

## **SINGLE-INCISION MINI-SLINGS VERSUS STANDARD MIDURETHRAL SLINGS IN SURGICAL MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE: AN UPDATED SYSTEMATIC REVIEW META-ANALYSIS OF EFFECTIVENESS AND COMPLICATIONS.**

### Hypothesis / aims of study

To evaluate the efficacy, safety and cost-effectiveness of Single-Incision Mini-Slings (SIMS) compared to Standard Mid-Urethral Slings (SMUS) (retro-pubic and transobturator tension-free vaginal tapes) in the Surgical Management of Female Stress Urinary Incontinence.

### Study design, materials and methods

An updated meta-analysis performed as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA) guidance. A peer reviewed protocol was prepared a priori; systematic review of the literature was performed using the Medline & Embase database. Trial registries were searched including: clinical trials.gov, Australian/Netherlands clinical trials registry, WHO registry, Cochrane database of systematic reviews and international conferences abstract databases. The literature search was performed in November 2012 and updated March 2013 with no language restriction. Risk of bias across studies was assessed using risk of bias tables generated through Review Manager. The primary outcomes were patient-reported and objective cure rates of SIMS versus SMUS at 12-24 month follow-up. Secondary outcomes include: operative data; peri-operative and postoperative complications; failure requiring repeat surgery for SUI; impact on women's quality of life (QoL), sexual function, and finally costs to health services. Data were analysed using Rev-Man5. Meta-analysis was performed using the random effects model and heterogeneity calculated using I<sup>2</sup> estimate. Meta-analysis was repeated for primary outcomes excluding RCTs evaluating TVT-Secur, a type of SIMS that was recently withdrawn from clinical practice.

### Results

25 RCTs (n=3114 women) were included in the updated meta-analysis; these RCTs compared SMUS vs. (a) Mini-Arc (n=6; 566 women); (b) Ajust (n=3; 350 women); (c) Ophira (n=1; 130); (d) Contasure (n=1; 257); (e) TFS (n=1; 80 women); (f) Solyx (n=1; 30 women) and finally (g) TVT-Secur (n= 12; 1606 women) The patient characteristics were comparable between both groups; the mean age (SMUS: 55.27 yr vs. SIMS: 50.88 yr), mean body mass index (SMUS: 24.98 kg/m<sup>2</sup> vs. SIMS: 24.80 kg/m<sup>2</sup>), and median parity (SMUS: 2 vs. SIMS: 2) were comparable. 217 women were lost to follow-up (SMUS: n = 92 vs. SIMS: n = 125).

Meta-analyses showed SIMS to be associated with inferior patient reported cure rates (RR: 0.90, 95%CI: 0.85, 0.95) and objective cure rates (RR: 0.90, 95%CI: 0.84, 0.95) when compared to SMUS (Fig 1a, b). However on excluding RCTs evaluating TVT-secur, there was no evidence of significant differences in patient-reported & objective cure with the currently available SIMS when compared to SMUS at 12-24 month follow-up (RR: 0.96, 95%CI: 0.88, 1.03 and RR: 0.97, 95%CI: 0.92, 1.02, respectively). These results pertained on comparing SIMS versus TO-TVT and RP-TVT separately (Fig. 2a, 2b) and on sensitivity analysis including only high quality RCTs (plots to be presented).

SIMS were associated with significantly shorter operative time (WMD -2.04 min; 95% CI, -3.51, -0.58) and significant lower incidence of postoperative groin pain (WMD: -2.51; 95% CI, -3.62, -1.40). Women in the SIMS group showed significantly earlier return to normal activities and to return to work (WMD: -5.08; 95% CI, -9.59, -0.59) and (WMD: -7.20; 95% CI, -12.43, -1.98 respectively). There was no evidence of significant differences in lower urinary tract injuries (RR: 0.90; 95% CI, 0.49, 1.165) or postoperative voiding difficulties (RR: 0.69; 95% CI, 0.41, 1.16) between the two groups however with trends towards favourable outcomes in the SIMS group. There was no evidence of significant differences in de-novo Urgency or and or worsening of pre-existing urgency (RR: 1.22; 95% CI: 0.96, 1.55) with trends towards favourable outcomes in the SMUS group. Vaginal erosion and repeat continence surgery were significantly higher in the SIMS group (RR: 1.95; 95% CI: 1.14, 3.34 and RR: 3.02.; 95% CI, 1.32, 6.94 respectively), that was mainly due to significant difference in the TVT Secur group (RR: 1.19.; 95% CI: 1.19, 4.79 and RR: 5.00.; 95% CI, 0.92, 27.27 respectively). There was no significant difference in QoL group (WMD: -6.54; 95%CI:-11.95, -1.13) and Sexual function (WMD: 0.39 95% CI -0.89, 1.67) between the groups. One study which compared SIMS versus SMUS in regards to cost to health services and showed that SIMS-Ajust® performed under local anaesthesia, as an opt-out policy, delivered cost savings to the health service provider when compared to the SMUS TVT-O™ and is likely to be cost-effective up to one year follow-up.

### Interpretation of results

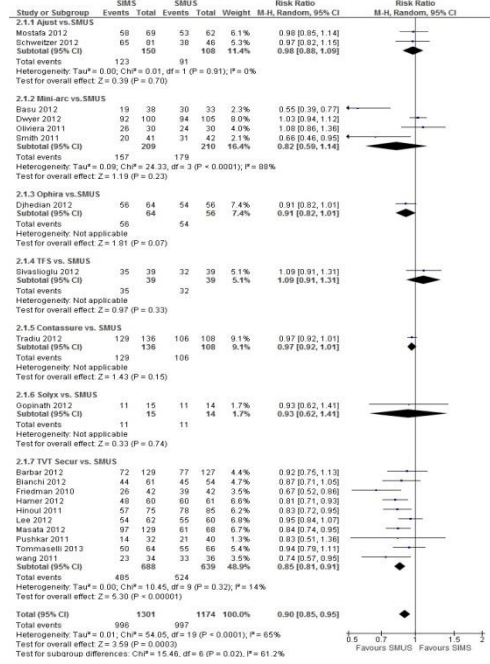
We updated our systematic review of the literature in the assessment of the efficacy of SIMS comparing to the SMUS, based on the recommendation of the Cochrane Collaboration to update systematic reviews at least every 2 yr. Excluding TVT-secur, which was recently withdrawn from clinical practice, currently used SIMS showed comparable patient-reported and objective outcomes when compared to SMUS at 12-36 month follow-up. 12 month follow-up has been widely accepted as the optimum point for postoperative assessment to capture real and non-transient effects of the surgical intervention for SUI. RCTs evaluating Mini-arc and TFS had the longer follow-up reflecting their earlier invention. SIMS were associated with favourable postoperative outcomes. These results are promising. However, learning from the lesson of TVT-Secur where the poor outcomes were only seen at later follow-up, it is crucial for RCTs evaluating these relatively new SIMS to report patient-reported and objective cure rates at a minimum of 3-years postoperative. The results of this meta-analysis have to be interpreted with

caution for a number of reasons: (a) the heterogeneity involved by including all types of SIMS in one arm and (b) apart from TVT-Secur, Ajust and Mini-arc, all other SIMS were evaluated by a single RCT each. To overcome these limitations, we presented individual meta-analysis for each SIMS vs. SMUS.

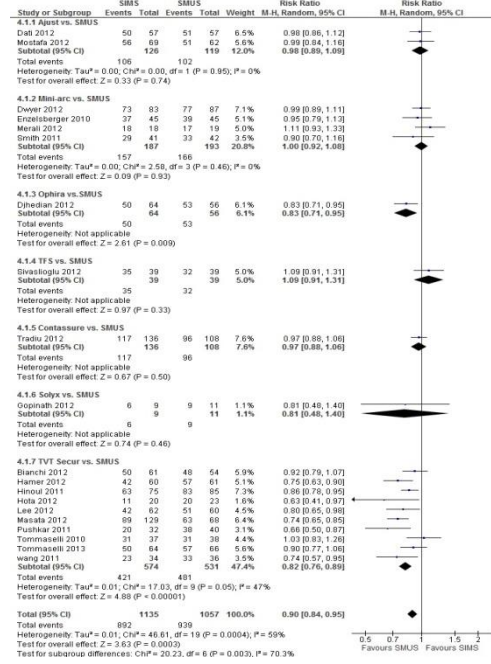
**Concluding message**

Excluding TVT-Secur, SIMS show promising results of no significant differences in patient-reported and objective cure rates and superior recovery time when compared to standard mid-urethral slings in surgical treatment of female SUI with 12-24 month follow-up. The results should be interpreted with caution and longer term follow-up is essential before SIMS are considered as primary treatment for women with SUI.

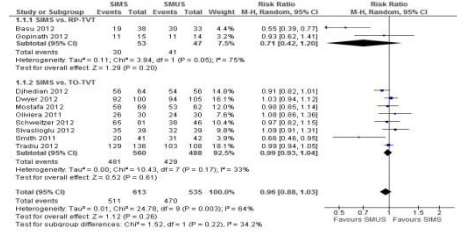
**Figure 1a: Patient-reported Cure rate**



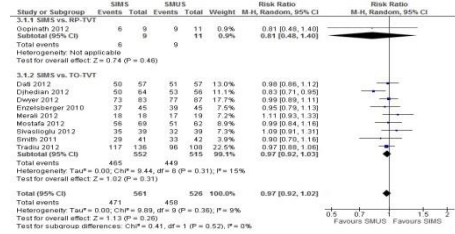
**Figure 1b: Objective Cure rate**



**Figure 2a: Patient reported cure rate: (Excluding TVT-Secur):**



**Figure 2b: Objective cure rate: (Excluding TVT-Secur):**



**Disclosures**

**Funding:** not applicable **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** it is updated systematic review **Helsinki:** Yes **Informed Consent:** No