

A MULTICENTRE, PROSPECTIVE, RANDOMISED TRIAL COMPARING THE RETROPUBIC (RP-SUS) APPROACH VERSUS THE TRANSOBTURATOR APPROACH (TO-SUS) FOR TENSION FREE, SUBURETHRAL SLING TREATMENT OF URODYNAMIC STRESS INCONTINENCE- THE TORP STUDY.

Hypothesis / aims of study

Tension free sub-urethral prosthetic slings have largely replaced the Burch colposuspension for stress incontinence, in view of the equal efficacy but shorter recovery times and better post-operative voiding function(1). The TVT[®], is the most commercially successful of the first generation slings, and now has published, long term data upto 7 years on large numbers of women, confirming its safety and efficacy(2). However, case reports of major complications prompted researchers to explore alternative sling placement, to reproduce the sub-fascial hammock of the urethra, while avoiding major vessel or bowel injury related to the passage of trocars through the retropubic space. The trans-obturator route has been described and initial reports suggest good short term results(3). This study aimed to test the hypothesis that the transobturator route results in fewer complications than the retropubic placement for tension free sub-urethral slings.

Study design, materials and methods

This was a multicentre, prospective, single blinded, randomised trial comparing the retropubic versus the transobturator approach for sub-urethral sling placement. This trial followed the CONSORT guidelines. Women were recruited from urogynaecology clinics in 4 hospitals. Primary outcomes were immediate and short term complications, with secondary outcomes being satisfaction and cure of stress incontinence. This was a pragmatic trial and all women with urodynamic stress incontinence were included except if they had a known allergy to polypropylene, were on immunosuppressants, had urogenital carcinoma or other factors that would preclude the insertion of either sling. ISD and prior incontinence surgery were controlled for. Randomisation was undertaken using computer generated blocks. Surgeons had to have undertaken at least 20 procedures of each technique before commencing the study. Placement of the slings were as recommended by accepted protocols (TVT[®], Gynecare, New York, USA; Monarc[®], AMS Minetoka, USA). Power calculations estimated that in order to reduce bladder injury from 8% to 2%, using 5% alpha levels and 80% power would require 200 subjects in each group.

Data included pre-op demographic data, urodynamic investigation, validated questionnaires (BFLUTS, IIQ-7), as well as peri-operative and post-operative data collection. Follow-up was at 3 months with the same evaluation. Ethics approval was granted from all hospitals and informed consent was obtained. Statistical analysis was undertaken using SPSS12.

Results

Of 187 women recruited 140 had complete datasets for analysis. 82 (58.6%) women underwent a TVT[®] and 58 (41.1%) a Monarc[®] TO. Demographic comparison confirmed satisfactory randomisation (Table 1, Table 2). There was no difference in the demographics of the group unavailable for analysis as compared to the study group for final analysis.

Significant differences for bladder perforation favoured the TO route, 7 (8.5) vs 0 ($p < 0.05$), peri-op blood loss 63.7 (41.4) TVT vs 48.7 (31.2) Monarc $p < 0.05$, and op time 18.5 (6.5) TVT vs 14.6 (6.0) Monarc ($p < 0.001$). One case of nerve entrapment occurred in the RP-SUS requiring release and one significant retropubic haematoma.

UDSI was cured or significantly improved equally for the TVT 65 (79.3) and Monarc group 49 (84.5) ($p = 0.51$). The same held true for symptoms of stress incontinence $p = 0.77$, OAB ($p = 0.67$), voiding function ($p = 0.65$), and satisfaction 85.4% TVT vs 84.2% Monarc ($p = 0.66$). There was a significant improvement in Quality of Life scores (QoL) in both groups, but with no significant difference between groups ($p = 0.35$).

Variable	TVT	TO	p-value
AGE	53.6 (12.1)	54.2 (11.4)	0.77
BMI	28.4 (5.4)	28.5 (5.8)	0.88
PARITY	2.7 (1.4)	2.9 (1.1)	0.45
DURATION FOLLOW UP	12.0 (3.8)	11.2 (3.6)	0.22
Ba pre-OP (POP-Q)	-1.5 (2.1)	-1.9 (1.4)	0.20

Table 1. Demographic data for both study groups. Standard deviation shown in brackets.

Variable	TVT	TO	p-value
Postmenopausal	44 (53.5)	31 (53.4)	0.68
Vaginal Oestrogens	23 (28)	14 (24.1)	0.70
Previous hysterectomy	33 (40.2)	13 (23.2)	0.05
Previous incontinence op	5 (6.1)	1 (1.17)	0.41
Previous prolapse repair	7 (8.6)	4 (6.9)	0.76

Table 2. Comparison of pre-operative treatments.

Variable	All	TVT	MONARC	p-value
Bladder perforation		7 (8.5)	0	< 0.05
Urethral perforation		0	1 (1.7)	0.42
UTI		11 (13.4)	9 (15.5)	0.81
Return to theatre		3 (3.7)	1 (1.7)	0.64
Urinary retention		14 (17.1)	5 (8.6)	0.21
Nerve entrapment		1 (1.5)	0	0.53
RP Haematoma		1 (1.5)	0	0.53

Table 3. Comparison of immediate and short term operative complications.

Interpretation of results

The the close proximity of the bladder anatomically, with the retro-pubic procedure appears to endanger the bladder. In addition the extra blood loss encountered may be as a result of the dorsal veins of the clitoris which run just behind the pubic rami, making them susceptible to injury. Final outcome does not seem to be altered however.

Concluding message

Both techniques appear to be safe with respect to major complications, although as these are rare events, this needs to be interpreted with caution. However the hypothesis with regards to bladder injury holds true. There were no significant differences between outcomes for stress incontinence between the two groups at 3 months. Further follow-up is planned at one year and then two years to study the long term side effects of both techniques together with cure, and satisfaction. The relative role of each technique in anti-incontinence procedures needs further assessment.

¹ Ward, K. and P. Hilton (2001). "A randomized trial of colposuspension and TVT for primary genuine stress incontinence - 2 yr follow-up." *Int Urogynecol J Pelvic Floor Dysfunct* **12**: S7.

² Holmgren, C., S. Nilsson, et al. (2005). "Long-term results with tension-free vaginal tape on mixed and stress urinary incontinence." *Obstet Gynecol* **106**(1): 38-43.

³ Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. *Prog Urol* 2001; **11**: 1306-1313.

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Townsville Hospital and followed the Declaration of Helsinki Informed consent was obtained from the patients.