Surgical Treatment of SUI: Is the sling the gold standard

SASOG 2014
Cape Town

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University of Stellenbosch
Introduction:

• 2005: Innovative procedures for treatment of SUI.

  Concluded: Worldwide shift towards minimal in invasive suburethral continence procedure
    - TVT gold standard
    - TOT technique safe and effective,
      - learning curve,
      - No cystoscopy required
  and May be in time TOT will become surgical procedure of choice

Combined Dutch/SA meeting Stellenbosch 2005
Introduction

• FDA warning 2008 Intra vaginal synthetic mesh
• FDA 2011
But did not include synthetic use of mesh in SUI
• FDA 2013 (website)
  “The safety and effectiveness of multi-incision slings for SUI is well-established in clinical trials that followed patients for up to one-year.”
• FDA April 2014 : No mentioning of synthetic use for Rx SUI.
Introduction: Aim

- Define gold standard surgical procedure
- Provide data current trend SUI surgery procedures
- Provide data on current status of surgical procedures
- Provide unpublished data from local SUI study from University of Stellenbosch and UCT
- Conclusion
Introduction: Definition

- **SUI**: Defined as the complaint of involuntary leakage of urine when cough or sneeze
- **UUI**: Complaint Involuntary loss of urine due to involuntary detrusor contraction accompanied or preceded by urgency
- **MUI**: Combination of SUI and UUI
What is meant by “Gold Standard surgery”

Most Safe, effective, durable, cost effective and fewest complications
Physiology of continence

Intrinsic Sphincter mechanisms “Mucosal seal”

Resting Urethral Tone        Under stress

- Intrinsic smooth muscle        30%        20%
- Intrinsic skeletal muscle      30%        > 70%
- Periurethral vasculature       30%        < 5%
- Fibroconnective tissue         10%        5%


2) P. Sand ICS 2011
What is SUI: Pathophysiology

• **Integral theory:**

Petros and Ulmsten:
Based on Zacharin’s anat studies:
Pubo urethral ligament at junction middle 2/3 and upper 1/3 of anterior vaginal wall

• **Hammock Theory:**

De Lancey: Posterior position of the vagina provides a backboard against which abd forces compress the urethra
Pathophysiology: Theories SUI

Intrinsic sphincter deficiency

Bladder neck/urethral hypermobility
Diagnostic Procedures in Urinary Incontinence
Continence Mechanism of Burch paracolpium suspension procedure

- Lost pressure transmission and support could be restored by:
  - Repositioning prolapsed urethra and bladder neck
  - Counteract the descent associated with raised intra-abdominal pressure.
What is the Burch paracolposuspension

- Attach periurethral fascia to Cooper’s ligament

But some variations in surgical technique
What is the new technology Mini invasive Mid-urethral SUI sling surgery?

- **1st Generation:**
  Retropubic TVT sling

- **2nd Generation:**
  Transobturator sling

- **3rd Generation:**
  Single incision (AMS)
Continence mechanism of the midurethral sling

- Dynamic “kinking” of the urethra with intra abdominal Pressure
- Mimic pubourethral ligament, endo-pelvic Fascia
## Trends of surgical choice

<table>
<thead>
<tr>
<th>Location</th>
<th>MUS (%)</th>
<th>TVT-R (%)</th>
<th>TOT combined (%)</th>
<th>Burch (%)</th>
<th>Anterior repair (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotland 2006</td>
<td>77%</td>
<td>60%</td>
<td>17%</td>
<td>12%</td>
<td>5%</td>
</tr>
<tr>
<td>Wales 2006</td>
<td>59%</td>
<td>45%</td>
<td>14%</td>
<td>18%</td>
<td>5%</td>
</tr>
<tr>
<td>USA 2003-2012</td>
<td>69%</td>
<td>83%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia 2009</td>
<td>85.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 2 Total number of each female incontinence procedure type among certifying urologists between 2003 and 2012. Dashed line, traditional procedures (urinary repositioning); dotted line, periurethral injections; solid line, midurethral slings. Urethrolysis excluded.

