A SYSTEMATIC REVIEW AND META-ANALYSIS OF SINGLE-INCISION MINI-SLINGS VERSUS STANDARD MID-URETHRAL SLINGS IN SURGICAL MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE.

Hypothesis / aims of study
To assess the current evidence of effectiveness and complications of Single Incision Mini-Slings (SIMS) compared to Standard Mid-Urethral Slings (SMUS): retropubic (RT-TV T) and transobturator (TO-TV T) tension-free vaginal tapes in the management of female stress urinary incontinence (SUI).

Study design, materials and methods
A prospective peer-reviewed protocol for this review was prepared a priori; a meta-analysis of all published RCTs comparing SIMS and SMUS in accordance with PRISMA. Studies were identified through MEDLINE, EMBASE, Cochrane library, clinicaltrials.gov, WHO database of clinical, IUGA/ICS conference and SGS conference abstract databases. Literature search was performed in August 2010 independently by two authors and updated in January 2011. Two authors independently extracted data and controversies were resolved by discussions with senior authors. Supplementary data was provided by six, out of nine, study authors. Articles were translated if required. Data was analysed using Rev-Man 5. Meta-analysis was performed using the random effects model and heterogeneity calculated using I² estimate. Sensitivity analysis was performed by excluding studies with unclear quality. Risk of bias across studies was assessed using risk of bias tables generated through Review Manager.

The primary outcome was the clinical cure/ improvement (both patient-reported and objective outcomes) of incontinence for SIMS versus SMUS at 6 month follow-up. The secondary outcomes were mainly surgical outcomes (such as duration of operation, operative blood loss, length of inpatient stay, time to return to normal activity level), peri-operative complications (such as major vascular injury, bladder, urethra or bowel perforation, and nerve damage) and postoperative complications (such as short and long-term voiding dysfunction, post operative pain, groin or thigh pain, de novo detrusor overactivity, de novo urgency, infection related to use of synthetic mesh, erosion to vagina/ bladder or urethra and repeat surgery for SUI). Other secondary outcomes included impact on women’s quality of life, sexual function and cost to health services. Subgroup analysis was performed for comparing, when appropriate, different types of SIMS versus SMUS as regards patient-reported and objective cure.

Results
Nine studies were included; comparing TVT-Secur™ (6 studies; n=548), Mini-arc™ (2 studies; n=160) and Ophira™ (one study; n=50) to SMUS. A total of 758 women were included; 60 women were lost to follow-up (SMUS n=23, vs. SIMS n=37). The mean age (SMUS - 52.3 years vs. SIMS - 52.1 years), mean BMI (SMUS - 27.4 Kg/m² vs. SIMS - 27.7 Kg/m²) and median parity (SMUS - 2 vs. SIMS - 2) were comparable.

The meta-analyses showed a significantly lower patient-reported cure rate with SIMS when compared to SMUS; specifically TO-TVT (RR 0.84 95%CI 0.71, 0.99), however a non-significant difference in favour of RT-TV T was seen (RR 0.79 95%CI 0.37, 1.67) (Figure 1). These results were supported on sensitivity analysis when studies of unclear quality were excluded. SIMS were associated with significantly lower objective cure rates when compared to SMUS; specifically TO-TVT (RR 0.88, 95%CI 0.77, 0.99). In addition there was a significantly different in favour of RT-TV T when compared to SIMS (Figure 2). This was also confirmed on sensitivity analysis when studies of unclear quality were excluded.

A shorter operation time was associated with SIMS (WMD -8.67 minutes 95%CI -17.32, -0.02), this is due to the significant difference in operation time in the single RT-TT study. Day-one VAS pain scores were reported in three studies comparing SIMS versus TO-TV T studies. There were significantly lower day-one pain scores in the SIMS group (WMD -1.74 95%CI -2.58, -0.09).

Repeat continence surgery was significantly higher in SIMS group (RR 6.72, 95%CI 2.39, 18.89). Tape erosion and de-novo urgency incontinence were significantly higher in the SIMS group (RR 3.86, 95%CI 1.45, 10.28 and RR 2.08, 95%CI 1.01, 4.28 respectively). There were non-significant differences between both groups in respect to post-operative voiding difficulties (RR 1.47, 95%CI 0.78, 2.74) and other minor (post operative wound infection, haematoma, UTI and haematuria) post-operative complications (RR 1.59 95%CI 0.74, 3.45).

There was no significant difference in the QoL scores between the groups (WMD -33.46, 95%CI -87.55, 20.62). No studies compared postoperative sexual function or cost to health services. Statistical heterogeneity was found throughout the analysis and was highest in patient reported cure rate, QoL scores and operation time.

Interpretation of results
Several observational and cohort studies have raised questions about the efficacy of SIMS, and were confirmed by this meta-analysis showing SIMS to be associated with significantly lower post-operative pain when compared to SMUS. However, they are associated with inferior patient-reported and objective cure rates on the short-term follow-up, as well as higher re-operation rates. The results of this study are unique as no previous meta-analysis was performed for SIMS.

SIMS relatively poor outcome may be attributed to the relatively short trajectory and less substantial fixation of SIMS compared to SUMS, resulting in reduced anchoring and support. Our results do not support routine use of SIMS in clinical practice.

Concluding message
Single incision mini-slings are associated with inferior patient reported and objective cure rates as compared to standard mid-urethral slings in surgical treatment of female stress urinary incontinence.
Figure 1: Patient Reported Cure Rate

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>SIMS Events</th>
<th>Total</th>
<th>SMUS Events</th>
<th>Total</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.2 SIMS vs RT-TVT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Abdelwahab 2010</td>
<td>29</td>
<td>30</td>
<td>28</td>
<td>29</td>
<td>16.9%</td>
<td>1.00 [0.91, 1.10]</td>
<td></td>
</tr>
<tr>
<td>Basu 2010</td>
<td>22</td>
<td>37</td>
<td>32</td>
<td>33</td>
<td>12.5%</td>
<td>0.61 [0.47, 0.81]</td>
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</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>67</td>
<td></td>
<td>62</td>
<td></td>
<td>28.3%</td>
<td>0.79 [0.37, 1.67]</td>
<td></td>
</tr>
<tr>
<td>Total events</td>
<td>51</td>
<td>60</td>
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</tbody>
</table>

Heterogeneity: Tau² = 0.28; Chi² = 26.78, df = 1 (P < 0.00001); I² = 96%
Test for overall effect: Z = 0.62 (P = 0.53)

Specify source of funding or grant
NONE

Is this a clinical trial?
No

What were the subjects in the study?
HUMAN

Was this study approved by an ethics committee?
No

This study did not require ethics committee approval because
This study was a systematic review. No primary research was carried out.

Was the Declaration of Helsinki followed?
Yes

Was informed consent obtained from the patients?
No