1

Abdel-Fattah M[1], Ford J[1], Lim C P[2], Madhuvrata P[3]
1. *University of Aberdeen,* ***2.*** *NHS Grampian,* ***3.*** *Sheffield Teaching Hospitals NHS Foundation Trust*

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-TVT) and transobturator (TO-TVT) 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 I^2 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^{TM} (6 studies; n=548), Mini-arc^{TM} (2 studies; n=160) and Ophira^{TM} (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/m^2 vs. SIMS - 27.7 Kg/m^2) 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-TVT 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 significant difference in favour of RT-TVT 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-TVT study. Day-one VAS pain scores were reported in three studies comparing SIMS versus TO-TVT 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

Study or Subgroup	SIMS Events	SIMS Total	SMUS Events	SMUS Total	Weight	Risk Ratio M-H, Random, 95% CI
1.1.2 SIMS vs RT-TVT						
Abdelwahab 2010	29	30	28	29	16.9%	1.00 [0.91, 1.10]
Basu 2010	22	37	32	33	12.5%	0.61 [0.47, 0.81]
Subtotal (95% CI)		**67**		**62**	**29.3%**	**0.79 [0.37, 1.67]**
Total events	51		60			
Heterogeneity: Tau² = 0.28; Chi² = 26.78, df = 1 (P < 0.00001); I² = 96%						
Test for overall effect: Z = 0.62 (P = 0.53)						
1.1.3 SIMS vs TO-TVT						
Djehdian 2010	25	29	15	15	15.1%	0.88 [0.74, 1.04]
Friedman 2010	26	42	39	42	13.1%	0.67 [0.52, 0.86]
Hinoul 2010	59	86	83	87	15.7%	0.72 [0.62, 0.84]
Kim 2010	18	20	17	20	13.5%	1.06 [0.84, 1.34]
Tommaselli 2010	28	37	30	38	13.2%	0.96 [0.75, 1.23]
Subtotal (95% CI)		**214**		**202**	**70.7%**	**0.84 [0.71, 0.99]**
Total events	156		184			
Heterogeneity: Tau² = 0.02; Chi² = 12.83, df = 4 (P = 0.01); I² = 69%						
Test for overall effect: Z = 2.10 (P = 0.04)						
Total (95% CI)		**281**		**264**	**100.0%**	**0.83 [0.70, 0.99]**
Total events	207		244			
Heterogeneity: Tau² = 0.05; Chi² = 39.15, df = 6 (P < 0.00001); I² = 85%						
Test for overall effect: Z = 2.03 (P = 0.04)						

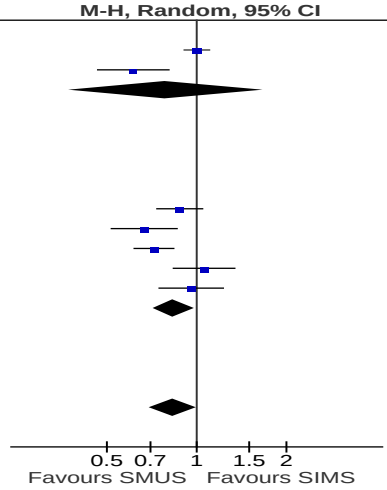
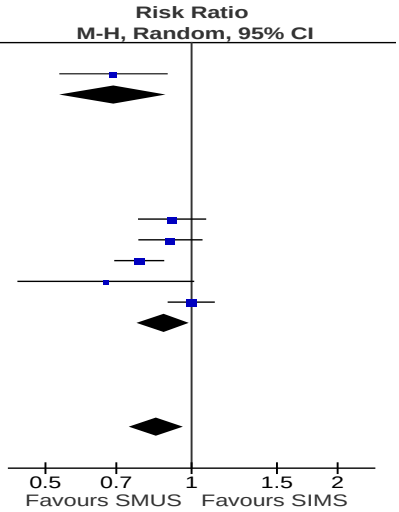


Figure 2: Objective Cure Rate

Study or Subgroup	SIMS Events	SIMS Total	SMUS Events	SMUS Total	Weight	Risk Ratio M-H, Random, 95% CI
2.1.2 SIMS vs RT-TVT						
Basu 2010	24	37	31	33	12.9%	0.69 [0.54, 0.89]
Subtotal (95% CI)		**37**		**33**	**12.9%**	**0.69 [0.54, 0.89]**
Total events	24		31			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.87 (P = 0.004)						
2.1.3 SIMS vs TO-TVT						
Djehdian 2010	26	29	15	15	18.4%	0.91 [0.78, 1.07]
Enzelsberger 2010	38	45	42	45	19.0%	0.90 [0.78, 1.05]
Hinoul 2010	67	86	87	87	21.1%	0.78 [0.70, 0.87]
Hota 2010	11	19	20	23	7.1%	0.67 [0.44, 1.01]
Tommaselli 2010	35	37	36	38	21.5%	1.00 [0.90, 1.11]
Subtotal (95% CI)		**216**		**208**	**87.1%**	**0.88 [0.77, 0.99]**
Total events	177		200			
Heterogeneity: Tau² = 0.01; Chi² = 13.88, df = 4 (P = 0.008); I² = 71%						
Test for overall effect: Z = 2.04 (P = 0.04)						
Total (95% CI)		**253**		**241**	**100.0%**	**0.85 [0.74, 0.97]**
Total events	201		231			
Heterogeneity: Tau² = 0.02; Chi² = 18.97, df = 5 (P = 0.002); I² = 74%						
Test for overall effect: Z = 2.49 (P = 0.01)						



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**