

RESEARCH ARTICLE

Tension-free Vaginal Tape vs Tension-free Obturator Tape for Treatment of Genuine Stress Urinary Incontinence: A 5-year Follow-up

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ABSTRACT

Objective: To compare the effectiveness of tension-free vaginal tape (TVT) and tension-free obturator tape (TOT) in treatment of genuine stress urinary incontinence and study the related complications.

Materials and methods: About 150 cases with complaints of stress urinary incontinence were taken during 5-year period, and they were confirmed urodynamically. Exclusion criteria included patients with diabetes mellitus, neurological disorders, other forms of incontinence, uterovaginal prolapse, urinary tract infection, and pregnancy. Out of 150 cases, 70 underwent TVT procedure and 80 were taken up for TOT. The outcome was studied at the end of 5 years.

Results: The cure rate in the TOT group was 94%, which was slightly higher than the TVT group, which came out to be 90%. The failure rate in the TVT group was 1.1%, but no failure was encountered in the TOT group. However, the improvement rates were similar in each group. Comparing the complications in each group, the rate of bladder perforation and postoperative retention of urine was much higher in the TVT group. Postoperative voiding difficulties were also noticeably less in TOT group compared with TVT group. However, none of the cases in either group had *de novo* urgency.

Conclusion: Both the procedures are a safe and effective method of curing stress incontinence; however, owing to slightly higher improvement rates and lower complications rate, TOT should be preferred over TVT.

Keywords: Retropubic transvaginal tape, Transobturator tape, Urinary incontinence.

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INTRODUCTION

Urinary incontinence in women is a very common condition, which negatively affects the quality-of-life (QoL) of the patients. There is underreporting of the incidence as many women think that their incontinence is a normal result of pregnancy and aging. Others do not seek help because of embarrassment. Hannestad et al,¹ in a study among more than 34,000 women, found that only 25% of incontinent women seek help and the reasons cited were a long history of incontinence and the impact of urine loss on the patient's lifestyle.

The treatment of this condition has evolved over many years, and various modalities ranging from medical to surgical techniques have been tried with varying results. Of the various surgical procedures available like retropubic urethropexy, vaginal needle suspension procedures, periurethral bulking agents and slings, sling surgeries have emerged as the treatment of choice in recent times as the success rate of the procedure is comparable to retropubic urethropexy, which has been considered as the gold standard till date. Also, the sling surgeries have an added advantage of being minimally invasive, shorter learning curve for the beginners and shorter hospital stay, and very few postoperative complications for the patient.

The most successful sling surgery has been the tension-free vaginal tape (TVT), which can be done either through a retropubic route called as TVT or through the transobturator route known commonly as TVT-O. It is thought that the tape simulates the support mechanism of the pubourethral ligament, hence, providing a firm anchoring for the muscles associated with urethral closure. The objective of this study is to compare the effectiveness and outcomes by both the routes.

MATERIALS AND METHODS

A total of 150 cases of genuine stress urinary incontinence (GSUI) requiring surgery were selected from the Department of Obstetrics and Gynaecology and Department of Urology at Safdarjung Hospital, New Delhi, India. Nonpregnant, nonlactating females with GSUI confirmed on urodynamic study were included in the study. The patients were divided randomly into two groups of 70 and 80, who underwent TVT or tension-free

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obturator tap (TOT) respectively, and the outcomes of the two groups were then compared.

Exclusion criteria involved patients with overactive bladder, neurological disorders, diabetes mellitus, urinary tract infection, other types of incontinence (urge/mixed incontinence urodynamically proved as detrusor instability, overflow incontinence), uterovaginal prolapse with urethrocele, cystocele, and/or rectocele.

