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IMPACT OF TRANSOBTURATOR TENSION FREE VAGINAL TAPES ON QUALITY OF LIFE AND SEXUAL FUNCTION IN WOMEN WITH MIXED URINARY INCONTINENCE.

Hypothesis / aims of study
To assess the efficacy and impact on quality of life and sexual function of transobturator tapes in the management of women with mixed urodynamics stress incontinence (USI) and detrusor overactivity (DO).

Study design, materials and methods
341 women, in the period between April 2005 and April 2007, were prospectively randomised to "inside-out" TVT-O (n=170) and the "outside-in" TOT-ARIS (n=171). All women had pre-operative urodynamics diagnosis of USI or mixed incontinence (with predominant SI) and failed/ declined pelvic floor muscle training. Women were excluded if they had concomitant surgery or prolapse (POP-Q≥ stage 2), un-controlled overactive bladder symptoms or specific co- morbidities e.g. multiple sclerosis and diabetes. 83 women (24%) had pre-operative urodynamics diagnosis of mixed USI & DO and are the basis of this study. Preoperative assessment included detailed history & examination, urodynamics assessment and completion of validated questionnaires: Birmingham Bowel Urinary Questionnaire (BBUQ-22), King's Health Questionnaire (KHQ) & Pelvic Organ Prolapse/ Incontinence Sexual Function Questionnaire (PISQ-12). At 12 month follow-up the same assessment was repeated by an independent clinician except for the urodynamics being replaced with standard ICS 1-hour pad test, Patient Global Impression of Improvement (PGI-I) and the International consultation on Incontinence Questionnaire (ICIQ-SF) were also completed. The primary outcome was the "patient-reported success" assessed by PGI-I as "Very Much Improved or Much Improved". Secondary outcomes were: Objective cure defined as negative pad test (≤1gm gain), Improvement in total KHQ scores (≥ 10%) and Impact on women sexual life as expressed by improvement in PISQ-12 total score. We also compared the "outside-in" vs. "inside-out" transobturator tapes. Statistical analyses with performed using SPSS version17, (SPSS, Chicago, IL, USA). Descriptive analysis is given. Categorical variables tested with Chi-square test and fisher's exact test for the two independent variables. Wilcoxon tests were used to test differences in scores pre to post-operation. Mann-Whitney tests used to compare between different groups. Factors associated with failure were assessed in a multivariate model. All statistical tests evaluated a significance level of 5%.

Results
83 women had pre-operative urodynamics diagnosis of mixed USI & DO; 77 women (93%) completed the 12 month follow-up and 68 women (82%) undertook the pad test. Table 1 shows the patient reported and objective success at 12-month (75% and 90.5% respectively). These results were not significantly different from women undergoing transobturator tapes as primary surgery: (75% vs. 81%, p=0.306 and 90.5% vs. 91.6%, p=0.784 respectively). In Table 2, with exception of General Health, all domains of KHQ and the total score showed clinically significant improvement (≥10 point improvement) following transobturator tapes. Similarly, total PISQ-12 showed significant improvement postoperatively (Table 3). On multivariate analysis; none of the tested variables proved to be an independent risk factor of failure of transobturator tapes in women with mixed incontinence. Comparing the inside-out & outside-in routes there were no significant differences in the patient reported success rates, objective success rates, improvement in quality of life or sexual function between the 2 groups.

Interpretation of results
These results are important in counselling women undergoing transobturator tapes being one of the largest reported studies on women with urodynamics diagnosis of mixed urinary incontinence. The findings of in-significant differences in the success rates between women with pre-operative USI versus those with MUI can be of high clinical significance in avoidance of pre-operative urodynamics investigations in women with pre-dominant symptoms of stress incontinence. However these findings need to be tested a larger adequately powered study. Additional strengths for this study are the prospective design and having an independent clinician performing the follow-up. It is important to note that the study was not powered to detect a significant difference between various transobturator routes (inside-out vs. outside-in).

Concluding message
Transobturator tapes have a good patient reported and objective cure rates at 12 month follow-up in women with with mixed urodynamics stress incontinence (USI) and detrusor overactivity (DO) with no significant difference from women with USI only. Majority of women showed significant improvement in their quality of life after the operation.

Table 1: Objective & Patient reported Success rates for the whole cohort & comparing Outside-in vs. Inside-out routes

	Total	**Outside-In ARIS**	**Inside-Out TVT-O**	**OR (95% CI)**	**P =**
	Success (%)	**Success (%)**	**Success (%)**		
PGI**	56/75 (74.7%)	31 (75.6%)	25 (73.5%)	0.9 (0.316 , 2.544)	0.900
	Cured (%)	**Cured (%)**	**Cured (%)**		
Standard ICS 1 hour pad test *	57/63 (90.5%)	31 (86.1%)	25 (73.5%)	4.19 (0.460 , 38.204)	0.203

	Success (%)	Success (%)	Success (%)		
Satisfaction Scale* **	54/72 (75.0%)	32(80.0%)	22(68.8%)	0.6 (0.187 , 1.614)	0.280
ICIQ-SF ♠	48/77 (62.3%)	26(61.9%)	22(62.9%)	1.0 (0.412 , 2.630)	0.930

♦ Cure = Negative Standard ICS Pad Test
** Success = "Very Much Improved or Much Improved"
***Success = Score ≥ 8/10
♠ Success = "Never leaked" or "Leak few drops once or less/ week"
*P is Significant <0.05

Table 2: King Health Questionnaire (KHQ) scores before & after transobturator tapes & comparing Outside-in vs. Inside-out routes

KHQ Variable	Median Difference (Pre-post)	p-value	Approx. 95% CI	Median Difference (ARIS-TVT-O)	p-value	Approx. 95% CI
General Health	0	0.608	(0.0, 0.0)	0	0.240	(0.00, 0.00)
Incontinence Impact	50	<0.001*	(33.3, 50.0)	0	0.812	(-33.33,33.32)
Role limitation	50	<0.001*	(41.7, 58.3)	0	0.515	(-33.35,16.66)
Physical limitation	41.67	<0.001*	(33.3, 50.0)	0	0.588	(-16.67, 16.67)
Social limitation	33.33	<0.001*	(22.2, 38.9)	0	0.943	(-22.22, 22.21)
Personal relations	16.67	0.001*	(0.5, 25.7)	0	0.367	(-33.34, 0.00)
Sleep/energy	25	<0.001*	(16.9, 33.3)	0	0.768	(-16.68, 16.66)
Severity measures	37.50	<0.001*	(33.345.8)	-8.33	0.198	(-25.00, 8.33)
Total KHQ Score	32.56	<0.001*	(25.6, 39.7)	-3.12	0.577	(-17.79, 10.45)

*P is Significant <0.05

Table 3: Prolapse/ Incontinence Sexual Function Questionnaire (PISQ-12) scores before and after transobturator tape & comparing Outside-in vs. Inside-out routes.

PISQ-12 Variable	Median Difference (Post-pre)	p-value	Approx. 95% CI	Median Difference (ARIS-TVT-O)	p-value	Approx. 95% CI
Frequency of sexual desire	0	0.822	(-0.5, 0.5)	1	0.194	(0.00,1.00)
Climax	0	0.904	(-0.5, 0.5)	0	0.515	(0.00,1.00)
Sexually excited	0	0.364	(0.0, 0.5)	1	0.100	(0.00,1.00)
Variety of activities	0	0.323	(0.0, 0.5)	0	0.608	(0.00,1.00)
Pain	0	0.022	(0.0, 0.5)	0	0.774	(-1.00,1.00)
Coital incontinence.	1.5	<0.001*	(1.0, 2.0)	0	0.956	(-1.00,1.00)
Fear of incontinence.	1.5	<0.001*	(1.0, 2.0)	0	0.534	(-1.00,1.00)
Avoid Sexual Intercourse	1	<0.001*	(0.5, 1.5)	0	0.838	(-1.00,1.00)
Negative emotions	1	<0.001*	(0.0, 1.0)	0	0.571	(-1.00,1.00)
Erectile dysfunction.	0	1.000	(-0.5, 0.0)	0	0.606	(-1.00,0.00)
Premature ejaculation	0	0.100	(0.0, 0.5)	0	0.567	(0.00, 0.00)
Intensity of orgasms	1	0.004	(0.5, 1.0)	1	0.073	(0.00, 1.99)
Total score	5	0.003*	(2.0, 8.0)	-5	0.193	(-9.99,2.00)

*P is Significant <0.05

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**

Specify Name of Public Registry, Registration Number	**www.clinicaltrial.gov**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**West of Scotland Research Ethics Committee** **Address: 1st floor Tennent Institute 38ChrchStreet Glasgow G11 6NT**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**