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# DO TRANSOBTURATOR TENSION FREE VAGINAL TAPE PROCEDURES IMPROVE LONG-TERM VOIDING FUNCTION?

**Hypothesis/ Aims of study:**
To compare the pre-operative and 12 month post-operative voiding function in women undergoing transobturator tapes for management of stress urinary incontinence. Also we aim to identify independent risk factors for long-term postoperative voiding difficulties.

**Study design, materials and methods:**
Data was prospectively collected and available for 299 women who underwent transobturator tapes in a tertiary referral centre in Scotland in the period between April 2005 & April 2007 and completed 12 month follow-up. All women underwent transobturator tension free vaginal tape as a sole procedure and as originally described using TVT-O™ (Ethicon Inc., Somerville, NJ, USA) for the Inside-out approach and TOT – ARIS (Coloplast Corp., Minneapolis, MN, USA) for the Outside-in approach under general anaesthesia. L women underwent pre-operative urodynamics assessment including free uroflowmetry and completed validated symptom severity questionnaire (Birmingham Bowel Urinary Questionnaire – BBUQ-22). 12 month follow-up was performed by an independent clinician; patients underwent standard ICS 1 hour pad test, uroflowmtery and residual urine volume assessment using a urethral catheter. In addition they re-completed the BBUQ-22.

Preoperative and postoperative group comparisons of five voiding function variables including voided volume, residual volume, voiding time, Q-max and Q-average rates and (Q-max and Q-average centiles) were carried out using Wilcoxon test. Significance level was set at 5%. Linear regression analysis was carried out to adjust for age, parity, HRT, BMI, and previous incontinence procedure. Statistical Analysis was performed using SPSS (version 17).

**Results:**
299 women completed the 12 month follow-up; 69 women (23%) declined to perform either standard ICS pad test and/or uroflowmetry at 12 month follow-up, while further 35 women (12%) had uroflowmetry (either pre or postoperative) which was deemed in valid due to a voided volume <100mls. Complete set of data was available for 195 women (65%) and would form the basis for this analysis; the mean (SD) age was 51.1 (10.4) years and the mean (SD) of BMI was 28.2 (4.5) while the median (IQR) parity was 2(2-3). 14.4% of patients were using HRT. Preoperative urodynamics revealed urodynamics stress incontinence in 136 patients and mixed incontinence in 59 patients. 20 patients had a history of a previous incontinence procedure, 63 patients had either a previous anterior pelvic floor repair or a previous hysterectomy.

One woman was on CISC (0.5%) at follow-up while 7.7% of women had subjective symptoms of incomplete bladder emptying and weak urinary flow at 12 month follow-up compared to 21.4% pre-operatively $p<0.001$, OR (95%CI) = 1.028 (1.767, 6.058). There was a statistically significant increase in the residual urine volume, significant reduction in the voided volume and the voiding time at 12 month postoperatively whereas Q-max and Q-average flow rates/ centiles had no significant change (Table 1). Using linear regression to adjust for age, parity, BMI, HRT use, and prior incontinence procedure, it was found that nulliparous women were at risk of a prolonged voiding time while HRT users and women with a failed prior incontinence procedure had a shorter voiding time postoperatively.

**Interpretation of Results:**
These results indicate a low rate of patient reported postoperative voiding difficulties at 1 year following transobturator tapes which was statically and clinically significant compared to pre-operative voiding difficulties rates. Uroflowmetry has been always considered as a non-invasive urodynamics test for voiding difficulties in both males and females. The voiding time and voided volumes can vary significantly between various voids in the same person and therefore the statistically significant changes seen above are unlikely to be of clinical significance where as the Q-max & Q-ave have been shown in various studies to be relatively reliable measure of voiding function. It was reassuring to show that there were no statistically significant differences between the pre-operative Q-max & Q-ave rates and centiles. The post voiding residual urine volume has significantly increased following the transobturator tapes operation however the mean difference was 35 mls (median difference = 24 mls) which are unlikely to be clinically significant except in cases of pre-operative borderline and high residual urine volume.

One of the limitations of this study was the relatively large number of women declining uroflowmetry at 1-year follow-up and those with low voided volume and consequently invalid uroflowmetry. Nevertheless, the remaining cohort was large (n=195) compared to other relevant studies in the literature. This study has a number of strengths being prospective and the follow-up was done by an independent clinician which helps reducing the doctor –patient relationship bias.

The results of this study are reassuring that women's voiding function is likely to improve following transobtuaror tapes. This is important in pre-operative women counselling, patient selection and sheds more light on the long-term safety of these procedures.

**Concluding message:**

Significantly lower number of women reported voiding difficulties at 1 year following transobturator tapes. Long-term voiding difficulties occur in 0.5%. Significant changes occurred on postoperative uroflowmetry parameters however unlikely to be of clinical significance.

**Table 1: Comparison of Pre and Postoperative Uroflowmetry Parameters**

| | Mean (SD) | Median (IQR) | Wilcoxon Test♦ | Adjusted p-value (Post op - Pre op) | Odds ratio | Confidence interval |
|---|---|---|---|---|---|---|
| (years) | 51.02(10.46) | | | | | |
| ty | | 2.00 (2.00-3.00) | | 0.014 | 2.47* | (9.53-85.32) |
| | 28.25(4.51) | | | | | |
| vious incontinence surgery | | | | 0.003 | -2.98* | (-58.60--11.97) |
| | | | | | | |
| -op. peak flow rate ml/s (Q-max) | 22.49 (10.70) | 21.00( 15.75- 27.25) | | | | |
| -op. Residual urine volume (mls) | 15.16 (40.52) | 5.00 (0-15) | | | | |
| -op. voided urine volume (mls) | 277.0 (141.81) | 257(175-399.25) | | | | |
| -op. average flow rate ml/s (Q- ) | 12.06 (6.38) | 11 (8-14.25) | | | | |
| -op. voiding time seconds | 41.97 (52.62) | 30.50(18-48) | | | | |
| | | | | | | |
| month Peak flow rate ml/s (Q- ) | 21.00 (11.19) | 19.00(13.00-26.00) | | | | |
| month Residual urine volume s) | 51.82 (68.41) | 29.5(0.00-73.00) | 0.0001 | | | |
| month Voided urine volume | 244.3(162.22) | 212.00 (115.00-347.00) | p<0.016 | | | |
| month Average flow rate ml/s (Q- ) | 12.65 (18.86) | 10.00 (6.5-14.00) | | | | |
| month Voiding time (sec) | 27.16 (14.12) | 23.50(17.00-35.00) | p <0.0001 | | | |

♦ Wilcoxon Test Unadjusted p-value (Post op compared to Pre op)


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|---|---|
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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.clinicaltrials.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**<br>**Address:**<br>**1st floor**<br>**Tennent Institute**<br>**38ChrchStreet**<br>**Glasgow**<br>**G11 6NT** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |