F/U years</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>94</td>
<td>85</td>
<td>5</td>
<td>Chene 2006</td>
</tr>
<tr>
<td>707</td>
<td>73</td>
<td>5</td>
<td>Ankardal 2006</td>
</tr>
<tr>
<td>970</td>
<td>85</td>
<td>5</td>
<td>Holmgren 2006</td>
</tr>
<tr>
<td>134</td>
<td>77</td>
<td>5</td>
<td>Doo 2006</td>
</tr>
<tr>
<td>129</td>
<td>74</td>
<td>6</td>
<td>Kuuva 2006</td>
</tr>
<tr>
<td>90</td>
<td>81</td>
<td>7</td>
<td>Nilsson 2004</td>
</tr>
<tr>
<td>52</td>
<td>79</td>
<td>4.5</td>
<td>Tsivian 2004</td>
</tr>
</tbody>
</table>

**Deaths Reported: FDA MAUDE**

**TVT:**
- Bowel perforation: 7
- Hemorrhage: 1
- Sepsis unknown origin: 2
- Pulmonary embolism: 1
- Hemorrhage (ancillary procedure): 1

**TOT:**
- Hemorrhage: 1


**Serious Complications With TVT**

- Vascular injury: ~1: 10,000
- Bowel perforation: ~1: 17,000
- Urethral erosion: ~1: 25,000
- Hematoma: ~1: 25,000
- Nerve injury: ~1: 125,000

**Other Complications Associated With TVT**

**Finnish TVT Registry**

<table>
<thead>
<tr>
<th>Incidence</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor voiding difficulty</td>
<td>7.6</td>
</tr>
<tr>
<td>UTI</td>
<td>4.1</td>
</tr>
<tr>
<td>Bladder perforation</td>
<td>3.8</td>
</tr>
<tr>
<td>Post-op urinary retention</td>
<td>2.3</td>
</tr>
<tr>
<td>Retropubic hematoma</td>
<td>2.4</td>
</tr>
<tr>
<td>Wound infection</td>
<td>0.8</td>
</tr>
<tr>
<td>Mesh exposure</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Other approaches:

- "Abdominal (top down) approach":
  - SPARC
  - TVT with abdominal guide
- "Lateral approach" = Transobturator
  - Outside-in (Delorme)
  - Inside-out (Gynecare-TVT-O)

RCT: SPARC vs TVT

<table>
<thead>
<tr>
<th></th>
<th>SPARC (N=147/154)</th>
<th>TVT (N=153/159)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder perforation</td>
<td>3</td>
<td>1</td>
<td>.6</td>
</tr>
<tr>
<td>EBL &gt; 100 or hematoma</td>
<td>18%</td>
<td>22%</td>
<td>.5</td>
</tr>
<tr>
<td>Readjust tape</td>
<td>6%</td>
<td>0%</td>
<td>.002</td>
</tr>
<tr>
<td>De novo urge UI</td>
<td>27%</td>
<td>21%</td>
<td>.5</td>
</tr>
</tbody>
</table>

Subjective cure @ 6 wks.

- SPARC: 77%
- TVT: 87%

Objective cure @ 6 wks.

- SPARC: 97%
- TVT: 97%

Mesh erosion

- SPARC: 11%
- TVT: 5%

Lord. BJU Int 2006;98:367-76.
Ref: Testing performed by P. Dietz MD and presented at ICS, 2001 Meeting; includes new data on SPARC.

**Transobturator Tape (TOT)**

**TOT Complications**

- **Complications:**
  - Perforation (vesical, urethral, vaginal)
  - Erosion/exposure
  - UTI
  - Obturator & perirectal abscess
Systemic Review #1 TVT vs. TOT

- 11 RCT’s containing 1261 women (9/06)
- 5 trials TVT-O vs. TVT
- 6 trials TOT vs. TVT


Systemic Review #1 TVT vs. TOT

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Odds Ratio (Cure of SUI)</th>
<th>95% C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVT-O vs. TVT</td>
<td>0.69</td>
<td>0.42-1.14</td>
</tr>
<tr>
<td>TOT vs. TVT (inside-out)</td>
<td>1.05</td>
<td>0.64-1.70</td>
</tr>
</tbody>
</table>


Systemic Review #1 TVT vs. TOT

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Odds Ratio</th>
<th>95% C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder injury</td>
<td>0.13</td>
<td>0.06-0.27</td>
</tr>
<tr>
<td>Voiding difficulty</td>
<td>0.56</td>
<td>0.32-0.99</td>
</tr>
<tr>
<td>Vaginal injury/erosion</td>
<td>2.08</td>
<td>0.89-4.95</td>
</tr>
<tr>
<td>Groin/thigh pain</td>
<td>9.34</td>
<td>3.02-28.9</td>
</tr>
<tr>
<td>De novo frequency/urgency</td>
<td>0.89</td>
<td>0.54-1.86</td>
</tr>
</tbody>
</table>


Systematic Review #2 TVT vs. TOT

- 6 RCTs containing 492 women (≤4/26/06)
- 13 cohort studies containing 2,099 women
- Includes SPARC

Systemic Review #2 TOT v. TVT

- Subjective failure: OR= 0.85 (0.38-1.92)
- Complications: OR= 0.40 (0.19-0.83)
  - Mostly bladder perforation
- De novo irritative voiding symptoms: OR=0.54 (0.26-1.1)


Evidence of Poor Results with TOT in Patients with Weaker Urethral Function

<table>
<thead>
<tr>
<th>Study</th>
<th>Measurement</th>
<th>TOT</th>
<th>TVT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biller 2006</td>
<td>&quot;ISD&quot;</td>
<td>57%</td>
<td>78%</td>
</tr>
<tr>
<td>O’Connor 2006</td>
<td>VLPP&lt;60</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Miller 2006</td>
<td>MUCP&lt;42</td>
<td>84%</td>
<td>97%</td>
</tr>
<tr>
<td>Six studies ~300 pts</td>
<td>ISD</td>
<td></td>
<td>83%</td>
</tr>
</tbody>
</table>

Conclusions (General and Preoperative)

- Surgery for stress incontinence is effective but associated with significant morbidity
- Patients should be counseled on nonsurgical treatments
- Post operative urgency / incontinence is a significant cause of patient dissatisfaction
- Preoperative evaluation to identify poor prognostic factors can help with patient counseling and choice of procedure

Conclusions (Old Standards)

- Pubovaginal slings are more likely to successfully treat SUI than are Burch procedures but are associated with increased morbidity
Conclusions (TVT vs. TOT)

- TVT is at least as effective as Burch
- TOT may have lower morbidity than TVT.
- TOT and TVT have similar short-term efficacy
- TOT (inside-out) seems to be less effective than TOT (outside-in)
- TOT appears to have lower efficacy in severe incontinence than TVT.
- And one last thing……

Burch with ASC (RCT)

<table>
<thead>
<tr>
<th></th>
<th>Burch (n=157)</th>
<th>No Burch (n=165)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUI @ 3 mo</td>
<td>24 %</td>
<td>44 %</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Bothersome SUI</td>
<td>6 %</td>
<td>24 %</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Urge UI @ 3 mo</td>
<td>33 %</td>
<td>38 %</td>
<td>NS</td>
</tr>
<tr>
<td>SUI @ 12 mo</td>
<td>21 %</td>
<td>40 %</td>
<td>.02</td>
</tr>
<tr>
<td>Urge UI @ 12 mo</td>
<td>28 %</td>
<td>35 %</td>
<td>NS</td>
</tr>
</tbody>
</table>


Ready or Not? TVT-Secur®

- Devices unregulated until 1976
  - (drugs regulated in 1902)
- “Premarket Notification Process: 510k”
  - Device does not require premarket approval if “shown” to be substantially equivalent to an existing device
Published Data for TVT-Secur®

- Application received by FDA: 11/17/2005
- Thanksgiving: 11/24/2005
- FDA approval given: 11/28/2005

The Data

- 15 patients no prior treatment
  » 10 - “hammock position”, 5 - “U-position”
- 93% “cure” between 1 and 3 months post op
  » Hammock position felt to be preferable
- Complications:
  » Slight SUI
  » Folded tape (2)
  » Vaginal pain
  » Erosion

Ceska Gynekol 2007;72:42-9
TOT Complications (MAUDE)

- 1/04-7/05: 173 complications in 140 reports
- Erosions (60%) - 1 urethral
- Infections (15%)
  - 2 ischiorectal fossa
  - 2 adductor muscle
- Neuropathy (2%)
- Excess bleeding (3%)
- Urethral & Bladder Injury (4%)