SUI surgery Trends

Current sales of MUS in USA:

- Retropubic: 30%
- Obturator: 50%
- Single incision: 20%

P Dwayer ICS 2013
Open Burch vs anterior colporrhaphy 5y and more

6 Trials Burch better continence rates subjective

Needle suspensions vs Open Burch

- Needle suspensions more likely to fail

<table>
<thead>
<tr>
<th>Needle suspension vs Open Burch</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First year failure rate: 29% vs 16%</td>
<td>2(1.47-2.72)</td>
</tr>
<tr>
<td>Peri-operative compl. Not ss</td>
<td>1.44(0.73-2.83)</td>
</tr>
</tbody>
</table>

Traditional sling vs Burch

• Seven trials.
  - Patient-reported UI lower, 1y better
    (RR 0.75; 95% CI 0.62 to 0.90)
  but not when assessed by clinicians.
• Colposuspension associated with
  ➢ fewer peri-operative complications,
    - shorter duration indwelling catheter
    - less long term voiding dysfunction.

But ↑ bladder injury.

Rehman H Traditional suburethral sling operations for UI in women. Cochrane 2011 Issue 1
Cochrane: Mid-urethral synthetic sling procedure vs paracolpium suspension

• As effective as Open Retro Pubic colposuspension
  Subjective cure at: 1y RR 0.96, 95% CI 0.90 - 1.03
  5y RR 0.91, 95% CI 0.74 - 1.12
with - perioperative complications,
  - postoperative voiding dysfunction,
  - OR time and hospital stay
but significantly more bladder perforations
(6% versus 1%, RR 4.24, 95% CI 1.71 to 10.52).

Cochrane: Mid-urethral synthetic sling vs Burch

20 trials slings (TVT or TOT) vs Open Burch no significant difference for SUI or MUI

Cochrane: Minimally invasive synthetic sling procedure vs. Lapscope Burch

• Conflicting evidence about effectiveness in short term:
  Objective cure, RR 1.15, 95% CI 1.06 to 1.24; Subjective cure RR 1.11, 95% CI 0.99 to 1.24).

• MISS sling operations had significantly
  - de novo urgency and UUI
  - OR time/hospital stay/return to daily activities.

Joseph Ogah et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women Cochrane 2010
62 trials involving 7101 women were included.

Minimally invasive synthetic vs. traditional sling:

As effective as traditional suburethral sling (n = 599, Risk Ratio (RR) 1.03, 95% (CI) 0.94- 1.13) but with operating time:
- post-operative voiding dysfunction
- de novo urgency symptoms.

2. Haroon Rehman et al Traditional suburethral sling operations for urinary incontinence in women Cochrane 2011 Issue 1
### Mid urethral synthetic sling: R-TVT vs. TOT

<table>
<thead>
<tr>
<th></th>
<th>R-TVT</th>
<th>TOT</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Success: Objective</strong></td>
<td>88%</td>
<td>84%</td>
<td>0.96 (0.93-0.99)</td>
</tr>
<tr>
<td>Subjective</td>
<td>NSS</td>
<td>NSS</td>
<td></td>
</tr>
<tr>
<td><strong>Complication: Bl /perforation</strong></td>
<td>5.5%</td>
<td>0.3%</td>
<td>0.14 (0.07-0.26)</td>
</tr>
</tbody>
</table>

Joseph Ogah et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women Cochrane 2010
R-TVT vs TOT: Complications