Preoperative Evaluation

History and Clinical Examination

All the patients underwent a thorough history taking, clinical examination, laboratory investigations, and urodynamics. The patients with complaints of leakage of urine on coughing, laughing, lifting heavy weight, or bending forward had detailed urological evaluation in terms of the duration, time of the day when affected more, number of times the leaking occurred, amount of urine leaked, symptoms suggestive of urinary tract infection, and associated sensory urgency. The clinical examination included a per-speculum and a per-vaginal examination to rule out uterovaginal prolapse in all the patients. Stress provocation test was performed in standing and supine position, with a comfortably filled bladder to confirm the finding of leakage of urine on stress.

Investigations

- Urine culture and sensitivity to rule out urinary tract infection
- Fasting blood sugar to rule out diabetes mellitus
- Transabdominal ultrasound for postvoid residual urinary volume
- *Urodynamic evaluation*: Uroflowmetry, urethral pressure profilometry, cystometrogram, and electromyogram. Urodynamic assessment was done to rule out any other associated factors like detrusor instability, obstructed urethra, or overflow incontinence. Thus, genuine stress incontinence was proved urodynamically. Residual volume on urodynamic assessment gave the idea about any component of obstructed outflow
- Valsalva leak point pressure (VLPP) was also assessed to know the associated sphincteric defect.

Postoperative Outcome and Documentation

The outcome of the treatment was evaluated at the end of 1, 3, and 6 months in terms of cure rate, improvement rate, and failure rate. Also, the intraoperative, immediate postoperative, and late postoperative complications were compared among the two groups.

RESULTS

The two groups compared were randomly distributed and the patient profile varied as shown in Table 1. Variables that were considered were the patient's age, parity, menstrual status, any sort of previous treatment taken for the particular problem, and other medical disorders.

The outcome of the procedure was documented at a follow-up of 1, 6 months, and 5 years, and when the outcomes were compared in terms of cure rates, improvement rates, and failure rates, it was found that TOT had slightly better cure rates (Table 2).

- *Cured*: subsymptom relief and no other voiding problem,
- *Improved*: *de novo* urgency or any other voiding difficulty.
- *Failed*: any complication requiring take down of tape or no subimprovement of symptoms.

Considering the intraoperative complications, there was no significant difference between the two procedures; however, a slightly higher rate of urinary retention was encountered in the immediate postoperative period after TVT. Higher rates of late postoperative complications, such as mesh erosion and voiding difficulties were also found with TVT when compared with TOT (Table 3).

Table 1: Demographic profile and symptomatology

	TVT (n = 70)	TOT (n = 80)
Age (years)	37–66	40–67
Parity	3 (2–8)	2 (2–5)
Menstrual status	28 (postmenopausal)	35 (postmenopausal)
Sensory urgency	9	8
Duration of incontinence	8 months–5 years	10 months–6 years
Previous treatment	2 – Kelly's repair 1 – Kegel's exercise	None
Any prolonged d/s or medication	1 – Depression 2 – Hypertensive	1 – Hypothyroid 1 – Hypertensive

Table 2: Results of the procedure

Outcome	TVT (n = 70)	%	TOT (n = 80)	%
Cured	63	90	75	94
Improved	6	8.9	5	6
Failed	1	1.1	0	0

Table 3: Comparison of the complications

Complication	TVT	TOT
Injuries	6 (8%) (bladder perforation)	2 (2.5%) (Urethral inj)
Increased bleeding/hematoma	None	None
Retention	14 (20%)	None
Signs of UTI	14 (20%)	16 (20%)
Erosion	1	None
Other voiding difficulties	14 (20%) (pain during micturition)	8 (10%) (postvoiding dribbling)

UTI: Urinary tract infection

Table 4: Five-year follow-up of both procedures

Sl. no.	Parameters	TVT	TOT	p-value
1	Subjective cure after 5 years	90%	94%	<0.05
2	Objective cure after 5 years	95%	100%	>0.05
3	QoL: UDI end scores for RPR vs TOR	11.40 ± 3.25	0	<0.05
4	QoL: IIQ end score for RPR vs TOR	12.05 ± 4.21	0	<0.05
5	Patient satisfaction rates	95%	95%	>0.05
6	Sexual problems	5%	10%	>0.05
7	Recommendation to a friend	95%	100%	>0.05

RPR: Retropubic route

COMPARISON OF RETROPUBIC TAPE AND TRANSOBTURATOR TAPE AFTER 5 YEARS

Table 4 considers the comparable subjective cure rates, reduced risk of intraoperative bladder injury, urethral injury, less voiding difficulties, shorter operating time, and duration of catheterization in TOT as compared with TVT.

