Five-Year Follow-up in Patients with Transobturator Tape – A Retrospective Observational Study

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Background: Stress urinary incontinence (SUI) could be due to urethral hypermobility due to the weakening of the pelvic floor muscles which support the urethra and bladder or the intrinsic sphincter deficiency. The mid-urethral tape acts as an anchored pubo-urethral neo-ligament thus increasing the level of mid-urethral support. The purpose of this study is to evaluate the safety and efficacy of transobturator tape (TOT) for SUI at 5 years of follow-up.

Materials and Methods: This was a retrospective observational single-arm study of 40 patients. Ten patients were lost to follow-up; hence, only 30 patients were included in the study. Patients who underwent TOT from 2010 to 2012 were followed up till December 2017. Patients were evaluated for early and late postoperative complications and efficacy of the tape at 5 years.

Results: The mean age of the patients with SUI was 48.07 (standard deviation ± 9.38). About 76.66% (n = 23) of patients had only pure stress incontinence, whereas 23.3% of patients (n = 7) had mixed urinary incontinence (MUI). The cure rate in our study was 93.33% at 5 years. Out of the seven patients with MUI, urge incontinence was cured in 71.42% (n = 5). De novo urgency was observed in 6.6% (n = 2). No major complications such as bladder and bowel perforation, vascular hemorrhage, or mesh erosion were seen. Patient satisfaction was graded as excellent in 46.66% (n = 14), good in 30% (n = 9), and poor in 23% (n = 7).

Conclusion: TOT for stress incontinence has a high cure rate and very good efficacy at 5 years. No major complications are seen when the procedure is performed by expert hands.

Keywords: Complications, stress urinary incontinence, transobturator tape

INTRODUCTION

Urinary incontinence affects 17%–45% of women worldwide and stress urinary incontinence (SUI) is responsible for 48% of all cases.[1]

The advent of tension-free suburethral tapes has revolutionized the treatment of SUI in the last decade. The mid-urethral tape acts as an anchored pubo-urethral neo-ligament thus increasing the level of mid-urethral support. Tension-free vaginal tape (TVT) has an objective cure rate of 91% and remained practically stable between 5 and 17 years.[2] However, TVT has its own set of major complications such as bladder and bowel perforation or vascular hemorrhage, as it follows a blind passage through the retropubic route. Thus, a safer approach through the transobturator route was devised which brought down these complication rates significantly. The transobturator tape (TOT) is passed through the obturator foramen piercing the obturator membrane through a relatively avascular area and also diminishing the chance of bladder and bowel perforation. In this study, we have studied 30 patients with SUI who underwent TOT at our institute with their 5-year follow-up for the efficacy of the tape and their short- and long-term complication rate.

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**Materials and Methods**

**Study design and sample size**

We conducted a retrospective observational single-arm study of 40 patients who underwent TOT at our institute from 2010 to 2012. Patients were followed up till December 2017. Ten patients were lost to follow-up; hence, only 30 patients were included in the study. Ethical clearance was obtained from the institutional ethical committee. An ethical committee approval letter with reference number IKDRC-ITS EC/App/26Mar21/22 was obtained.

**Statistical analysis**

Statistical analysis was done using the data analysis software system IBM SPSS VERSION 20.0 (IBM, Bangalore). Continuous data are expressed as mean standard deviation (SD) ±.

**Inclusion criteria**

- Genuine stress incontinence
- Mixed incontinence with predominant stress component on urodynamic studies
- Patient fit for surgery

**Exclusion criteria**

- Patients with predominant urge incontinence on urodynamic studies
- Overactive bladder
- Neurological bladder
- Patient unfit for surgery
- Overflow incontinence due to small bladder capacity

**Procedure**

All patients underwent a proper preoperative workup and patients full filling the inclusion criteria were included in the study. All patients’ full bladder capacity and postvoid residual (PVR) volume were done as a part of preoperative work up, hence, any patient with high PVR could be recognized before surgery. Urodynamic study was done only for patients with mixed incontinence or patients with diabetes mellitus or previous TOT failure. Patients with *de novo* urgency were treated medically.

The tape used was freedom virtual machine (Lotus Surgicals, India) designed at our institute and made up of polypropylene macroporous type 1 mesh approved by the Food and Drug Administration [Figure 1]. All surgeries were performed by the same surgeon and hence confounding factor of the type of mesh and technique used due to surgeon variability was ruled out.

The out-to-in technique of insertion was used. One centimeter incision was given 1 cm below the urethra, and paraurethral space was dissected up to the inferior pubic ramus. A stab incision was given in the groin on either side after surface marking. The TOT needle was passed through the stab incision in the groin and guided over the finger in the vaginal incision. The tape was fixed under aseptic precautions and tightened over the Metzenbaum scissors so that tension-free support is obtained. The vaginal and skin incision was closed, and vaginal packing was done. The vaginal pack and per urethral catheter were kept for 4 h and removed. Patient was discharged on the next day with instructions to avoid intercourse, squatting down, and straining activities for a minimum of 3 months. The first follow-up was on the 7th postoperative day, followed by second follow-up 1 month later and third follow-up 6 months later. Patients then followed up yearly for 5 years up to December 2017.

Any complication that was detected on first and second follow-up was taken as an early complication and that which aroused 6 months or later was considered to be a late complication of the surgery.

Patient satisfaction was noted at every visit and was graded as excellent, good, and poor.

**Results**

The total number of patients included in the study was 30 with a complete 5-year follow-up. The patients were in the age group of 30–60 years with a mean age of 48.07 [Table 1]. The distribution of parity is shown in Table 2. It was observed that stress incontinence was more

| Table 1: Age range of patients (n=30) |
|---------------------------------------|
| Age (years)   | n (%) |
| 30           | 0     |
| 31-40        | 6 (20) |
| 41-50        | 15 (50)|
| >50          | 9 (30) |
| Mean±SD      | 48.07 |

**Table 2: Distribution parity of patients (n=30)**

| Parity (FTND) | n (%) |
|---------------|-------|
| <2            | 2 (6.6)|
| 2-4           | 22 (73.33)|
| >4            | 4 (13.3)|
| LSCS          | 2 (6.6)|

LSCS: Lower-segment cesarean section, FTND: Full term normal delivery
prevailant in a patient with higher parity with full-term normal delivery. Two patients had only one cesarean delivery yet suffered from stress incontinence. Out of 30 patients, 76.66% \((n = 23)\) of patients had only pure stress incontinence, whereas 23.3% of patients \((n = 7)\) had mixed incontinence with mild urge component to it. Postoperative continent status of the patients was studied at 5 years of follow-up which showed a cure rate of 93.33% \((n = 28)\) [Table 3]. About 6.6% \((n = 2)\) of patients had a failure of surgery and showed positive stress tests on examination. The immediate and late postoperative complications were analyzed, as shown in Table 4. No major complications such as bladder, bowel perforation, or vascular hemorrhage were observed. Mesh tenderness and dyspareunia were seen, but there was no mesh erosion in our patients. Repeat surgery for incontinence was required in two patients after 5 years for stress incontinence. Out of the seven patients with mixed urinary incontinence, urge incontinence was cured in 71.42% \((n = 5)\) of patients while 28.5% \((n = 2)\) of patients had urge incontinence even post-TOT and were treated medically. 

### Table 3: Postoperative continent status at 5-year follow-up

| Continent status | Immediate \((n=30), n (%)\) | 5 years \((n=30), n (%)\) |
|------------------|-----------------|-----------------|
| Fully continent  | 30 (100)        | 28 (93.33)      |
| Incontinent      | 0               | 2 (6.6)         |

### Table 4: Immediate and late complication

| Complication                  | Immediate \((n=30), n (%)\) | Late \((n=30), n (%)\) |
|-------------------------------|-----------------|-----------------|
| Dysuria                       | 1 (3.33)        | -               |
| Retention                     | 4 (13.33)       | 3 (10)          |
| Incomplete evacuation in squatting | -               | 4 (13.33)       |
| Denovo urgency                | -               | 2 (6.66)        |
| Dyspareunia                   | -               | 4 (13.33)       |
| Mesh tenderness               | -               | 2 (6.66)        |
| Repeated UTI                  | -               | 1 (3.33)        |
| Features of overactive bladder* |                 |                 |
| Increased frequency           | 1 (3.33)        | 4 (13.33)       |
| Nocturnal enuresis            | -               | 2 (6.66)        |
| Urgency                       | -               | 2 (6.66)        |
| Urge incontinence             | 2 (6.66)        | 2 (6.66)        |

