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MULTICENTRE PROSPECTIVE RANDOMISED STUDY OF SINGLE-INCISION MID-URETHRAL SLING (SIMS- AJUST©) VERSUS TENSION-FREE VAGINAL TAPE-OBTURATOR (TVT-OTM) IN MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI): A MINIMUM OF ONE YEAR FOLLOW-UP

Hypothesis / aims of study:

To compare the relatively new "Adjustable" single incision mid- urethral slings (SIMS-Ajust®) vs. standard mid-urethral slings (SMUS - TVT-O™) in surgical management of SUI in women with a minimum of 1 year follow-up.

Study design, materials and methods:

A Multicenter prospective randomized study in 6 Urogynaecology Centre, in the period between October 2009 and October 2010.

- **Inclusion Criteria:** All women would have had failed or declined PFMT; undergoing a primary continence procedure; and have the ability to understand the information leaflet.
- **Exclusion Criteria:** Mixed incontinence with un-controlled OAB symptoms or Neurological conditions e.g. MS.
- **Intervention**: Women were randomised for SIMS-Ajust® performed under L.A as an opt-out policy or TVT-O™ under GA; both procedures were performed as originally described.
- **Primary outcome** was the postoperative pain profile up to 4 weeks postoperative which was previously reported with all peri-operative complications(1). In this 1-year follow-up study we report: the patient-reported and objective success rates, re-operation rates, impact on women urinary symptoms, pre-operative urgency, quality of life and sexual function and women satisfaction.
- **Sample size** was estimated for the primary outcome: A total cohort of 100 women was required, with 95% power, to show a clinically significant 1 point difference on 10 point-pain scale between both groups. 137 women were recruited and randomised within the time period of the study (October 2009-2010) and are the basis for this analysis.
- **Randomization**: Block randomisation was done for each centre using number-allocation software; allocation to each group was performed via a telephone randomisation.
- **Pre-operative assessment** included urodynamic assessment, completion of International Consultation of Incontinence Questionnaire - Frequency of Lower Urinary Tract Symptoms (ICIQ-FLUTS), King's Health Questionnaire (KHQ), Pelvic Organ Prolapse/ Incontinence Sexual Function Questionnaire (PISQ-12) &Urgency perception scale (UPS)
- **Post-operatively, at 12-month,** women completed the above questionnaires in-addition to the Patient Global Impression of Improvement (PGI-I) and performed cough stress test.
- **Statistical Analysis**: was performed with "intention to treat. Comparison of scores between different groups was done using a Mann- Whitney test, Wilcoxon test was done to test for differences in scores pre to post-operation. All analyses were done using SPSS (version 19) at a significance level of 5%.

Results:

All137 women have received their assigned procedure (CONSORT flow chart will be presented): 131 (95.6%) women completed a minimum of 1-year follow-up: SIMS-Ajust vs. SMUS-TVT-O (n=62).

- **Success rates at 1-year:** There were no significant differences in the patient-reported success rate (84% vs. 85.5%; OR 0.895; 95%CI 0.344, 2.330; p= 1.000) or objectives success rate (81.2% vs. 82.3%; OR 0.929; 95%CI 0.382, 2.258; p=1.00) between SIMS -Ajust® vs. SMUS –TVT-OTM groups respectively (Table 1). ***Re-operation rates***: 8/137 women (5.8%) required repeat surgery within 1 year: 5/69 (7.2%) vs. 3/68 (4.4%); OR 0.591; 95%CI 0.136, 2.576; P= 0.721in the SIMS -Ajust® vs. SMUS –TVT-O™ groups respectively. ***Sensitivity analysis*** was performed with the lost for follow-up (all in TVT-O group) considered as failures/ success or applying technique of last observation carried forward and will be presented.
- **Impact on** Qol & Sexual function: 122/131 (93.1%) women completed KHQ pre & postoperatively: 100/122 (82%) women had significant (≥ 18 points) postoperative improvement with no significant differences between groups (Table 3). 80/ 131 (61.1%) women completed a valid PISQ-12 pre & postoperative; 61/80 women (76.3%) showed an improvement (≥1) in their total PISQ-12 scores (Table 2).
- Impact on various urinary symptoms (ICIQ-FLUTS) and pre-operative urgency (urgency perception scale) are presented in Table 1

Interpretation of results:

