

Long-term Outcomes of 100 Transobturator Tape Procedures

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Abstract

Aim

Satisfactory short-term outcomes of transobturator tapes (TOTs) are recognized, yet a lack of long-term data exists. We investigated long-term patient-reported outcomes of TOTs.

Methods

A retrospective review was performed of 100 female patients post TOT insertion by a single surgeon (2005-2010). Results and postoperative complications were identified. At long-term follow-up, patients completed ICIQ-Short Form, PGI-S and PGI-I questionnaires.

Results

Mean age was 51.7 years (33-75), mean follow-up 9.4 years (7.25 – 12.75). Clinically, 68/100(68%) had mixed and 32/100(32%) pure stress urinary incontinence (SUI). Short-term cure/significant improvement in SUI was seen in 98/100(98%). Grade >2 Clavien-Dindo complications occurred in 10/100(10%) within 6 months of surgery. Long-term questionnaire response rate was 76/100(76%). 62/76 (81.57%) described current urinary condition as “much” or “very much” “better.” No new complications emerged at long-term follow-up.

Conclusion

TOTs demonstrate high success rates in treatment of SUI, with no late-onset complications identified in our study. Recent concerns surrounding use of polypropylene tapes make reporting of long-term outcomes both desirable and necessary.

Keywords: Transobturator tape, Midurethral sling, stress urinary incontinence, long-term outcomes, PROMs

Introduction

Stress urinary incontinence (SUI), defined by the International Continence Society (ICS) as the involuntary leakage of urine on effort, exertion, coughing or sneezing,¹ has a reported mean prevalence of 48% in adult females,² and consistently demonstrates negative impact on quality of life.

Surgical management offers the best chance of SUI cure when conservative measures are ineffective. Relatively recent European and North American data showed mid-urethral slings (MUS) to have surpassed traditional incontinence procedures to become the most common surgery for SUI,^{3, 4} likely due to their minimally-invasive nature and comparable short-term efficacy.

However, as a 21st century technique, the MUS lacks long-term data. Some evidence suggests a decline in TOT efficacy with time.⁵⁻⁷ Furthermore, the safety profile of pelvic tapes/mesh has recently been questioned.^{8,9} A 2017 Cochrane review emphasised the need for reporting of longer-term data to “provide clarification regarding uncertainties about long-term effectiveness and adverse event profile.”¹⁰

We aimed to assess the long-term safety results and patient reported clinical outcomes of TOTs performed for patients with both stress and mixed urinary incontinence.

Methods

A retrospective review of 100 female patients who underwent transobturator MUS insertion over a 5-year period (2005-2010) was performed. All patients were assessed and operated on by a single surgeon. Transobturator tapes (TOTs) were offered to patients with stress incontinence (SUI) and stress-predominant mixed urinary incontinence, following failure of conservative measures. Routine preoperative work-up consisted of clinical assessment, flexible cystoscopy, stress test, uroflow, post-void residual measurement (PVR) and cystometrogram.

All patients were taught the technique of intermittent self-catheterisation (ISC) preoperatively. Transobturator tapes were inserted via an outside-in approach. The Monarc[®] subfascial hammock (AMS) was the tape of choice during the study period.

Postoperatively, PVRs were measured. Patients performed ISC until PVRs measured < 100ml, where necessary. Postoperative uroflow and cystometrogram were performed at 6-12 weeks post procedure.

To ascertain long-term outcomes, an attempt to contact all patients from this study population with TOT in situ was made. Patients were telephoned and consent to participation was requested. Patients were then posted the International Consultation on Incontinence Questionnaire (ICIQ-Short Form),¹¹ a Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Improvement (PGI-I) measure,¹² with a free-text box to record urological medications, complications suffered or other unstructured feedback.

Complication data was recorded by retrospective review of medical notes, and updated where necessary following long-term patient feedback. Complications were classified as per the Clavien-Dindo system.

Results were compiled with statistical analysis performed using SPSS.

Results

Cohort Demographics

Patient characteristics are described Table 1. Long-term follow-up data was obtained at mean 9.25 years (7.5 – 12.75). Questionnaire response rate was 76/100 (76%).

