A SYSTEMATIC REVIEW AND META-ANALYSIS OF SURGICAL TREATMENT OF WOMEN WITH RECURRENT STRESS URINARY INCONTINENCE

Hypothesis / aims of study
To assess the current evidence of effectiveness and complications of the various surgical procedures used for treatment of women with recurrent stress urinary incontinence (R-SUI).

Study design, materials and methods
A prospective, peer-reviewed protocol was prepared a priori. A systematic literature review of all published RCTs comparing any two surgical procedures for treatment of SUI was performed in accordance with PRISMA. Studies were identified through MEDLINE, EMBASE, Cochrane library, clinicaltrials.gov, and Web of Science Library as well as IUGA/ICS conference abstract databases. Literature search was performed in July 2011 independently by two authors and updated in March 2012. There were no language restrictions. Authors of RCTs for surgical treatment of R-SUI and those of RCTs for surgical treatment of SUI who had included a subgroup of patients with R-SUI, were contacted to provide further data. Two authors independently extracted data and controversies were resolved by discussions with senior authors.

The primary outcome was the clinical cure/improvement (both patient-reported and objective outcomes) of incontinence for procedure A versus procedure B at 6-24 month follow-up. The secondary outcomes were: intra-operative complications (such as major vascular injury, bladder, urethra or bowel perforation); postoperative complications (such as voiding dysfunction, erosion to vaginal/ bladder or urethra); and impact on women’s quality of life and sexual function. Data was analysed using RevMan 5. Meta-analysis was performed using the fixed effect model and heterogeneity calculated using I2 estimate.

Results
Out of 45 RCTs with confirmed subgroups of patients with R-SUI in their populations, complete data were available from 9 RCTs (n= 309) towards our pre-specified 4 different comparisons: (a) retropubic tension-free vaginal tape (RP-TVt) vs. transobturator tape (TO-TVt): 5 RCTs, n=135; (b) RP-TVt vs autologous fascial sling (AFS): 2 studies; n=35; (c) Burch colposuspension vs. AFS: 1 study, n=93; and (d) inside-out vs. outside-in TO-TVt: 1 study, n=46.

Meta-analysis was possible only for comparisons (a) and (b). There was no evidence of statistically significant difference between RP-TVt and TO-TVt in either the patient-reported (OR 0.84 95%CI 0.41, 1.69) or the objective cure/improvement (OR 1.75 95%CI 0.86, 3.54). However, there was a higher risk of bladder/urethral injury with RP-TVt although not statistically significant (OR 0.27 95%CI 0.06, 1.20, p=0.09).

Similarly, there was no significant difference between AFS and RP-TVt in the patient-reported (OR 2.10 95%CI 0.48, 9.11) or objective cure/improvement (OR 1.43 95%CI 0.22, 9.26).

Meta-analysis and estimates of effects were not possible in the other 2 comparisons of surgical techniques as data were available from only one study in each comparison. There was no significant difference between AFS and Burch colposuspension (one study) in the cure/improvement rate (OR 0.62 95%CI 0.27, 1.41). However, in comparison (d) between inside-out and outside-in TO-TVt, there was a trend towards higher rate of patient-reported cure/improvement (OR 3.00 95%CI 0.85, 10.57, p=0.09) and objective cure/improvement (OR 3.32 95%CI 0.96, 11.41, p=0.06) in favour of the inside-out route, but this did not reach statistical significance (one study).

Interpretation of results
The lack of understanding of the aetiology of R-SUI, following previous continence surgery, means that management of these women represents a clinical and surgical dilemma which is only set to increase with the on-going increase in rates of primary continence surgery. The current evidence in medical literature is limited to a number of small observational studies and very few, if any, RCTs with limited populations. This is a systematic review, and meta-analysis when possible, of subgroups of women with R-SUI within larger RCTs comparing surgical treatments for women with SUI. The meta-analyses have shown that the TO-TVt is associated with similar patient-reported and objective cure/improvement when compared to RP-TVt and there was no significant difference between AFS and RP-TVt in patient-reported and objective cure/improvement in women with R-SUI. The TO-TVt (and preferably the inside-out approach) may prove to be the favoured procedure in this context to reduce the risk of lower urinary tract injuries which can be a specifically high risk in these patients.

The results of this study are unique as no previous meta-analysis was performed for R-SUI; however, they are limited by the small number of RCT’s and women included in the analysis.

Concluding message
TO-TVt has similar patient-reported and objective cure/improvement rates when compared to the RP-TVt in the surgical treatment of women with recurrent SUI. There was a trend towards higher success rate with the inside-out TO-TVt when compared to the outside-in approach. Similarly, there was no significant difference between AFS and RP-TVt in the patient-reported and objective cure/improvement rates. The results should be interpreted with caution as evidence in this field is quite limited and is of low quality. Further primary research is urgently needed to guide clinicians and patients towards the best surgical treatment of this increasingly prevalent and distressing condition.
Figure 1: Patient Reported Outcome RP-TVT vs TO-TVT

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Events</th>
<th>Total</th>
<th>Weight</th>
<th>Odds Ratio M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anidiné</td>
<td>13</td>
<td>18</td>
<td>16</td>
<td>0.87 [0.19, 4.01]</td>
</tr>
<tr>
<td>Barry</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>2.14 [0.06, 77.54]</td>
</tr>
<tr>
<td>Costantini</td>
<td>6</td>
<td>8</td>
<td>2</td>
<td>0.52 [0.02, 15.10]</td>
</tr>
<tr>
<td>El-Hennawy</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>0.03 [0.00, 3.10]</td>
</tr>
<tr>
<td>Richter</td>
<td>18</td>
<td>41</td>
<td>38</td>
<td>0.97 [0.40, 2.25]</td>
</tr>
</tbody>
</table>

Total (95% CI) 71 64 100.0% 0.84 [0.41, 1.69]
Total events 39 37
Heterogeneity: Chi² = 1.99, df = 4 (P = 0.74); I² = 0%
Test for overall effect: Z = 0.50 (P = 0.62)

Figure 2: Patient-reported Outcome AFS vs RP-TVT

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Fascial Sling</th>
<th>Synthetic MUS</th>
<th>Odds Ratio M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amane</td>
<td>4</td>
<td>5</td>
<td>18.8 [6.5, 54.40]</td>
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<tr>
<td>Shafitaghdas</td>
<td>10</td>
<td>13</td>
<td>86.2 [9.11, 6.26]</td>
</tr>
</tbody>
</table>

Total (95% CI) 18 17 100.0% 2.10 [0.48, 9.11]
Total events 14 10
Heterogeneity: Chi² = 2.06, df = 1 (P = 0.15); I² = 51%
Test for overall effect: Z = 0.99 (P = 0.32)

Disclosures
Funding: None Clinical Trial: No Subjects: HUMAN Ethics not Req’d: This study was a systematic review. No primary research was carried out. Helsinki: Yes Informed Consent: No