

EVALUATION OF THE IMPACT OF THE TRANSOBTURATOR TAPE PROCEDURE ON FEMALE VOIDING FUNCTION

Hypothesis / aims of study

Voiding difficulty (VD) is a recognised complication following surgery for stress urinary incontinence (SUI). It has been suggested that the trans-obturator tape (TOT) approach may be associated with a lower rate of VD compared to TVT, but there is currently a paucity of data to support this claim. The aim of our study was to evaluate the impact of the TOT on female voiding function (VF) using accepted definitions and appropriate subjective and objective parameters.

Study design, materials and methods

Women with urodynamically confirmed SUI, without demonstrable detrusor overactivity, significant prolapse (\leq grade 2), recurrent cystitis, or neuropathic bladder were recruited. TOT placement was performed according to a standard protocol under local anaesthesia and sedation. 200ml of normal saline was left in the bladder to facilitate early voiding. Time to first void, volume of first void and post-void residual (PVR) were recorded. Pre- and 6-week post-operative assessment included completion of UDI-6, 1-hr pad test, urethral pressure profilometry (UPP), uroflowmetry, and measurement of PVR. Six, 12, and 24-month follow-ups were identical but omitted UPP.

Results

80 women were recruited. Median age 55(IQR 51-62)yrs, parity 3(IQR 1-3) and BMI 28(IQR 25-32)kg.m⁻². Post-operatively, 34% had a PVR>150ml at first void. 6% had an unsatisfactory trial of void (TOV), and were catheterized for a mean duration of 16(R 12-32)hrs, after which they all had a successful TOV. Pre-operatively, the median pad loss was 23(IQR 4-78)g and decreased at follow-up visits to (0.4-0.6g) up to 24 months. UDI-6 scores were also reduced post-operatively for all visits. Scores for question 5(Q5) of UDI-6, which evaluates VD, were unchanged following surgery up to 24 months. Pre-operatively, 29% had symptoms of VD. Some had >1 symptom (Table1). There was a significant improvement in symptoms of VD following surgery (incomplete emptying and double voiding).

Table 1. Symptoms of voiding difficulty

	Pre-op	6 w	6 m	12 m	24 m
No of patients	80	73	53	44	24
Strain to void	6	5	1	3	0
Poor stream	9	6	1	4	0
Incomplete emptying	17	5*	3*	2*	0**
Double voids	11	3**	3	3	0
Post-micturition dribbling	6	2	0	1	0

*p<0.01, **p<0.05 (Chi-square test)

Pre-operative voiding cystometry parameters were within normal limits and were not influenced by either age or BMI. Correlation of pre-operative voiding cystometry parameters to UPP demonstrated a relationship between tQmax, mean MUCP(0.26) and maximum FUL(0.24) (p<0.05, Spearman's test). MUCP and mean MUCP values also correlated with tvoid (r = 0.30 and 0.32, p = 0.02 and 0.01), tflow (r=0.29, 0.31;p=0.02, 0.01), and PdetQmax (r=0.30, 0.32; p=0.02, 0.01).

Uroflowmetry results were analysed using a PVR of <150mls and the Liverpool Nomograms (LN)(Table2). At pre-operative uroflowmetry, more than half had voided volumes(vvol) of >150ml. Flow analysis was normal, pre- and post-surgery, using Qmax>15ml/sec and PVR<150ml. On LN, the majority had normal flow. When post-operative and pre-operative data were correlated there was no significant change (Chi squared test).

Table 2. Uroflowmetry values using voided volume value of 150ml & Liverpool Nomogram

Parameter	Pre-op	6 weeks	6 months	12 months	24 months
N	80	73	53	44	22
Uroflowmetry*	69	71	47	39	19
Uroflowmetry values in patients with voided volume of >150ml					
N	37(54%)	59(83%)	39(83%)	27(61%)	17(89%)
▪ Qmax(ml/sec)†	28(22-36)	24(18-33)	32(19-40)	27(19-34)	25(15-29)
▪ Res (ml)†	10 (0-26)	10 (0-40)	11 (0-52)	10 (0-32)	0 (0-20)
Liverpool Nomogram					
Normal flow**	52(75%)	51(72%)	35(74%)	26(67%)	14(74%)

†median values(IQR), p< 0.05(Kendall's tau b=0.235),**chi-square test, p ≤ 0.05

Interpretation of results

After TOT placement, objective and subjective data demonstrated significant improvements in incontinence symptoms and urinary loss including symptomatic cure and reduction in 1-hr pad loss. The UDI-6 showed improvement in total scores suggesting satisfaction with surgery and improvement in QoL. Symptom screening included straining to void, poor stream, incomplete emptying, double voiding, and post-micturition dribbling. Based on these symptoms, 29% had VD pre-operatively. However, using Q5 of UDI-6 none of the patients experienced pre-operative VD. Pre-operative urodynamics (voiding cystometry and uroflowmetry values) demonstrated no evidence of VD. Urodynamic values also correlated with data obtained from UDI-6 but not with information collected from direct patient interviews. Based on our findings it would seem that symptoms of VD alone are a poor indicator of VD.

Using a validated QoL questionnaire (UDI-6) appears to be a more reliable way of eliciting symptoms of VD. There was a significant correlation between Q5 of UDI-6 and PVR (<150ml) ($p<0.01$) for all visits. Using chi-test, there was also a significant correlation between Q5 and Qmax during the pre-operative, 6mths($p<0.01$) and 12mths($p<0.01$) follow-up. Published data regarding VD after TOT is scarce. This is the first study in large numbers with long term follow-up to look at VF following TOT. We evaluated VF using symptoms and urodynamic parameters pre- and post-TOT. There was no deterioration of VD based on symptoms. Scores from Q5 of UDI-6 showed no change at follow-up. Symptoms of double voiding and sensation of incomplete emptying statistically improved at short and long-term follow-up. Other studies have reported up to a 46% rate of VD post-TOT based on symptoms alone (ref) these were confirmed objectively in only 4.8%. In our study, although there was a statistically significant decrease in Qmax at 6 weeks, this was normal (24ml/sec) and not clinically significant. At long-term follow-up, Qmax and PVR remained normal. Using the LNs there was no increase in the number of people with abnormal flow. These findings suggest that TOT does not alter VF. The rate of VD in this study for TOT is significantly lower compared to other series for TVT.

Concluding message

Symptoms of VD based on history are unreliable in women with USI. Other objective parameters such as UDI-6 or uroflowmetry are non-invasive and should be considered. The TOT is a safe and effective procedure for the treatment of USI with a low risk of VD.

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Audit Committee of St. George's Hospital Medical School
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes