

Patients with transobturator tape: a retrospective observational study of ten-year follow-up

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Abstract

Stress urinary incontinence (SUI) may result from intrinsic sphincter weakness or urethral hypermobility brought on by weakened muscles in the pelvic floor that sustain the urethra and bladder. The amount of mid-urethral support is increased by the mid-urethral tape's function to serve as an anchored pubo-urethral neoligament. This study's objective is to assess the safety and effectiveness of transobturator tape (TOT) for SUI after a 10-year follow-up period. There were 103 patients included in this retrospective observational single-arm research. Only 95 participants were included in the trial since 8 patients were lost to follow-up. Patients

who had TOT between 2010 and 2013 were monitored until December 2022. The effectiveness of the tape was assessed at 10 years for both early and late surgical problems in the patients. Those diagnosed with SUI were 52.27 years old on average (standard deviation ± 8.48). 24% of patients (n=21) experienced mixed urinary incontinence (MUI), compared to 79.61% (n=82) of patients who had just pure stress incontinence. At 10 years, the success rate in our research was 97.09%. Demand incontinence was healed in 57.14% (n=12) of the 21 MUI patients. 7.69% of *de novo* urgency was noted (n=7). There were no significant side effects including mesh erosion, bladder and intestine perforation, or vascular hemorrhage. Excellent patient satisfaction was rated in 43% of cases (n=44), good in 54% of cases (n=56), and low in 3% of cases (n=3). At 10 years, TOT for SUI shows an impressive cure rate and excellent effectiveness. When the treatment is carried out by experienced hands, there are no significant difficulties.

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Introduction

Worldwide, 17-45% of women experience urine incontinence, with stress urinary incontinence (SUI) accounting for 48% of all instances.¹ The last 10 years have seen a change in the management of SUI thanks to the development of tension-free suburethral tapes. The amount of mid-urethral support is increased by the mid-urethral tape's function to serve as an anchored pubo-urethral neoligament. The objective cure rate for tension-free vaginal tape (TVT) is 93%, and it remained essentially steady between 6 and 18 years.² On the other hand, TVT has its own set of serious risks since it travels blindly through the retropubic pathway and can result in vascular hemorrhage, bladder rupture, and bowel perforation. As a result, a safer method using the transobturator channel was developed, which considerably decreased these complication rates. By penetrating the obturator membranes through a comparatively avascular area and reducing the risk of bladder and bowel perforation, the transobturator tape (TOT) is inserted through the obturator foramen. In this study, we looked at the effectiveness of the tape and the rate of short- and long-term complications in 103 patients with SUI who received TOT at our center with a 10-year follow-up.

Materials and Methods

Sample size and study design

Retrospective observational single-arm research was done on 103 individuals who received TOT at our facility between 2010 and 2013. Up until December 2022, patients were followed up with. The institutional ethics committee granted permission after receiving ethical clearance.

Statistic evaluation

Data analysis software, IBM SPSS version 20.0 (IBM, Armonk, NY, USA), was used for the statistical analysis. The mean standard deviation (SD) is the unit of measurement for continuous data.

Inclusion standards

Inclusion standards comprise: i) genuine stress incontinence; ii) urodynamic investigations on mixed incontinence with a predominating stress component; iii) surgically fit patient.

Exclusion standards

Exclusion standards comprise: i) patients with urodynamic tests who have a predominance of urge incontinence; ii) overactive bladder; iii) neurological bladder; iv) unfit for surgery; v) due to a restricted bladder capacity, overflow incontinence.

Procedure

All participants in the research got a thorough preoperative evaluation and had to meet all inclusion criteria. As part of the preoperative workup, the postvoid residual (PVR) volume and full bladder capacity of every patient were measured; as a result, any patient with a high PVR could be identified before surgery. Only individuals with mixed incontinence, those with diabetes mellitus, or those who had previously failed a TOT had a urodynamic examination. *De novo* urgent patients received medical care. Our institute developed the freedom virtual machine (Lotus Surgicals, India) tape, which consists of polypropylene macroporous type 1 mesh that has been accepted by the Food and Drug Administration. The confounding effect of the kind of mesh and method employed owing to surgeon discrepancies was ruled out because the same surgeon performed all of the procedures. The insertion method employed was out-to-in. The paraurethral area was dissected all the way to the inferior pubic ramus after a 1 cm incision was made 1 cm below the urethra. After surface marking, a stab incision was made in the groin on either side. The TOT needle was directed across the finger in the vaginal incision after being inserted through the stab wound in the groin. To achieve tension-free support, the tape was applied over the Metzenbaum scissors and tightened while following aseptic procedures. Vaginal packing was performed after the skin and vaginal incisions were closed. The urethral catheter and vaginal pack were left in place for 4 hours before being withdrawn. The next day, the patient was released with orders to refrain from sexual activity, squatting, and exerting themselves for at least 3 months. The first follow-up took place on the seventh postoperative day, and then there were 2 more 1 month later and 3 more 6 months later. Patients were then monitored yearly for the next 10 years, through December 2022. Any complications found during the first and second follow-up visits were regarded as early complications, whereas those that surfaced 6 months or later were regarded as late complications of the operation. Every time a patient visited, their level of satisfaction was recorded and categorized as outstanding, good, or bad.

Table 3. Postoperative continent status at 10-year follow-up.

Continent status	Immediate (n=103), n (%)	10 years (n=103), n (%)
Fully continent	103 (100)	100 (97.09)
Incontinent	0	3 (2.91)

Results

A total of 103 patients were involved in the trial, and a full 10-year follow-up was conducted on all of them. The patients' mean age was 52.27 and they ranged in age from 30 to 70 (Table 1). Table 2 displays the parity distribution. Stress incontinence was shown to be more common in patients with greater parity in full-term normal deliveries. A total of 5 individuals experienced stress incontinence despite having only had one cesarean birth. Among the 103 patients, 82 (or 79.61%) had solely pure stress incontinence, while 21 (or 24%) had mixed incontinence with a slight urge component. A 10-year postoperative continent status examination of the patients revealed a 97.09% cure rate (n=100) (Table 3). A complaint of involuntary urine loss is defined as urinary incontinence, according to the International Continence Society. Fully continent is a subjective term defining patients with no symptoms of urinary incontinence. On assessment, 4.85% (n=5) of the patients had failed surgery and had positive stress tests. The analysis of the early and late postoperative problems is displayed in Table 4. There were no significant side effects, including bladder, bowel, or vascular bleeding. Although we observed mesh pain and dyspareunia in our patients, there was no mesh erosion. 5 patients needed a second operation for incontinence after 10 years due to stress incontinence. Of the 21 patients with mixed urinary incontinence, 12.57% (n=12) had urge incontinence cured, whereas 9.73% (n=9) continued to have it after TOT, so they were treated medically. At 6 months of follow-up, 6.69% (n=7) of the individuals had *de novo* urgency. 7.76% (n=8) of the patients showed signs of an overactive bladder, including higher frequency, nocturnal enuresis, or urgency, along with or without urge incontinence. However, none of the patients met the diagnostic criteria for an overactive bladder since a complex of symptoms was not present. After 10 years, the average postresidual volume was 84.70 mL (SD±34.07). In Figure 1, patient satisfaction is rated.

Table 1. Age range of patients (n=103).

Age (years)	n (%)
30	0
31-40	17 (16.5)
41-50	55 (53.4)
>50	31 (29.1)
Mean±SD	52.27

SD, standard deviation.

Table 2. Distribution parity of patients (n=103).

Parity (FTND)	n (%)
<2	12 (11.65)
2-4	42 (40.77)
>4	13 (12.62)
1 LSCS	5 (4.85)

FTND, full term normal delivery; LSCS, lower-segment cesarean section.

Discussion

The TOT technique for the treatment of SUI was first published by Delorme *et al.* in 2001. It comprised the outside-in placement of a polypropylene tape *via* a tunnel in the horizontal direction under the midurethra between the 2 obturator foramina.³ The TOT is a tension-free sling since neither the treatment nor the need to treat urethral hypermobility alters the urethral angle at rest.⁴ In this study, 103 individuals who had received TOT for SUI underwent a 10-year follow-up. 82% of patients who presented with stress-related incontinence were older than 40, and 63% had multiple pregnancies.

Twelve of the 21 individuals who had mixed incontinence when they had surgery had both stress and urge incontinence completely cured. Surgery to cure mixed incontinence has always been accompanied by some anxiety due to the aggravated urge component. Contrarily, data suggests that detrusor overactivity after anti-incontinence surgery has significantly improved. Rezapour and Ulmsten reported a subjective cure of mixed incontinence in 85% of women following TVT in a prospective study with a 4-year follow-up.⁵ According to postoperative urodynamic investigations, the adoption of the transobturator sling is associated with the lowest degree of persistent detrusor overactivity.⁵ However, compared to mixed incontinence, pure stress incontinence has greater cure rates. At 10 years, 6.79% (n=7) of patients had *de novo* urgency. This was in line with the findings of Angioli *et al.*, who discovered a 6.4% 5-year *de novo* urgency rate in TOT.⁶

According to the 10-year follow-up study by Natale *et al.* on TOT using the out-to-in approach published in 2019, the objective cure rate was 87.1% and the subjective cure rate was 72.2% in uncomplicated patients. In this study, urgency as well as urge incontinence were also dramatically decreased. In our study, *de novo* urgency also arose in 6.7% of cases.⁷ According to published research, the subjective and objective cure rates for TOT are between 75% and 89.3% and 78% and 91%, respectively.⁸ At the 10-year follow-up, we achieved an objective as well as a subjective cure rate of 97.09%, which is greater than that stated in the literature. The subjective cure rate of the transobturator route was reported to vary from 68% to 98% in a Cochrane review of studies on mid-urethral sling surgeries in 2017, which is comparable with our data.⁹ However, only 43% (n=44) of participants in our study gave this method an outstanding rating, while 54% thought it was decent. Three patients were dissatisfied with the procedure. Due to the minor postoperative lower urinary tract symptoms of dysuria,

retention, frequency, *de novo* urgency, and dyspareunia, the patients' satisfaction levels were reduced. However, no significant issues were found.

The degree of voiding dysfunction following mid-urethral slings (MUS) might range from frequent urination to pee retention. The patient may experience urge incontinence, incomplete evacuation, incomplete evacuation while squatting, and straining to urinate. The mean PVR volume in our patients was 84.70 mL (SD±34.07), which was on the larger side. Although the etiology of voiding dysfunction following MUS is not well understood, it is generally believed to be brought on by urethral blockage or irritation from the mesh.⁸ A cystoscopy should be performed to rule out any of the aforementioned etiologies, as well as other reasons such as bladder perforation, pelvic hematoma, urethral erosion, or vaginal extrusion of the mesh.¹⁰ One patient with dysuria and failure of TOT performed at a private facility participated in our investigation. A cystoscopy was performed, and it revealed a 6-month-old bladder perforation. A subsequent TOT was performed after the mesh was removed through cystoscopy. All symptoms of the



Figure 1. Patient satisfaction after 10-year follow-up.

Table 4. Immediate and late complications.

Complication	Immediate (n=103), n (%)	Late (n=103), n (%)
Dysuria	3 (2.91)	-
Retention	5 (4.85)	6 (5.82)
Incomplete evacuation in squatting	-	9 (13.33)
<i>De novo</i> urgency	-	7 (6.79)
Dyspareunia	-	8 (7.76)
Mesh tenderness	-	4 (3.88)
Repeated UTI	-	8 (7.76)
Features of overactive bladder*		
Increased frequency	4 (3.88)	9 (8.73)
Nocturnal enuresis	-	8 (7.76)
Urgency	-	6 (5.82)
Urge incontinence	-	9 (8.73)

UTI, urinary tract infection; *a total of 19 patients had symptoms of overactive bladder but no patient had complete complex symptoms of overactive bladder as defined by the International Continence Society.

patient were resolved. There was no evidence of fistulas on follow-up. Cystoscopy should be reserved for patients with hematuria, bladder pain, or recurrent cystitis, especially when bladder perforation or urethral mesh erosion are suspected.¹⁰ 4.85% (n=5) of individuals experienced urinary retention immediately following surgery, whereas 5.82% (n=6) of patients experienced urinary retention as a delayed consequence. Urinary retention is characterized as either a considerable PVR of over 100 mL or the failure to pass urine following catheter removal post-TOT in the early postoperative interval. The substantial PVR was estimated to be greater than 100 mL at the 10-year follow-up. Significant PVR has not been given a definition. However, a large PVR may be defined as more than 90 to 160 mL, or between 30% and 60% of bladder capacity.

