4

Mostafa A[1], Agur W[2], Abdel-All M[3], Guerrero K[4], Allam M[5], Lim C[6], Yousef M[4], Abdel-Fattah M[1]
1. *University of Aberdeen,* ***2.*** *Aryshire &Arran NHS,* ***3.*** *Borders & General NHS,* ***4.*** *Greater Glasgow Health Board,* ***5.*** *Lanarkshire NHS,* ***6.*** *Five NHS*

A MULTICENTRE RANDOMISED TRIAL OF SINGLE-INCISION MINI-SLING (AJUST©) AND TENSION-FREE VAGINAL TAPE-OBTURATOR (TVT-OTM) IN MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE.

Hypothesis / aims of study
To compare Single-incision Mini-slings (SIMS- Ajust©) versus standard mid-urethral sling (TVT-O™) in women with stress urinary incontinence (SUI) as regards:

- Postoperative Pain Profile (primary outcome).
- Short-Term Patient-Reported & Objective Cure Rates.
- Peri-operative Complications; Hospital stay, Time to return to normal activities/ work.
- Impact on Pre-operative urgency, Women's Quality of Life (Qol) & Sexual Function.

Study design, materials and methods
A multicentre prospective randomised trial in 6 UK centres. Ethical committee approval was obtained and the study was registered on www.clinicaltrials.gov. All eligible women admitted for mid-urethral slings (MUS) as a sole procedure, in the period between October 2009 and October 2010 were invited to participate. Women were included if they had Urodynamic SUI or mixed incontinence with pre-dominant bothersome SUI; having failed or declined pelvic floor muscle training. Women were excluded if they had pelvic organ prolapse (≥ stage 2), previous continence surgery and/or concomitant surgery.

Randomisation was done through a number-allocation software and using a telephone randomisation on the procedure day. Women underwent either SIMS- Ajust© (C. R. Bard, Inc., New Jersey, USA) under L.A as an opt-out policy or TVT-O™ (Ethicon Inc., Somerville, USA) under GA. Procedures were done as originally described; cystoscopy was routinely performed.
Postoperative pain profile was assessed on a 10point visual analogue scale at five fixed-time points. All women received a structured telephone interview at 4-days & 4-weeks postoperatively to assess pain score and time to return to work/ normal activities.

Pre-operatively, women completed symptom severity questionnaires (International Consultation on Incontinence Questionnaire of Lower Urinary Tract Symptoms (ICIQ-FLUTS), ICIQ-SF, Urgency Perception Scale (UPS)) and quality of life questionnaires; Kings Health Questionnaire (KHQ), Pelvic Organ Prolapse / Incontinence Sexual Questionnaire (PISQ-12). At 3-month follow-up; women completed all the above and in addition; Patient Global Impression of Improvement (PGI-I) and underwent cough stress test and vaginal examination.

Power analysis was done & Data was analysed using SPSS 18.0 (Chicago, Illinois). Descriptive analyses are given and between group comparisons were performed using Chi-Square, Fischer Exact test & Mann-Whitney test as appropriate. Significance level set at 5%.

Results
137 women were randomised; SIMS- Ajust© (n=69) vs. TVT-O (n=68) during the study period; all women have completed their 3month follow-up. Women in the SIMS group had significantly lower postoperative pain scores ($p<0.001$) at all time points of assessment except for 4 weeks; Figure1&2 shows the postoperative pain profile of both procedures. Table 1 shows the comparison of the operative, peri-operative complications and postoperative events between the groups. Table 2 shows the patient reported and objective outcomes between both groups.

133 Women (97.1%) completed a valid KHQ pre &postoperatively; 117 (88.0%) women had ≥ 10 points improvement in total KHQ score; No significant differences between both groups (SIMS n= 57 (82.6%) vs. TVT-O™ n= 60 (93.8%), OR 3.158, 95%CI 0.962, 10.362, p=0.088). All KHQ domains showed significant postoperative improvement following both procedures however with no significant differences between groups. Only 75 women (54.7%) have resumed sexually activity at 3month; 74.7% (n=56) showed an improvement in their PISQ-12 scores with no significant differences between groups (SIMS n= 29 (72.5%) vs. TVT-O™ n= 27 (77.1%), p = 0.645, OR 1.280, 95%CI (0.448, 3.661).

Interpretation of results
SIMS avoid the groin trajectory of insertion for TVT-O and therefore may be associated with less postoperative pain. Adjustable SIMS has a robust anchoring mechanism to the obturator complex and therefore seems to address previous concerns with earlier SIMS. Our study shows significantly improved postoperative pain profile, shorter hospital stay and earlier return to normal activities in women undergoing SIMS when compared to TVT-O however this was not reflected in a significantly better improvement in women's QoL in the SIMS group. Interestingly, intra-operative pain scores were consistently low in women undergoing SIMS under LA. There was no evidence of significant differences in short term patient-reported cure, objective cure rates or impact on women's sexual function between both groups. Our results were comparable to Meschia et al (1) who showed objective and patients reported cure rate of 91.4% & 85.7% respectively in 105 women undergoing SIMS–Ajust© at 6 month.