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Treatment</th>
<th>Control</th>
<th>OR (fixed) 95% CI</th>
<th>Weight %</th>
<th>OR (fixed) 95% CI</th>
<th>Heterogeneity P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bladder injuries</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TVTO</td>
<td>0/291</td>
<td>9/296</td>
<td>0.14 [0.02, 0.78]</td>
<td>30.55</td>
<td>0.14 [0.02, 0.78]</td>
<td>0.81</td>
</tr>
<tr>
<td>TOT</td>
<td>0/264</td>
<td>9/292</td>
<td>0.12 [0.04, 0.39]</td>
<td>69.45</td>
<td>0.12 [0.04, 0.39]</td>
<td>0.95</td>
</tr>
<tr>
<td>Combined</td>
<td>0/575</td>
<td>20/588</td>
<td></td>
<td>100.00</td>
<td>0.12 [0.05, 0.22]</td>
<td>0.09</td>
</tr>
<tr>
<td><strong>Vaginal erosions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TVTO</td>
<td>2/168</td>
<td>2/177</td>
<td>0.68 [0.17, 4.35]</td>
<td>56.91</td>
<td>0.68 [0.17, 4.35]</td>
<td>0.63</td>
</tr>
<tr>
<td>TOT</td>
<td>5/157</td>
<td>2/165</td>
<td>2.37 [0.50, 10.60]</td>
<td>42.09</td>
<td>2.37 [0.50, 10.60]</td>
<td>0.20</td>
</tr>
<tr>
<td>Combined</td>
<td>16/576</td>
<td>7/572</td>
<td></td>
<td>100.00</td>
<td>1.51 [0.51, 4.40]</td>
<td>0.81</td>
</tr>
<tr>
<td><strong>Voiding difficulty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TVTO</td>
<td>12/215</td>
<td>19/205</td>
<td>0.50 [0.20, 1.21]</td>
<td>59.10</td>
<td>0.50 [0.20, 1.21]</td>
<td>0.50</td>
</tr>
<tr>
<td>TOT</td>
<td>8/228</td>
<td>12/250</td>
<td>0.51 [0.20, 1.29]</td>
<td>40.90</td>
<td>0.51 [0.20, 1.29]</td>
<td>0.69</td>
</tr>
<tr>
<td>Combined</td>
<td>18/453</td>
<td>32/455</td>
<td></td>
<td>100.00</td>
<td>0.55 [0.31, 0.98]</td>
<td>0.79</td>
</tr>
<tr>
<td><strong>De novo urgency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TVTO</td>
<td>13/71</td>
<td>6/63</td>
<td>1.94 [0.68, 5.54]</td>
<td>15.92</td>
<td>1.94 [0.68, 5.54]</td>
<td>0.49</td>
</tr>
<tr>
<td>TOT</td>
<td>22/254</td>
<td>31/261</td>
<td>0.69 [0.36, 1.24]</td>
<td>84.08</td>
<td>0.69 [0.36, 1.24]</td>
<td>0.37</td>
</tr>
<tr>
<td>Combined</td>
<td>35/325</td>
<td>37/324</td>
<td></td>
<td>100.00</td>
<td>0.89 [0.54, 1.46]</td>
<td>0.47</td>
</tr>
<tr>
<td><strong>Groin/thigh pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TVTO</td>
<td>25/159</td>
<td>3/153</td>
<td>8.01 [2.63, 29.52]</td>
<td>85.04</td>
<td>8.01 [2.63, 29.52]</td>
<td>0.25</td>
</tr>
<tr>
<td>TOT</td>
<td>2/65</td>
<td>0/66</td>
<td>5.24 [0.25, 111.20]</td>
<td>14.96</td>
<td>5.24 [0.25, 111.20]</td>
<td>N/A</td>
</tr>
<tr>
<td>Combined</td>
<td>27/224</td>
<td>3/219</td>
<td></td>
<td>100.00</td>
<td>8.28 [2.70, 25.41]</td>
<td>0.60</td>
</tr>
</tbody>
</table>

Figure 4. Risk of complications with TOTs used for stress incontinence (compared with TVT). N/A, not applicable.
Meta-analysis:
TOT inside out vs Outside in

• 5 RCT and 3 prospective cohort studies
No ss difference between the above 12/12 for:
• Patient-reported cure (OR 1.25, 95%CI 0.78, 1.99; p = 0.35)
• Objective cure (OR 1.66, 95%CI 0.8, 3.43, p = 0.17)

Priya Madhuvrata et al. Systematic review and meta-analysis of “inside-out” vs “outside-in”
TOT in Mx of SUI in women. EJOG and reproductive Biol. 162 (2012) 1-10
SIMS vs Standard MUS

• 25 RCTs (n=3114 women) in the updated meta-analysis SIMS vs. SMUS (R-TVT / TOT)

   - Mini-Arc (n=6; 566 women)
   - Ophira (n=1; 130)
   - TFS (n=1; 80 women)
   - TVT-Secur (n= 12; 1606 women)
   - Ajust (n=3; 350 women)
   - Contasure (n=1; 257)
   - Solyx (n=1; 30 women)

Mostafa A et al. SIMS VS STANDARD MUS IN SURGICAL Mx OF FEMALE SUI: AN UPDATED SYSTEMATIC REVIEW META-ANALYSIS OF EFFECTIVENESS AND COMPLICATIONS. ICS 2013
Single incision Midurethral Sling vs Standard Midurethral Sling

• Metanlysis SIMS associated with:
  - patient reported cure (RR: 0.90, 95%CI: 0.85 - 0.95)
  - objective cure rates (RR: 0.90, 95%CI: 0.84, 0.95)

But, excluding TVT-Secure:
- no evidence of significant differences 1-2y f/u
  - patient reported cure (RR: 0.96, 95%CI: 0.88, 1.03)
  - Objective cure: RR: 0.97, 95%CI: 0.92, 1.02

Mostafa A et al. SIMS VS STANDARD MUS IN SURGICAL Mx OF FEMALE SUI: AN UPDATED SYSTEMATIC REVIEW META-ANALYSIS OF EFFECTIVENESS AND COMPLICATIONS. ICS 2013
<table>
<thead>
<tr>
<th>SIMS vs Std TVT-R</th>
<th>RR( 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>( 5 Trials ; 4 TVT Secure)</td>
<td>2.08 (1.04 - 4.14).</td>
</tr>
<tr>
<td>Remain incontinent (41% vs 26%)</td>
<td>2.86(1.33-6.12)</td>
</tr>
<tr>
<td>SIMS ▲ De Novo Urgency</td>
<td>2.55(1.93– 3.36)</td>
</tr>
<tr>
<td>SIMS ▼ OR time</td>
<td></td>
</tr>
<tr>
<td>TVT-Secure vs inside-out TOT</td>
<td></td>
</tr>
<tr>
<td>SUI rate</td>
<td></td>
</tr>
</tbody>
</table>

SIMS vs. Standard MUS
Cochrane 2014 (Under review)

• Not enough evidence on other single-incision slings compared to retropubic or TOT slings to make reliable comparisons.

• Trials should also clearly describe the fixation mechanism of these single-incisions slings: it is apparent that, although clubbed together as a single group, there is a significant difference in fixation mechanisms that may influence outcomes.

Summary:

- Burch better: Anterior repair
  Needle suspension
  Equal: Traditional sling
- Standard MUS: Equal Burch
  Traditional sling

But less complications

- TVT-R vs TOT: Objective cure better but subjective equal with more complications
- SIMS vs Std MUS: Not enough evidence
Local RCT SIMS vs TOT: Preliminary data

- Multicentre, Clinical equivalence trial
- **Subcategories:** Pure SUI, ISD, MUI, SUI and POP
- Randomisation computer generated
- Aim 100 patients
- Currently (n)=92; GSH (n)=10; TGBH (n)=82
- All clinical, UDS evaluation. Excluded pregnant/suprapubic pain/bleeding disorders
- Data for total group
Local RCT SIMS vs TOT: Preliminary data

- Total N = 92
- Needleless n = 51
- TVT-O n = 41
- SUI and POP = 47 (51%)
- MUI = 20 (22%)
- Pure SUI = 17 (18%)
- SUI+ISD = 8 (9%)
### Demographic data pre-operative

<table>
<thead>
<tr>
<th></th>
<th>Needleless 95% (CI)</th>
<th>TVT-O 95% (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age years</td>
<td>54.37 (50.7-57.2)</td>
<td>55.7 (52.2-59.4)</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>31.5 (30.2-32.8)</td>
<td>33.7 31.2-34.3</td>
</tr>
<tr>
<td>Pad changes/day</td>
<td>3.8 (2.5-5.1)</td>
<td>3.3 (2.0-4.5)</td>
</tr>
</tbody>
</table>
### Intraoperative

<table>
<thead>
<tr>
<th></th>
<th>Needleless 95%(CI) N(49)</th>
<th>TVT-O ( 95%CI) N(41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery time min</td>
<td>15.87 (13.4-28.5)</td>
<td>20.07 (18.86-21.27)</td>
</tr>
<tr>
<td>Intra-op bleeding ml</td>
<td>21.1 (14.5-16.9)</td>
<td>23 (12.83-33.2)</td>
</tr>
</tbody>
</table>
**Local RCT SIMS vs TVT-O:**

**Preliminary Objective data**

<table>
<thead>
<tr>
<th></th>
<th>F/U</th>
<th>Contasure</th>
<th>TVT-O</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SUI demonstrated</strong></td>
<td>6/52, 6/12, 1y</td>
<td>N(10) 22.7%</td>
<td>n(2) 6.06%</td>
<td>P= 0.046, p=0.027, P=0.123</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N(6)(15.8%)</td>
<td>n(0) 0%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N(6) 18.2%</td>
<td>N(1) 4.4%</td>
<td></td>
</tr>
<tr>
<td><strong>1 H pad test &lt;1g</strong></td>
<td>6/12, 1y</td>
<td>n(28) 54 %</td>
<td>n(21) 51 %</td>
<td>P=0.79, P=0.125</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n(17) 33 %</td>
<td>N(13) 31%</td>
<td></td>
</tr>
</tbody>
</table>
Local RCT SIMS vs TOT: Preliminary data Patient reported

<table>
<thead>
<tr>
<th>Sandvick</th>
<th>F/U</th>
<th>Contasure (Needleless) Total N</th>
<th>TVT-O Total N</th>
<th>Mann-Whitney U Test. P-Value &lt;0.05 sign</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often do you leak?</td>
<td>6/52</td>
<td>43</td>
<td>31</td>
<td>P=0.26</td>
</tr>
<tr>
<td>2. How much do you leak?</td>
<td>6/12</td>
<td>42</td>
<td>31</td>
<td>P=0.35</td>
</tr>
<tr>
<td>1. How often: do you leak?</td>
<td>6/12</td>
<td>40</td>
<td>31</td>
<td>P=0.83</td>
</tr>
<tr>
<td>2. How much do you leak?</td>
<td>6/12</td>
<td>40</td>
<td>31</td>
<td>P=0.87</td>
</tr>
<tr>
<td>1. How often do you leak?</td>
<td>1y</td>
<td>37</td>
<td>30</td>
<td>P=0.25</td>
</tr>
<tr>
<td>2. How much do you leak?</td>
<td>1y</td>
<td>37</td>
<td>30</td>
<td>P=0.09</td>
</tr>
</tbody>
</table>
Quality of Life:

Local Validated Kings Health Questionnaire

- Symptoms no ss difference 6/12 and 1y
- KHQ showed improvement Needleless and TVT-O 6/52, 6/12, 1y
## Complications

<table>
<thead>
<tr>
<th>Pain visual analoque</th>
<th>Valid N Needleless</th>
<th>Valid N TVT-O</th>
<th>Mann-W. U Test P &lt; 0.05 ss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge: R leg</td>
<td>48</td>
<td>39</td>
<td>0.004</td>
</tr>
<tr>
<td>L Leg</td>
<td>48</td>
<td>38</td>
<td>0.015</td>
</tr>
<tr>
<td>6/52</td>
<td>R leg</td>
<td>42</td>
<td>31</td>
</tr>
<tr>
<td>L leg</td>
<td>42</td>
<td>31</td>
<td>0.995</td>
</tr>
</tbody>
</table>

No ss. Difference at 6/12 and 1y for pain
Local RCT Needleless vs. TVT-O

- **Reoperation** recurrent USI for Needleless = 4
  TVT-O = 1
- **Extrusion** Needleless = 2
  TVT-O = 0

Appears in this study that the outcome in the Single incision sling trend to be inferior to TOT

Caution with interpretation of this data still necessary as it is only preliminary
Special Population groups

- MUI
- ISD
- Recurrent SUI
- POP
- Obesity
Conclusion

Position Statement AUGS on Mesh Midurethral Slings for Stress Urinary Incontinence

• Polypropylene safe/effective surgical implant.
• Monofilament polypropylene MUS most studied SUI procedure in history.
• Polypropylene MUS standard of care for the surgical treatment of SUI

And currently the TOT most commonly used

But not to use Single incision MUS routine practice until more data is available
Thank you!