Table 1: Patient Population

Mean Age at Operation	51.7 years (33-75)
Mean Symptom Duration	7.44 years (0.75-34)
Previous Pelvic Surgery	34/100 (34%)
Pre-Operative Urinary Incontinence	
Clinically Mixed Urinary Incontinence n=68	Urodynamic Detrusor Overactivity 28/68 (41.2%)
	No Urodynamic Detrusor Overactivity Demonstrated 40/68 (58.8%)
Clinically Pure Stress Urinary Incontinence n=32	Urodynamic Detrusor Overactivity 8/32 (25%)
	No Urodynamic Detrusor Overactivity Demonstrated 24/32 (75%)

Outcomes: Stress Urinary Outcomes

Short and long-term outcomes pertaining to stress urinary incontinence are displayed in Table 2. Clinical ‘significant improvement’ was applied to patient-reported status of being “almost entirely dry.” Urodynamic ‘significant improvement’ was applied to patients who had 2 or less small volume leaks at maximum bladder filling with vigorous coughing/jumping/Valsalva, having previously demonstrated frequent, large volume leaks at lower bladder volumes with less provocation.

Subgroup analysis of patients who had ‘pure’ SUI with no clinical urgency or detrusor overactivity (n=24) showed no statistically significant difference in long-term cure of SUI versus the mixed group. (‘Pure’ SUI group with long-term data, n=19, recurrence in 42.1% and cure in 57.9%; ‘Mixed’ group with long-term data, n=56, recurrence in 41%, cure in 58.9%)

Outcomes: Urge Urinary Incontinence

Patient outcomes related to urgency and urge urinary incontinence are outlined in Table 2.

Outcomes: Overall

Details of overall improvement and current condition in patients’ perspective are outlined in Table 2. The ICIQ questionnaire is scored on a scale of 0 – 21, with 21 representing the ‘worst’ continence control and effect on quality of life.

Table 2: Outcomes

<i>Stress Urinary Incontinence (SUI)</i>			
<i>Short Term</i> (3-12 weeks post procedure)			
	<i>Cure</i>	<i>Cure / Significant Improvement</i>	
<i>Clinical SUI</i>	91% (91/100)	98% (98/100)	
<i>Urodynamic SUI</i>	68% (68/100)	93% (93/100)	
<i>Long Term</i> (Mean 9.25 years (7.5 – 12.75))			
	<i>Sustained Cure</i>		
<i>Clinical SUI</i>	59% (45/76)		
<i>Urge Urinary Incontinence (UUI)</i>			
<i>Short Term</i> (Mean 6 months (3-12))			
<i>Clinical Urgency: Improvement/Cure</i>	<i>De Novo Urgency</i>	<i>De Novo Detrusor Overactivity</i>	
85.29% (58/68)	1% (1/100)	1% (1/100)	
<i>Long Term</i> (Mean 9.25 years (7.5 – 12.75))			
	<i>Clinical Urgency: Any Present?</i>		
	67% (51/76)		
<i>Long Term Global Patient Reported Outcomes</i>			
<i>Current ICIQ Score</i>	<i>Mean</i>		
	6.32		
<i>Patient Global Impression of Severity: Current Urinary Condition</i>	<i>‘Normal or Mild’</i>	<i>Moderate</i>	<i>Severe</i>
	73.68% (56/76)	25% (19/76)	1.31% (1/76)
<i>Patient Global Impression of Improvement: Current Urinary Condition</i>	<i>Much Better / Very Much Better</i>	<i>A Little Better</i>	<i>No Change / Worse</i>
	81.57% (62/76)	11/84% (9/76)	6.58% (5/76)

Outcomes: Postoperative Voiding

Postoperative voiding data is outlined in Table 3. We observed no statistically significant correlation between a requirement for intermittent self-catheterisation and either short-term urodynamic cure of SUI ($p = 0.31$) or long-term patient reported cure of SUI ($p = 0.6$).

Table 3: Pre and Postoperative Voiding Function

	Preoperative	Postoperative	Statistically Significant?^
Need for ISC	N/A	44/95 (46.32%) Median 3 days (2-84)	-
Mean PVR	95.83ml (0-400ml)	79.8ml (0-400ml)	No, $p = 0.08$
Mean Uroflow QMax	32.07ml/sec (5-76)	25.08ml/sec (2-55)	Yes, $p < 0.00001$
<i>Data available on 95/100 patients</i> <i>*Mean PVR of patients able to volitionally void for uroflow (n – 3)</i>			^Paired t-test

Global Patient Reported Outcomes at Long-Term Follow-Up

Global patient reported outcomes (PROMs) at long-term follow-up are illustrated in Table 2.