Symptoms that last longer than 4 weeks seldom go away on their own, according to the literature.¹⁰ Urine retention that occurred immediately after surgery was treated by a urethral catheterization for 7 days, followed by a trial of voiding. The catheter was left in place in cases of retention even on the seventh postoperative day for an additional 2 weeks, after which time the PVR decreased to <100 mL in 4 patients. Dual voiding of the urine was described for all patients, who were instructed to sit and void again after each passage of pee. In contrast, 4 patients had a large PVR after 10 years of follow-up, and one patient's retention grew slowly throughout that time. Due to the clinical asymptomaticness of these individuals (increased PVR was the ultrasonography diagnosis), dual urination was sufficient for their therapy.

At a 10-year follow-up, 13.33% (n=9) of patients had incomplete evacuation in the squatting posture. These individuals were able to relieve themselves in the English toilets or while standing. All 9 patients were found to have grade II cystocele, which had slowly grown over the previous 10 years. The most likely explanation for patients' retention in the squatting posture is cystocele, which causes a shift in urethral angle when squatting. 7.76% (n=8) of patients reported dyspareunia, of whom 4 had mesh soreness that was ascribed to it, while the remaining 4 had no pain at the mesh area. Although the actual etiology of dyspareunia is unknown, painful post-TOT coitus may be due to vaginal injury, vascular or neural damage, or both.¹¹ For these individuals, local lignocaine jelly treatment may be helpful. It aids in symptom relief, and there was no reduction in orgasm. In a comparison between TOT and retropubic tape, the incidence of dyspareunia with TOT is 18.5%.¹² Due to its excellent cure rates and low complication rates, TOT has now established itself as the gold standard. Bowel damage and major vascular injury are also extremely uncommon, occurring in only 0.07% and 0.04% of cases, respectively.¹⁰ The retropubic approach exhibited greater rates of morbidity and complications compared to the transobturator route, according to the 2017 Cochrane Review on MUS surgeries.⁹ With TOT, the probability of bladder damage drops from 5% with TVT to less than 1%.¹³ No bowel or bladder damage or vascular bleeding were found in our investigation. Postoperative leg discomfort is a distinct complication peculiar to TOT. The reported incidence ranges from 2.3% to 15.9%.¹⁰ However, there was never any postoperative leg discomfort in our group.

But in 2018, the British government issued a nationwide moratorium on the use of synthetic mesh for the management of stress incontinence. Even though the overall mesh erosion rate is simply 2.4%, there is a worry that mesh-related problems following MUS may have a negative impact on the patient's mental outcome.¹⁴ In a study regarding autologous TOT by Cubuk *et al.*, the mean operative time was 43.8±8.1 minutes, and the overall complication rate was 9%. The mean visual analogue scale scores at postoperative 24 hours were 2.6±1.2. At 18 months postoperative, no patient had a

positive cough test, and the mean patient global impression of improvement score was 2, while 2 patients had moderate urinary incontinence according to the pad test. The international consultation on incontinence questionnaire total score and total quality of life score at baseline and 18 months after surgery were 27.9±6.6, 68.4±13.8 and 20.4±4.8, 39.7±9.2, respectively.¹⁵ To demonstrate the security and effectiveness of mesh surgery for SUI, more research is necessary. Our research's strength was the thorough 10-year follow-up of the 103 study participants. Since a single surgeon with competence in TOT performed all procedures, there was no physician bias. Additionally, the identical tape substance was applied to every patient.

The limited sample size in our study is a drawback. Another drawback is the fact that a subjective rating of patient satisfaction was used. For the same, a standard questionnaire was used.

Conclusions

When carried out by qualified hands, TOT has an outstanding subjective as well as objective cure rate and an excellent safety profile. Due to its low complication rates and the minimally invasive nature of the procedure, it has now established itself as the gold standard of therapy for SUI. To prevent a change in the urethral angle after TOT, the accompanying pelvic floor defect needs to be addressed before the procedure.

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