*Total 6 patients had symptoms of OAB but no patient had complete symptom complex of OAB as defined by the International Continence Society. OAB: Overactive bladder, UTI: Urinary tract infection.

of patients, however, none of the patients fitted in the diagnosis of the overactive bladder as complex of symptoms was not seen. The mean postresidual volume after 5 years was 74.70 ml \((SD \pm 44.17)\). Patient satisfaction was graded, as shown in Figure 2.

### Discussion

Delorme et al. in 2001 described the TOT technique for the treatment of SUI that involved the tension-free insertion of a polypropylene tape through a tunnel in a horizontal plane under the midurethra between the two obturator foramina in an outside-in orientation. The TOT is a tension-free sling as the resting urethral angle is not changed by the procedure, nor is it necessary to correct urethral hypermobility.

This study involved a 5-year follow-up of 30 patients who had undergone TOT for SUI. Eighty percent of the patients presenting with stress incontinence were above the age of 40 years and 86.66% were multiparous. Seven patients presented with mixed incontinence with 71.4% \((n = 5)\) had complete cure of stress and urge incontinence after surgery. There has always been some trepidation on surgical treatment of mixed incontinence for the aggravation of the urge component. However, on the contrary, we have evidence suggesting significant improvement in detrusor overactivity (DO) post anti-incontinence surgery. In a prospective study with 4-year follow-up, Rezapour and Ulmsten reported a subjective cure of mixed incontinence in 85% of women after undergoing TVT. The use of the transobturator sling is reported to have the lowest rate of persistent DO, demonstrated by postoperative urodynamic studies. However, cure rates are higher in pure stress incontinence as compared to mixed incontinence. 

De novo urgency was seen in 6.6% \((n = 2)\) of patients at 5 years. This was consistent with Angioli et al. who studied the patient satisfaction at 5-year follow-up post-TOT. TOT: Transobturator tape.
found a 5-year de novo urgency rate of 6.4% in TOT.\[6\] Another 10-year follow-up study of TOT by out-to-in method by Natale et al. in 2019 showed similar results consistent with our study with an objective cure rate of 87.1% and subjective cure rate of 72.2% in uncomplicated cases. Furthermore, the urgency and urge incontinence were significantly seen reduced in this study. De novo urgency appeared in 7.3% which was also the case in our study.\[7\]

Literature suggests that the subjective cure rates of TOT range between 78% and 91%, and objective cure range between 75% and 89.3%.\[8\] We had a subjective and objective cure rate of 93.33% at a 5-year follow-up which is higher than that suggested in the literature. A Cochrane review on mid-urethral sling operations in 2017 suggested that the subjective cure rate of transobturator route ranged from 68% to 98% which is consistent with our study.\[9\] However, in our study, only 46.66% (n = 14) graded this procedure as excellent while 30% considered it to be good. About 23.3% (n = 7) of patients were not satisfied with the procedure. Satisfaction level in the patients was less due to the mild postoperative lower urinary tract symptoms in the form of dysuria, retention, frequency, de novo urgency, and dyspareunia. However, no major complications were noted.

Voiding dysfunctions after mid-urethral slings (MUS) may vary in severity from urinary frequency to retention in urine. Patient may have straining to void, incomplete evacuation, incomplete evacuation in squatting position, urgency, and urge incontinence. The PVR volume was on the higher side in our patients with a mean PVR of 74.70 ml (SD ± 44.17). The pathophysiology of voiding dysfunction after MUS is not well understood, although it is assumed to be caused by urethral obstruction or irritation by the mesh in most cases.\[8\] Other causes such as bladder perforation, pelvic hematoma, urethral erosion, or vaginal extrusion of the mesh should always be considered in the differential diagnosis and hence a cystoscopy should be done to rule out any of the above etiology.\[10\] In our study, we had one patient who presented with dysuria and failure of TOT done at a private institute. Cystoscopy was done which revealed bladder perforation 6 months old. The mesh was excised by cystoscopy and a repeat TOT was done. All symptoms of the patient were resolved. There was no evidence of fistula on follow-up. Cystoscopy should be reserved for patients with hematuria, bladder pain, or recurrent cystitis, especially when bladder perforation or urethral mesh erosion is suspected.\[10\]

