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THE TRANS-OBTURATOR APPROACH FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI): EFFICACY AND MORBIDITY

Hypothesis / aims of study
This study evaluates long-term subjective and objective continence outcomes and morbidity following TOT. It also evaluates the impact of SUI and TOT on quality of life (QoL) using validated questionnaires.

Study design, materials and methods
Patients with urodynamically-proven SUI, a stable bladder, and a ≤grade2 prolapse were recruited. Pre- and post-operatively, uroflowmetry, measurement of post-void residual volume(PVR), 1-hour pad test and vaginal examination were performed. Patients were questioned pre- and post-TOT for presence of SUI, asked if they felt 'cured', 'improved' or 'not changed' by surgery, scored the degree of bother and severity using a visual analogue scale(VAS)(0-10) and the Stamey grading scale(1-3) and completed the short forms of the Urogenital Distress Inventory(UDI-6), Incontinence Impact Questionnaire(IIQ-7), International Consultation on Incontinence Questionnaire(ICIQ-SF), Abbreviated Sexual Function Questionnaire (ASFQ), and the Genitourinary Treatment Satisfaction Score(GUTSS).

TOT was placed using the outside-in technique with cystoscopy performed to exclude bladder/urethral injury. 300ml of normal saline was left in the bladder to facilitate an early trial of void (TOV). Patients were not catheterised post-operatively. A standard TOV was undertaken with voided volume (vvol) and PVR recorded.

Patients were followed-up at 6weeks, 6, 12, and 24months. Symptoms of SUI, vaginal/groin/thigh pain, vaginal discharge, voiding dysfunction, and dyspareunia were evaluated. Vaginal examination was performed to evaluate continence, tape exposure and vaginal/groin tenderness.

Results
84 women were recruited with median age 55(IQR 51-62)years, parity 2(IQR 2-3), and BMI 28(IQR 25-33)$kg•m^{-2}$. There was no correlation between severity of urinary loss using the pad test and age, parity, or BMI. Median operating time was 35(IQR 30-45)mins with median blood loss 25(IQR 20-50)mls. There were 3(4%) cases of vaginal perforation but no bladder perforation, bowel/urethral injury, or major haemorrhage. Median time to first void was 180(IQR75-240)min, voided volume (vvol) 250(IQR198-400)ml and PVR 54(IQR10-156)ml. Five(6%) patients had unsatisfactory TOV and were catheterised for 16(R12-32)hours. Repeat TOV was then successful.

The 1-hr pad test demonstrated a significant decrease in urinary loss post-TOT($p<0.05$). Subjective symptoms of SUI were significantly improved as reflected by the Stamey grading scale, VAS scores, and QoL questionnaires (Table 1). 73-81% of patients considered their condition 'improved' or 'cured'. There was a high satisfaction with the operation and care received as indicated by GUTSS scores. Three patients had persistent SUI which required further surgery. 39(46%) patients had symptoms of urinary urge incontinence (UUI) which improved post-operatively(Table 1). At 24months, only 5(14%) had persistent UUI. 5(14%) developed UUI post-operatively. The degree of bother was low [median VAS score 3(IQR 0-5)]. 80% of the patients were sexually active. None reported de novo dyspareunia at follow-up. There was no significant improvement in ASFQ scores post-operatively.

The most common complication was tape exposure 7(8%): 6/57 with ObTape® and 1/27 with Aris® (Table 3). There were no cases of groin/thigh pain or abscess formation/infection. There was no significant change in voiding function.

Table 1.Comparison of pre- and post-operative outcomes

	Pre-op	6 w	6 m	12 m	24 m
Patients attended (N)	84	81	59	54	37
Presence of SUI on symptoms and signs					
Based on history	84	8* (10%)	5*(8%)	7*(13%)	7*(19%)
Demonstrated on exam	39(46%)	1*(1%)	0*	0*	1*(3%)
Presence of UUI					
Based on history	39(46%)	15*(19%)	16*(27%)	21*(39%)	10*(27%)
Patient perception regarding treatment (Cured/ Improved/ No change)					
Cured		35(43%)	36(61%)	33(61%)	22(59%)
Improved		24(30%)	12(20%)	11(20%)	8(22%)
No change		3 (4%)	2 (3%)	2(4%)	2 (5%)
No answer		17(21%)	9(15%)	8(15%)	5(14%)
Stamey grading scale score	1 (IQR 1-2)	0* (IQR 0-1)	0* (IQR 0-1)	0* (IQR 0-1)	0* (IQR 0-1)
Visual analogue scale score	7 (IQR 5-8)	0* (IQR 0-0)	0* (IQR 0-0)	0* (IQR 0-0)	0* (IQR 0-0)

*statistically significant ($p<0.05$) when compared to pre-operative values
SUI=stress urinary incontinence; UUI=urinary urge incontinence

Table 2. Questionnaire scores pre- and post-placement of TOT

	Pre-op	6 w	6 m	12 m	24 m
Patients attended (N)	84	81	59	54	37
UDI-6†	50(34-67)	14(1-22)*	6(0-22)*	11(0-22)*	6(0-28)*
IIQ-7†	33(22-62)	0(0-14)*	0(0-5)*	0(0-11)*	0(0-5)*
ICIQ-SF†	14 (10-16)	3 (0-6)*	0 (0-4)*	1 (0-4)*	0 (0-6)*
GUTSS					
OS†		15 (14-16)	16 (14-16)	16 (14-16)	16 (15-16)
CS†		16 (14-16)	15 (14-16)	16 (14-16)	16 (15-16)
Total score		32 (28-32)	31 (28-32)	32 (28-32)	32 (30-32)

*p<0.05 when compared to pre-operative values using paired t-testing, †median score (IQR)

Table 1 Complications at the early (6 weeks) and late (>6weeks) post-operative period

N=84	6 w	6 m	12 m	24 m
Patients attended (n)	**81**	**59**	**54**	**37**
Tape erosion	4	2	1	0
Vaginal pain	1	0	0	0
Recurrent UTI	0	0	1	0

Interpretation of results

The severity of pre-operative SUI is not influenced by age, parity, or BMI. SUI has a moderate to severe impact on QoL with a significant improvement post-operatively. The TOT significantly improves the QoL in women with SUI at 6weeks, 6, 12, and 24months. TOT may improve UUI in patients who have mixed symptoms. Although post-operative UUI may occur, the risk is low and comparable to the TVT™. Its complication profile is different from TVT™. Intra-operative complications including bladder/urethral injury and major haemorrhage are significantly reduced compared to TVT™. The most common short and long-term complication is tape exposure. This may be asymptomatic and follow-up with vaginal examination is essential.

Concluding message

The TOT is an effective and safe continence procedure for the treatment of female SUI.

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**