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EVALUATION OF TRANSOBTURATOR TENSION FREE VAGINAL TAPES IN MANAGEMENT OF WOMEN WITH STRESS URINARY INCONTINENCE AND PREVIOUS FAILED INCONTINENCE SURGERY.

Hypothesis / aims of study: To assess the efficacy of transobturator tapes in the management of women with urodynamic stress incontinence (USI) following one or more previous incontinence surgery at 1 year follow-up.

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 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 such as multiple sclerosis and diabetes.

46 women had one or more previous incontinence surgery 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). 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: 46 women had previous continence surgery; colposuspension (n=15), retro-pubic TVT (n=15), transobturator tapes (n=11), both Colposuspension and a sub-urethral tape (n=5). All 46 women completed the 12 month follow-up though 12 declined to undertake the pad test. Table 1 shows the patient reported and objective success at 12-month (68% and 77% respectively). These results were significantly different from women undergoing transobturator tapes as primary surgery: (68% vs. 82%, p=0.048 and 77% vs. 94%, p=0.003 respectively). With exception of "General Health", all domains of KHQ and the total score showed statistically & clinically significant improvement (≥10 point improvement - Table 2) following transobturator tapes. Similarly the total PISQ-12 scores showed significant improvement (Table 3). On multivariate analysis of various risk factors; MUCP <30cmH_2O was the only independent risk factor of failure (P= 0.016, OR 9.206 95%CI 1.511, 56.104). Comparing the inside-out & outside-in routes there were no significant differences in the patient reported outcomes, improvement in quality of life or sexual function, However significantly more women in the inside-out route had negative postoperative pad test.

Interpretation of results: These results are important in counselling women undergoing transobturator tapes being one of the largest reported studies on women with previous failed incontinence surgery. Additional strengths for this study are the prospective design and having an independent clinician performing the follow-up. The results though have to be interpreted cautiously due to the relatively small cohort to detect a significant difference between various transobturator routes (inside-out vs. outside-in). The authors have stopped offering transobturator tapes to women with previous failed surgery and low MUCP.

Concluding message: Transobturator tapes have acceptable patient reported and objective cure rates at 12 month follow-up in women with previous failed incontinence surgery though significantly lower than primary surgery. Majority of women showed significant improvement in their quality of life after the operation. MUCP <30cmH_2O was the only independent predictor for failure.

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**	30/44 (68.25)	8/16 (50)	22/28 (78.6)	3.667(0.967, 13.897)	0.105
	Cured (%)	**Cured (%)**	**Cured (%)**		
Standard ICS 1 hour pad test ♦	26/34 (76.5)	7/12 (58.3)	19/22 (86.4)	0.221(0.041, 1.178)	0.07*
	Success	**Success**	**Success**		

	(%)	(%)	(%)		
Satisfaction Scale* **	31/43 (72.1)	10 (62.5)	21 (77.8)	0.476(0.122, 1.854)	0.285
ICIQ-SF ♠	30/46 (65.2)	9 (52.90	21(72.4)	0.429(0.122, 1.50)	0.309

♦ 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	0.855	(0.0, 12.5)	0	0.28	(-24.99,-0.00)
Incontinence Impact	50	<0.001*	(33.3, 66.7)	0	0.832	(-33.33,33.34)
Role limitation	50	<0.001*	(33.3, 58.3)	0	0.695	(-33.35,16.68)
Physical limitation	50	<0.001*	(33.3, 58.3)	0	0.854	(-33.33,16.66)
Social limitation	33.33	<0.001*	(22.2, 50.0)	-11.11	0.39	(-33.33,11.11)
Personal relations	20.67	0.001*	(3.2, 36.5)	0	0.534	(-33.33,33.32)
Sleep/energy	16.67	0.001*	(8.3, 33.3)	-16.67	0.44	(-33.33,16.66)
Severity measures	41.67	<0.001*	(29.2, 54.2)	-16.67	0.222	(-33.33,8.33)
Total KHQ Score	34.79	<0.001*	(25.8, 43.5)	-7.72	0.369	(-23.93,12.65)

*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	0.706	(0.0, 0.5)	0	1	(-1.00,1.00)
Climax	0	0.636	(-0.5, 0.5)	0	0.439	(-1.00,1.00)
Sexually excitation	0	0.683	(-0.5, 0.5)	0	0.349	(-0.00,1.00)
Variety of activities	0	0.293	(0.0, 0.5)	0	0.677	(-1.00,1.00)
Pain During Intercourse	0	0.977	(-0.5, 0.5)	0	0.983	(-1.00,1.00)
Coital incontinence	1.5	<0.001*	(1.0, 2.0)	0	0.482	(-1.99,0.99)
Fear of incontinence	1	0.001*	(0.5, 1.5)	0	0.709	(-1.00,1.00)
Avoid Sexual Intercourse	0.5	0.038*	(0.0, 1.0)	0	0.255	(-2.00,0.00)
Negative emotions	0.5	0.012*	(0.0, 1.0)	0	0.325	(-2.00,-0.00)
Erectile dysfunction.	0	0.386	(-0.5, 0.0)	0	0.145	(-1.00,0.00)
Premature ejaculation	0	0.361	(0.0, 0.0)	0	0.871	(0.00, 0.00)
Intensity of orgasms	0.5	0.094	(0.0, 1.0)	0	0.413	(-1.00,0.00)
Total score	5	0.003*	(2.0, 8.0)	-5	0.193	(-9.99,2.00)

*P is Significant <0.05

Specify source of funding or grant	**The study has funded by a grant from the Henry Smith Charity.** **Address:** **6th floor** **65Leadenhall Street,** **London** **EC3A 2AD** **Regestered Charity Number: 230102.**
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.clinical trials.com**
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** **38Church Street** **Glasgow** **G11 6NT**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**