Urinary retention was seen in 13.33% (n = 4) of patients in the immediate postoperative period, while 10% (n = 3) patients had retention of urine as a delayed complication. In the immediate postoperative period, retention of urine was defined as inability to pass urine after removal of catheter post-TOT or a significant PVR of more than 100 ml. At 5-year follow-up, the significant PVR was taken as more than 100 ml. There is no proposed definition of significant PVR. However, 20% to 50% of bladder capacity or more than 100–150 ml may be taken as significant PVR. As the literature suggests symptoms that persist beyond 4 weeks rarely resolve spontaneously.\[10\] The immediate postoperative retention of urine was managed by per urethral catheterization for 7 days and a trial of voiding was given after 7 days. In case of retention even on the 7th postoperative day, the catheter was kept for another 2 weeks following which there was a decrease in PVR below 100 ml in two patients. All patients were explained dual voiding of urine (patient was explained to sit and void again second time everytime they passed urine). Two patients, however, had a significant PVR at 5 years of follow-up and one patient developed retention insidiously over 5 years. These patients were clinically asymptomatic (increased PVR was Ultrasonography diagnosis) and thus dual voiding of urine sufficed in their management.

Incomplete evacuation in squatting position was seen in 13.33% (n = 4) at 5-year follow-up. These patients were able to pass urine while standing or in the English toilet. On examination, all four patients had grade II cystocele which had gradually developed over 5 years. The presence of cystocele leads to the change in urethral angle on squating which is the probable explanation for retention in squating position in patients. Dyspareunia was seen in 13.33% (n = 4) in which two patients had mesh tenderness which was attributed to dyspareunia, while other two had no tenderness at the mesh site. The exact cause for dyspareunia is not known, however, painful coitus post-TOT may be related to vaginal injury and narrowing vascular or neuronal detriment.\[11\] The application of local lignocaine jelly can help in these patients. It helps in relieving symptoms and no decrease in orgasm was seen. The incidence of dyspareunia for TOT in a comparative study between TOT and retropubic tape is 18.5%.\[12\]

TOT has now become the gold standard as it has high cure rates with minimal complication rates. Major vessel injury and bowel injury are exceedingly rare and are found in 0.07% and 0.04% of cases, respectively.\[10\] The 2017 Cochrane Review on MUS surgeries concluded that the retropubic route had higher morbidity and complication rates compared to the transobturator route.\[9\] The risk of bladder injury
with TVT is 5% which is reduced to less than 1% with TOT.[13] In our study, no vascular hemorrhage or bowel and bladder injury were noted. An unique complication specific to TOT is postoperative leg pain. The incidence is reported to be 2.3% to 15.9%. [10] However, we had zero incidence of postoperative leg pain. In 2018, however, a national pause was imposed by the government in the United Kingdom for the use of synthetic mesh in the treatment of stress incontinence. Although the mesh erosion rate is just 2.4%, the concern is that mesh-related complications post-MUS can adversely affect the psychiatric outcome of the patient.[14] Further studies are required to prove the safety and efficacy of mesh surgeries for SUI.

The strength of our study was a proper 5-year follow-up of the 30 patients included in the study. There was no surgeon bias as all surgeries were done by the same surgeon with his expertise in TOT. Furthermore, the same tape material was used in all patients.

The limitation of our study is the small sample size. Second, patient satisfaction was subjectively graded. There was no standard questionnaire followed for the same.

**Conclusion**

TOT has a high subjective and objective cure rate with good safety profile when performed by expert hands. It has now become the gold standard treatment for SUI due to its minimal complication rates and minimal invasive nature of the surgery. Associated pelvic floor defect should be repaired before TOT so that there is no change in urethral angle post-TOT.

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**Conflicts of interest**

There are no conflicts of interest.

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