Complications

Grade 3b Clavien Dindo complications occurred in 10/100 (10%). All complications were apparent within 6 months of surgery (Table 4). Tape removal or release, where required, was performed within 2 weeks of surgery. Tape removal was not required for infection. No patients reported new symptoms suggestive of mesh erosion or other late complications.

Table 4: Complication Data

Complication	Number Affected	Time of Diagnosis	Management	Grade (Clavien - Dindo)	Outcome
Acute Urinary Retention	6	Early	Tape loosening	3b	5/6 – resolution 1/6 – persistence – tape removed
Infection (skin & soft tissue abscess)	1	Early	Incision & drainage	3b	Resolution
Pain & lower limb weakness, aetiology unclear despite neurological work-up	1	Early	Tape removed	3b	Resolution
Dyspareunia (severe)	1	Early	One limb of tape divided	3b	Persisted
Dyspareunia (mild)	1	Early	Conservative	1	Persisted
Pain (greater than expected)	1	Early	EUA & Cystoscopy – no cause identified. Treated empirically with 1 week oral antibiotics	3b	Resolution
Infection (urinary tract or superficial skin)	4	Early	Oral antibiotic/antifungal	2	Resolution

Discussion

This is one of a limited number of papers reporting on long-term outcomes of the transobturator tape. Analysis is of a population with mixed urinary incontinence, representative of clinical practice.

Our patient population reported 91% subjective cure of SUI at short-term follow up, similar to the 87.9% reported by Jun et al. at 6 month follow-up,¹³ and at the upper end of the 62-98% range observed by Ford et al. at 12 month follow-up in systematic review.¹⁰ Our 'outside-in' method of TOT placement appears to be equal to the 'inside-out' approach in achieving continence.^{6,10}

We note a discordance between clinical and urodynamic cure of SUI at short-term follow-up. This is surprising, as in our experience patients are more sensitive to leakage at CMG than mechanical detectors. It may represent more exaggerated provocative exercises at greater bladder volumes being performed at CMG than patients were experiencing day-to-day.

Our data suggests a decline in complete cure rate with time, with 59% (n=76) surveyed reporting sustained cure of SUI at long-term follow-up. This has been observed by several other authors; TOT success rates of 73% at 3 years and of 43.4% at 5 years have been reported by the E-TOT RCT⁶ and Kenton et al.⁷ respectively. Our figures, at longer-term follow-up, were strikingly similar to the 59.6% at mean 8.33 years, and 59.2% at 10 years, reported by other authors.^{5,14} The 4 trials (pooled n=714) reporting on results at >5 year follow-up in a recent Cochrane review, describe subjective cure of SUI of the range 43-92%.¹⁰ Our long-term follow-up was by questionnaire, with recurrence of SUI recorded where patients reported leaking urine on coughing/sneezing/physical exertion. We recognise that this is an imperfect assessment and SUI could be mimicked by, for example, cough-induced detrusor overactivity in this evaluation. Despite the decline in SUI cure rates, we were encouraged by high satisfaction rates, with 81.57% of patients at long-term follow-up reporting their condition remained 'much'/'very much' better.

At short-term follow-up, we observed improvement or cure of clinical urgency in 85.29% (58/68), similar to Laurikainen et al. who noted 96% of urgency to have disappeared two months post TVT-O placement.¹⁵ Our rate of de-novo urgency was 1%, below literature reported rates of 3.6-11.2% at short/medium-term follow-up.^{10, 16, 17}

At long-term follow up, 67% (51/76) of our patients reported some degree of urge incontinence on ICIQ questionnaire. Whilst this appears quite high, we note that 68% of the original cohort had clinically mixed urinary incontinence, and 25% with clinically pure SUI had demonstrable detrusor overactivity on pre-procedure CMG. Furthermore, high rates of urge incontinence have been reported in the general female population, with a 2-year cumulative incidence of urge urinary incontinence of 1.5 – 9.5% in women aged ≥ 50 recorded in one large study.¹⁸ Our rate of urge urinary incontinence may represent some loss of the original improvement, and/or the natural history of UUI in this patient demographic. We should also note that this figure does include minor urge incontinence in patients with good overall satisfaction with their urinary condition.

