558

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EVALUATION OF TRANSOBTURATOR TAPES IN MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE WITH VERSUS WITHOUT CONCOMITANT PROLAPSE REPAIR AT 1 YEAR FOLLOW-UP.

Hypothesis / aims of study
To assess the efficacy of transobturator tension-free vaginal tapes (TO-TVT) in the management of symptomatic female stress urinary incontinence (SUI) when associated with concomitant pelvic organ prolapse (POP) repair as regards:
- Patient reported & objective cure rates at 12month.
- Quality of life and Sexual function

Study design, materials and methods
A prospective study of 133 women who underwent TO-TVT with concomitant POP repair in the period between April2005 and April2007 (study group). Outcomes were compared to 299 women who underwent TO-TVT as a sole procedure in the same time period within the same institution with the same inclusion and exclusion criteria (control group). The inclusion criteria included women with failed or declined pelvic floor muscle training (PFMT), pre-operative urodynamic SUI or mixed incontinence (MUI) with predominantly bothersome SUI symptoms (self-reported), symptomatic prolapse and SUI. Pre-operative assessment included: urodynamic assessment, completion of validated symptom severity and quality of life (QOL) questionnaires; King's Health Questionnaire (KHQ) & Pelvic Organ Prolapse/ Incontinence Sexual Function Questionnaire (PISQ-12). An independent clinician performed the 12-month follow-up. Primary outcome was the patient-reported success rate for SUI on Patient Global Impression of Improvement Questionnaire- PGI-I; defined as "Very Much Improved/ Much Improved". Secondary outcomes included impact on women's QOL and peri-operative complications. Multivariate regression model was used to assess potential risk factors for failure of TO-TVT with concomitant POP repair including the TO-TVT surgical approach used outside-in versus inside-out.

Results
121 women (91%) completed 12month follow-up; patient-reported success rates for TO-TVT with and without concomitant POP repair were 61% and 79.5% at 12 month respectively; p<0.001 OR 2.995 95%CI 1.690, 5.307 (Table 1). 28 women declined to attend for pad test; 77% (n=72/93) had negative ICS 1-hour pad test at 12 month which was significantly lower than 91% (n= 210/230) in the control group (p= 0.0013, OR 0.112 95%CI 1.57, 5.975). Analysis of KHQ showed median (IQR) postoperative KHQ improvement of 27.5 (-1.7, 43.2) points versus 35.1 (16.4, 53.1) in the study and control groups (Table 1) respectively (p=0.001). Multivariate regression analysis showed BMI>30kg/m^2 (p=0.017, OR0.932 95%CI 0.879, 0.987) and previous continence surgery (p=0.001, OR0.324 95%CI 0.164, 0.638) to be independent risk factors of failure of TO-TVT with concomitant POP repair (Table 2). Results of prolapse surgery in the study group were comparable to the current literature (Table 3).

Interpretation of results
Concomitant surgical treatment of SUI and POP are often required. This cohort in this study represents a "real-world clinical setting" far from the experimental setting of RCTs. Our study shows a significantly lower patient-reported & objective success for TO-TVT in surgical treatment of SUI when associated with POP repair compared to TO-TVT as a sole procedure (61% vs. 79.5% at 12month follow-up respectively). The reasons for this apparently lower efficacy are unclear; regardless of the timing of TO-TVT insertion i.e. before/after POP repair, the surgeons always adjusted the tape after correction of prolapse and once the final axis for the vagina was established. Neither the tape material nor route of TO-TVT seemed to have a significant effect on the success rates. The procedures were all carried out by surgeons who are experienced in both SUI/POP surgical treatments. Our results of prolapse surgery in the study group were comparable to the current literature with only one woman had a repeat surgery in same compartment within the study period (12 month). On multivariate analysis, only increased BMI and previous continence surgery were independent risk factors for the lower success rate associated with TO-TVT when associated with POP repair. Unlike some other studies in the literature we only included women with symptomatic SUI; inclusion of women with occult SUI may partially account for higher success rates previously reported.

Concluding message
Transobturator tension free vaginal tapes are associated with significantly lower patient-reported success rates in management of symptomatic female stress urinary incontinence when associated with concomitant POP repair.

Table 1: Patient-reported Outcomes

Characteristics	Group		p	95% CI (if applicable)
	Control Group (n= 299)	Study GROUP (n=121)		
PGI-I, n (%)			**<0.001**	
Failure	60 (20.5)	47 (38.8)		
Success	232 (79.5)	74(61.2)		
Median improvement in KHQ Domains (quartiles)				
General Health	0 (0,0)	0 (-25,0)	**<0.001**	
Incontinence Impact	66.7 (33.3, 100)	33.3 (0, 66.7)	**0.001**	
Role Limitation	50 (16.7, 83.3)	33.3, (0, 66.7)	**0.012**	
Physical Limitation	50 (16.7, 66.7)	33.3, (0, 66.7)	**0.005**	
Social Limitation	22.2 (11.1, 55.6)	11.1 (11.1, 55.6)	**0.021**	
Personal Relation	1 (0, 33.3)	16.7 (0,66.7)	0.199	
Emotions	33.3 (11.1, 66.7)	22.2 (-11.1, 50.0)	**<0.001**	
Sleep/ Energy	16.7 (0, 50)	16.7 (-16.7, 33.3)	**0.002**	
Severity Measures	50 (16.7, 66.7)	33.3 (-8.3, 58.3)	**<0.001**	
Average KHQ	35.1 (16.4, 53.1)	27.5 (-1.7, 43.2)	**0.001**	
Mean improvement in PISQ12 score (SD)	4.9 (7.1)	6.5 (6.0)	**0.082**	-1.6 (-3.4, 0.2)

Table 2: Logistic Regression For Primary Outcome – PGI-I[*];

	Odds Ratio (95% CI)	p value
TO-TVT with prolapse repair	2.995 (1.690, 5.307)	**<0.001**
Age	1.003 (0.979, 1.028)	0.817
BMI	1.073 (1.013, 1.137)	**0.017**
Parity	0.937 (0.754, 1.165)	0.558
Pre-MUCP > 30	1.532 (0.794, 2.959)	0.204
Mixed Urinary Incontinence	1.132 (0.625, 2.049)	0.683
Type of TO-TVT Performed	1.382 (0.809, 2.361)	0.236
Previous Continence surgery	3.091 (1.567, 6.097)	**0.001**

Table 3: Pre & Postoperative (6 Month) Staging Of Prolapse

Number of patients	n= 112
Preoperative Stage/ Grade Of Prolapse	
B/W grade 4 / POP-Q IV	27 (24%)
B/W grade 3 / POP-Q III	52 (46%)
B/W grade 2 / POP-Q II	34 (30%)
Postoperative Stage/ Grade in Same Compartment	
B/W grade 4 / POP-Q IV	1 (1%)
B/W grade 3 / POP-Q III	1 (1%)
B/W grade 2 / POP-Q II	14 (12%)
B/W grade 1 / POP-Q I or less	96 (86%)

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**South Glasgow Research Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**