Therefore, TOT as the primary choice for the treatment of SUI can be considered. Groin pain though higher with TOT is not life-threatening and is amenable to treatment and cure. Therefore, TOT should be offered as the first surgical choice in women seeking relief from SUI.

DISCUSSION

The primary aim of this study was to compare the two available procedures – TVT and TOT – for the treatment of SUI in terms of outcome and procedure-related complications.

The mean age in the present study was 45.05 ± 2.536 years for group I and 42.80 ± 1.876 years for group II, which is comparable in both groups, with no statistical significance ($p = 0.720$). Most of the patients in both the study groups were of age 35 to 45 years. The mean age in many studies was more than 50 years. This difference could be due to the overall higher life expectancy in the developing world.¹⁻³

The mean parity in group I was 3.1 ± 0.35 , while in study group II, mean parity was 3.2 ± 0.21 , with a mean of 3.10 and 3.20 respectively. In both the study groups, none of them was nulliparous. Increasing parity and vaginal delivery are related to an increased risk of stress incontinence as stated by Wilson et al.⁴

Mean body mass index (BMI) (in kg/m^2) was 25.30 ± 4.2 for group I and 26.40 ± 3.8 for group II, which is comparable in both groups with no statistical significance ($p = 0.713$) and none of the patients were obese in the present study. In a study by de Tayrac et al,⁵ mean BMI in TOT group was 24 (SD 3.21), and in TVT group was 25.2 (SD 4.3), which was similar to our study. The Norwegian Epidemiology of Incontinence in the County of

Nord-Trodelaag (EPICONT) study showed that a BMI of $\geq 40 \text{ kg}/\text{m}^2$ increased the risk of severe mixed incontinence sixfold compared with women of normal weight.⁶

In the present study, all the patients had pure SUI and none of the patients had sensory or motor urgency confirmed by the finding of stable detrusor on urodynamic evaluation. Only 10% in each group had very low VLPP (less than $60 \text{ cm H}_2\text{O}$), and those patients had severe SUI symptoms of longer duration with high preoperative incontinence impact questionnaire (IIQ) and urogenital distress inventory (UDI) scores. Most of the patients in TVT group (50%) and TOT group (45%) leaked moderate, which was mainly in the day (85% in TVT and 80% in TOT). In both the study groups, symptoms were persisting for a longer duration, i.e., 2.65 ± 0.46 years in TVT group and 3.32 ± 0.33 years in TOT group ($p = 0.503$).

Most of the studies conducted till date had included patients with both stress and mixed incontinence including patients with prolapse and previous incontinence surgery.

de Tayrac et al⁵ enrolled patients with urodynamically proven SUI with associated uterovaginal prolapse and excluding patients with predominant urge incontinence. Symptom duration of SUI in TVT group was 3.1 ± 1.4 years and in TOT group was 4 ± 4.3 years.

Studies conducted by Liapis et al,⁷ Riva et al,⁸ and Porena et al⁹ had mean duration of SUI symptoms for 3 to 4 years.

The outcome was assessed at the end of 5 years, and patients were considered cured if there was subjective symptom relief and no other voiding difficulty. Patients with relief of symptoms, but development of *de novo* urgency or any other voiding difficulty were considered improved, and failure was defined as any procedure-related complication that requires the take down of the tape or no subjective improvement of the symptoms.

Our study showed slightly higher cure rates of 94% with TOT as compared with 90% with TVT. Similarly, in a study by Porena et al,⁹ subjective cure rates were higher after transobturator procedure in comparison with retropubic procedure, i.e., 33/42 (78.6%) TOT vs 33/47 TVT (70.2%). A slightly higher rate of cure was also published by de Tayrac, with TOT (90%) as compared with TVT (83.9%). Both the studies have also shown a higher failure rate with TVT in comparison with TOT as concluded by our study also. According to 8 years follow-up in an Indian study by Trivedi et al,¹⁰ 209 women who had undergone TVT (101 patients) and TOT (108 patients) procedure stated similar cure rates of both procedures, i.e., 95% in TOT and 94.5% in TVT.

According to a recent Cochrane review (2009),¹¹ objective cure was assessed by 17 studies with 2,434 participants using a variety of measures, such as urodynamic

assessment, negative cough stress test, 1-hour pad test of ≤ 2 g, 1-hour pad test of ≤ 1 g, and 24-hour pad test of ≤ 5 g. The cure rate using the obturator route was significantly lower at 84 vs 88% for the retropubic route (relative risk: 0.96, 95% confidence interval [CI]: 0.93–0.99). The difference between the groups (4%) was not a statistically significant difference in the short term. There was heterogeneity in assessment criteria of objective cure rates as many studies included patient with prolapse and urge incontinence, so their cure rates were lower.

In a systematic review and metaanalysis of effectiveness and complications of TOT vs TVT, Latthe et al¹² assessed 11 randomized controlled trials including 1,261 women and showed equivalent cure rates in the TOT group vs TVT (odds ratio: 1.05; 95% CI: 0.64–1.70).

Difference in objective cure rates in our study, TVT (95%) vs TOT (100%), is statistically not significant ($p > 0.05$), which is in accordance with studies included in Cochrane (2009)¹¹ and systematic review by Latthe et al.¹²

Studying the complications of the procedures, Mellier et al¹³ have also reported an incidence of 8% for bladder injury with TVT, while no such injury was encountered with TOT. Our study also did not encounter any bladder injury with TVT; however, there was one case of urethral injury. This occurred in the female who had previously undergone Kelly's repair leading to some adhesions in that area. de Tayrac et al⁵ also reported a 10 times higher rate of bladder injury of 9.7% with TVT as compared with none with TOT. This reported that the high incidence of bladder injury with TVT is due to the placement of the tape, which is retropubically and in more proximity of the bladder in TVT rather than the obturator placement of the tape in TOT.

A postoperative complication like urinary retention is reported to be higher in TVT rather than TOT. Abouassaly et al¹⁴ showed a rate of retention up to 19.7% with TVT as compared with 1% with TOT. While we encountered a case of mesh erosion with TVT, Mellier et al¹³ reported it with TOT rather than TVT. This could be due to the inherent property of the tape *per se* rather than the approach of placement. Other complications like voiding difficulties were again higher with TVT as reported by Mellier et al,¹³ which is in sync with our study.

The present study confirmed the improved QoL in the patients treated by either TVT or TOT using validated questionnaire, although improvement observed was more in TOT as compared with TVT ($p < 0.05$), which is statistically significant and can be attributed to complications encountered in the TVT procedure. According to the recent Cochrane review (2009),¹¹ 11 of the 24 studies reported QoL data from women and the varieties of measures were used by different studies including IIQ-7, UDI-6, and others. The data were reported in different

ways, precluded in meta-analysis, and all studies found that women's QoL improved significantly after operation within each group, but no statistically significant differences were found between randomized TVT and TOT groups postoperatively.

Sexual function was not affected by the type of sling. The TOT and TVT had similar satisfaction rates and positive outlook toward the procedure in our study. Murphy et al¹⁵ examined 239 stress incontinent women treated with retropubic or transobturator procedure and found no significant difference in sexual function between the two groups. Another study by Long et al¹⁶ reported similar improved results in sexual functions after both procedures.

CONCLUSION

From the above data, it seems that both the procedures are safe and effective, with good patient satisfaction rates for the treatment of the condition; however, owing to the slightly higher cure rates and lower postoperative complications with TOT, it should be the preferred option.

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