Six patients underwent tape loosening due to acute urinary retention (AUR) with inability to void or voiding minimal amounts only. Patients voiding but with post void residual volumes >100ml were considered to need to perform intermittent self-catheterisation (ISC). All 44 patients requiring ISC performed this at home. No discharges were delayed due to ISC requirements; likely due to ISC education preoperatively. No change in ISC requirements was observed over the study timeframe. Ford et al., reported an average rate of voiding dysfunction post TOT insertion of 5.53%.¹⁰ Some heterogeneity in the definition of voiding dysfunction is noted throughout the literature however,¹⁹ and voiding dysfunction is sometimes evaluated at short-term follow up rather than immediately postoperatively.²⁰ Interestingly, medial-lateral methods of TOT insertion, the opposite to our approach, seem associated with higher rates of voiding dysfunction.¹⁰

Long-term patient reported satisfaction post TOT has been scarcely reported. We found 81.57% (62/76) respondents to view their current urinary condition as 'much better' or 'very much better' than pre-operatively. Two other published studies using similar assessment instruments also demonstrated similar results; the urinary condition was described as 'much better' or 'very much better' in 92% of women at 10-year follow-up in one,²¹ and in 88% of women at 5 years in the other.⁷

Ford et al's Cochrane review identified an overall major visceral/vascular injury rate of 0.42% and a bladder perforation rate of 2.54%. The TOT was demonstrated to be associated with a lower incidence of these complications than the

retropubic tape. Al-Zahrani et al. noted a rate of bladder or vaginal perforation of 1.5% (3/220).⁵ No cases of major intraoperative injury were identified in our study.

Urinary tract infection occurred in 4% of our patients postoperatively. Early, Clavien-Dindo 2 complications are not discussed in all papers. Our rate is similar to the 5.9% rate of postoperative UTI reported by Al-Zahrani et al.⁵ Return to theatre for tape loosening or division took place in 6/100 cases all in the early postoperative phase, higher than the 24/2,543 cases in data from the Austrian national registry.²² However, thresholds for intervention for voiding dysfunction may vary.

Two patients suffered severe pain postoperatively. This prompted an examination under anaesthesia and cystoscopy in one patient, with normal findings, and pain subsequently resolved. Another patient suffered pain in association with adductor muscle spasm. Neurological dysfunction has previously been described with TOT; Kenton et al. reported 2/404 cases persisting after TOT at 5-year follow-up.⁷ Our patient underwent tape removal, and symptoms fully resolved. Our rate of significant postoperative pain is lower than the 5.85% groin pain identified in Ford et al's Cochrane review, where it was associated with transobturator more than retropubic routes of MUS placement.¹⁰ It is possible that we did not capture mild and transient cases, given the retrospective nature of the first component of our study.

Two patients in our study reported persistent dyspareunia at long-term follow-up. Rates of de-novo dyspareunia of 1% (2/220) to 9% are described in patients undergoing mid-urethral sling placement.^{5, 10, 21, 23} We note with interest some improvement reported by Serati et al.²¹ with the use of topical steroids, which is not something we tried in this study. We emphasise the importance of pre-operative patient counselling in this regard.

None of our patients reported new onset dysuria, bleeding, or other symptoms indicative of tape erosion at long-term follow-up.^{24, 25} Similarly, Lo et al. reported no cases of mesh erosion with use of the Monarc[®] subfascial hammock at 5-year follow up.¹⁷ Kenton et al. noted a 1.73% (7/404) mesh erosion rate in a mixed transobturator/retropubic population at 3-5 years of follow up.⁷ Ford et al, identified no cases of urethral or bladder erosion with the transobturator tape from results of 4 studies (n=180), but report a vaginal erosion rate of 2.09% from the pooled results of 31 trials (n=4743) with either TOT or retropubic MUS placement.²⁴ We do acknowledge that, as with virtually all long term studies, our response rate is less than 100%, and it is possible that patients we could not contact suffered complications managed elsewhere. We did write to all patients at last recorded address and check contact details with GP in an effort to capture such cases. Mesh erosion appears to remain an unusual complication of TOT placement, however given its significant consequences it does mandate preoperative patient counselling.

In conclusion, we found a high patient satisfaction rate post transobturator tape insertion for both SUI and stress-predominant MUI at long-term follow up in this study. An overall low complication rate was observed, with no new complications emerging at long-term follow-up. Recent controversies surrounding use of pelvic mesh make this data particularly pertinent. We feel that the reporting of long-term prospective outcomes for this procedure is imperative, and that multi-centre studies would facilitate analysis of the risk-benefit equation and inform policy.

Declaration of Conflicts of Interest:

The authors have no conflicts of interest to declare.

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