Concluding message

Adjustable SIMS Ajust© had significantly better postoperative pain profile, earlier return to work and normal activities when compared to TVT-O™ with no evidence of significant differences in cure rates, QoL & sexual function on short term follow-up. Long-term follow-up of this RCT is underway to ascertain if this new procedure lives up for its potential.

Table 1: Operative Data

	TVT-O™	SIMS-AJUST©	P – value
Operative Data:			
Operating time (min); Mean ±SD	00:33 ± 00:09	00:33 ± 00:10	0.516
Estimated Blood loss: <50 ml 50-100 ml >100 ml	28(41.8%) 36(53.7%) 3 (4.5%)	45(65.2%) 22(31.9%) 2(2.9%)	0.023
Peri-operative Complications:			
Bladder/Urethral Injuries; n (%)	0	0	0
Difficulties in Kit insertion; n (%)	2 (3.0%)	4 (5.8%)	0.681
Severe post-operative pain (score>5/10)	5 (7.5%)	2 (2.9%)	0.271
Voiding dysfunction: Requiring Catheterisation CISC at 3 month	8 (11.8%) 2 (2.9%)	3 (4.3%) 1 (1.4%)	0.200 0.619
Hospital stay (hours); Median(IQR)	5:13(03:49,09:27)	4:06 (02:58, 05:33)	0.001
Post-operative data:			
Admission over night; n (%)	16 (23.5%)	11 (15.9%)	0.367
Vaginal Erosion; n (%)	2(2.9%)	0 (0%)	0.496
Time To Return To Normal Activities (days)- Median(IQR)	8 (5.25, 14)	7 (3,14)	0.029
Time To Return To Work (days) - Median(IQR)	21(11, 28)	14(7, 21)	0.047

Table 2: Patient Reported & Objective Outcomes:

	TVT-O™	SIMS-AJUST©	P – value
Patient-Reported Success (PGI-I) ♣; n (%)	63 (92.6%)	58 (85.3%)	0.273
Change in ICIQ-SF (Pre-Post); Mean ±SD	12.32 ± 4.50	11.21 ± 5.61	0.205
Objective Cure (Negative cough stress test); n (%)	66 (97.1%)	61 (89.7%)	0.165
Patient Satisfaction on Visual Analogue Scale; median (IQR)	9 (8,10)	10 (8,10)	0.243
Recommend To Friend; n (%)	61(91.0%)	63 (92.6%)	0.980
Changes in Urgency Perception Scale; n (%)			
Cure of Urgency	20 (29.4%)	19 (27.5%)	0.957
Improvement of Urgency	16 (23.5%)	14 (20.3%)	0.801
No Changes	26 (38.2%)	20 (29.0%)	0.334
Worsening of Urgency	3 (4.4%)	5 (7.2%)	0.718
De-Novo Urgency	3 (4.4%)	10 (14.5%)	0.085

Figure: 1 Postoperative Pain Profile

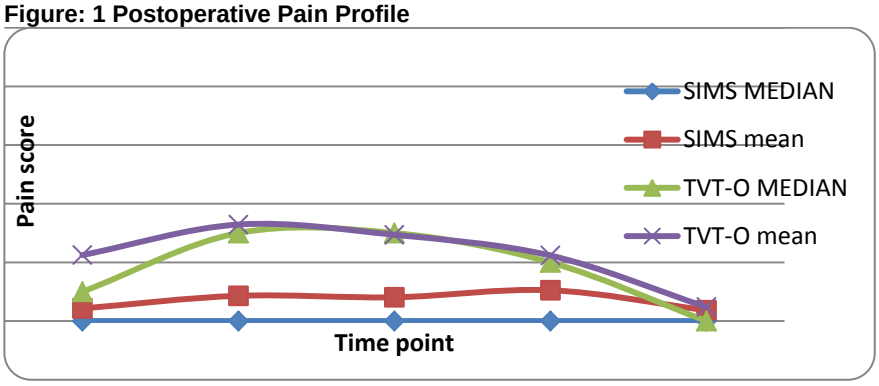
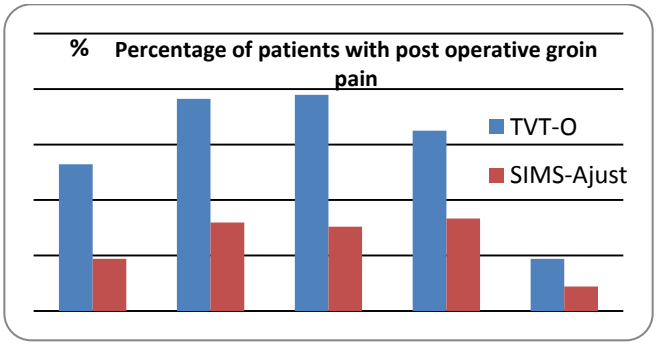


Figure: 2 Percentage of Patients with Postoperative Groin Pain



References

1. 1. Short-term outcomes with the Ajust™ system: a new single incision sling for the treatment of stress urinary incontinence. Int J Urogynaecol 2010. DOI 10.1007/s00192-010-1254-6

Specify source of funding or grant	**Henry Smith Charity**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov** **Regestration Number: NCT01230450**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**North of Scotland Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**