This is the first RCT to compare the relatively new concept of "anchored and adjustable SIMS" to the tension free vaginal tapes concept utilised in SMUS. The results show that SIMS-Ajust were associated with significantly favourable postoperative pain profile, earlier return to work with no evidence of significant difference in objective success rate and patient-reported success when compared to SMUS –TVT-O at one year follow-up. Our results were comparable to Mesicha et al (2) who showed objective and patients reported cure rate of 91.4% & 85.7% respectively in 105 women undergoing SIMS–Ajust© at 6-month follow-up. The health-related QoL, urinary symptoms and sexual function scores showed comparable improvement in both group. The results are encouraging however should be interpreted with caution as the study was not powered for differences in success rates. The differential lost to follow-up rates (8 vs. 0 in the SMUS-TVT-O and SIMS-Ajust groups respectively) is a limitation of the results however we performed sensitivity analysis with all possible assumptions included and results are presented.

Concluding message: The results show that SIMS-Ajust were associated with significantly favourable postoperative pain profile, earlier return to work with no evidence of significant difference in objective success rate and patient-reported success when compared to SMUS –TVT-O at one year follow-up. An adequately powered RCT with formal health economic analysis is required to ascertain these results before these procedures can become a routine clinical practice.

Table 1: Postoperative pain Profile, Patient-reported & Objective Outcomes: 12month follow-up.

	TVT-O™	SIMS-Ajust©	P-value	95% CI
Post operative pain Median (IQR)	2.00 (0.00, 4.00)	0.00 (0.00,0.00)	<0.001	1.245, 1.853
Time To Return To Normal Activities (days)-Median(IQR)	8 (5.25, 14)	7 (3,14)	0.025	6.141, 9.383
Time To Return To Work (days) - Median(IQR)	21(11, 28)	14(7, 21)	0.006	11.756, 17.217
Patient Reported & Objective Outcomes				
Patient-Reported Success (PGI-I)	53 (85.5%)	58 (84%)	1.000	0.344, 2.330
Mean Change in ICIQ-SF (Pre-Post); Mean ±SD	11.65 ± 4.33	10.43 ± 5.95	0.187	-3.037, 0.600
Objective Cure (-ve cough stress test)	51 (82.3%)	56 (81.2%)	1.000	0.382, 2.258
Changes in Urgency on UPS				
Cure of Urgency	23 (37.1%)	22 (31.9%)	0.658	0.385, 1.635
Improvement of Urgency	11 (17.7%)	8 (11.6%)	0.454	0.227, 1.626
No Changes	20 (32.3%)	27 (39.1%)	0.525	0.658, 1.626
Worsening of Urgency	4 (6.5%)	6 (8.7%)	0.748	0.371, 5.141
De-Novo Urgency	4 (6.5%)	6 (8.7%)	0.748	0.371, 5.141
Median Change ICIQ-FLUTS Score: (Pre- Post); Median (IQR)				
Filling Domain	2 (1.0, 4)	1(0.0, 3)	0.087	0.698, 1.831
Voiding Domain	0 (-2, 1)	0 (-1, 1)	0.694	-0.917, 0.635
Incontinence Domain	9 (6, 11)	8 (5, 11)	0.402	-0.806, 2.068
Total ICIQ-FLUTS	10 (5, 14)	9 (5, 14)	0.292	-0.992, 3.306

Table 2: Comparing the Median Change In The KHQ & PISQ-12: Data presented as median (IQR)

	TVT-O Difference [pre– post]	SIMS-Ajust Difference [pre– post]	P-value
General Health	0.00 (0.00, 0.00)	0.00 (-25.0, 0.00)	0.840
Incontinence Impact	66.67 (66.67, 100.0)	66.67 (33.33, 1.00)	0.688
Role limitation	50.0 (33.33, 66.67)	33.33 (16.67, 66.67)	0.056
Physical limit	50.0 (33.33, 83.33)	50.0 (33.33, 66.67)	0.160
Social limitation	22.22 (11.11, 55.56)	22.22 (11.11, 44.44)	0.290
Personal Relation	33.33 (0.00, 66.67)	33.33 (0.00, 50.00)	0.211
Emotion	33.33 (22.22, 55.56)	33.33 (11.11, 63.89)	0.529
Sleep/energy	16.67 (0.00, 33.33)	16.67 (0.00, 33.33)	0.468
Severity Measure	50.00 (25.00, 66.67)	41.67 (25.0, 66.67)	0.616
Average Total KHQ	36.42 (24.69, 51.54)	33.33 (19.91, 51.23)	0.270
Total Score PISQ	3.00 (2.00, 9.00)	4.00 (0.00, 6.00)	0.699

References

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