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# A randomized trial of tension free vaginal tape and tension free transobturator tape for female stress urinary incontinence

**Neelu Yadav, Rajendra Prasad Ganguly, Gargi Pal, Khushboo and Ananya Agarwal**

**Abstract**
**Objective:** We compared success rates of tension free vaginal tape outside in method (TVT) and tension free transobturator tape outside in method (TOT) in case of female urodynamic stress urinary incontinence at 6 months.
**Material and method:** 80 patients with urodynamically proven stress urinary incontinence were randomized into TVT (40) and TOT (40) group after excluding urge incontinence and patients with a previous history of incontinence surgery. The outcome of surgical treatment was observed as objective and subjective cure rate and satisfaction score at 6 months.
**Results:** There was no significant difference between the groups for baseline characteristics. Mean operative time was significantly longer in the TVT group (35.9 min) as compared to TOT group (26.8 min) (p value<0.0001). The mean post void residual urine on the next day of surgery and at 6 months were insignificant (p value>0.05)
A case of mesh erosion was diagnosed at 6 months in TOT group. There was no major perioperative complications in either group. Time to return to normal activity were similar in both groups (p value>0.05) of patients. De novo urinary urgency developed in two (5%) patients in TVT group and one (2.5%) patient in TOT group (p value>0.05). The objective and subjective cure rates of TVT and TOT were comparable (85% vs 87.5% and 80% vs 85% respectively).
**Conclusion:** We concluded that both TVT (outside in) and TOT (outside in) procedures for surgical treatment of stress urinary incontinence were equally efficacious and safe.

**Keywords:** Female SUI, TOT, TVT, Incontinence surgery

## Introduction
Urinary incontinence is experienced by 25% of women and lifetime risk of undergoing a single operation for urinary incontinence or pelvic organ prolapse is 11% [1]. It is estimated to affect up to one third of women older than the age of 18 yrs, with a median age of 45 yrs [2].
Stress urinary incontinence (SUI), the most prevalent type of urinary incontinence (UI) [1], is the involuntary leakage of urine due to increased abdominal pressure during exertion, sneezing or coughing [3].
The rationale of the surgical treatment of SUI has changed over a past few years; because the techniques using urethral suspension were responsible for acute urinary retention and chronic voiding troubles, techniques recreating a backboard between the urethra and the vaginal anterior wall were developed [4].
Tension free vaginal tape (TVT) is a standard minimally invasive procedure used to treat urinary stress incontinence since 1995 when it was first described by Ulmsten [5, 6]. Although success ranges from 84 to 95%, complications described include bladder, bowel and major blood vessel injuries as well as post operative voiding difficulties [1] and de novo urgency and urge incontinence [7].
In 2001, Delorme [8] described a new method of inserting the tape, which passes through the obturator foramen (termed TOT, transobturator tape), thus theoretically avoiding some of the complications such as bladder perforation with a cure rate of 90.6%.
In 2003, de Leval [9] described TVT-O with tape passage through obturator foramen from inside to outside. Outcomes from several prospective multicenter randomized trials with short follow-up times have shown TVT-O to be as effective as TVT with similar cure rates and fewer post-operative complications [10, 11].

There have been several non- comparative studies that have reported good short term [10, 12] to medium term [9] success rates with either route but studies on Indian population is quite few [13].

Also, as outside in method of TVT procedure has not been practiced widely, we have performed this method in our study.

The aim of our study was to compare the success rates of tension-free vaginal tape outside in method and tension free transobturator tape outside in method at 6months as primary outcome and to compare the complications of tension free vaginal tape and transobturator vaginal tape like bladder injury, bowel injury, vascular injury, leg pain, erosion of tape, de novo urgency etc. in the two procedures.

## Materials and methods

### Study population

The study was performed in the Department of Gynecology & Obstetrics, R.G. Kar Medical College, Kolkata, India during the time period of one year (July 2011-June2012). The study was approved by the committee for Ethical consideration and Approval for Human Research, R.G. Kar Medical College and a written informed consent was obtained from every participant. Only patients with urodynamically proven stress incontinence were taken. Patients with urge incontinence, uterovaginal prolapse greater than stage I based on Pelvic Organ Prolapse Quantification staging system and those with voiding dysfunction( defined as maximum flow rate less than 15 ml per sec or post void residual urine 100 ml or greater) were excluded from the study. Patients with a history of previous continence surgery were also excluded from the study.

Success rate of the two surgical procedures was assessed at 6 months along with variables like operative time and time to return to normal activity. Also complications like bladder injury, bowel injury, great vessel injury, leg pain, erosion of mesh, de novo urgency were compared.

### Data collection

Data were collected from the different investigation reports and from the case record sheet where all the demographic data, procedure outcome and complications were written.

Randomisation was done by computer generated list randomised in blocks of 5 to ensure balanced allocation. Allocation concealment was done by numbered sealed opaque envelope. Due to the nature of the study surgeon and patient were not blinded. Assessor however was blinded.

Investigations like urine routine examination and culture sensitivity, ultrasonography of lower abdomen and KUB with urodynamic study were performed in all patients. A detailed history of urinary incontinence was taken. The following data were recorded such as age at surgery, body mass index (BMI), menopausal status, parity and number of pregnancies. An indepth physical examination was done before surgery. The examination included a cough stress test and Bonney test. After going through inclusion and exclusion criteria, patients enrolled in the study were randomized to undergo surgery either TVT or TOT. Surgical procedures were done by surgeons who were experienced.

TVT procedure was performed as follows;

The operation was carried out under spinal anaesthesia. The patient was placed in lithotomy position. A sagittal incision 2 cm long was made in the suburethral vaginal wall starting 1.5 cm from the external urethral meatus. After minimal bilateral para urethral dissections of the vaginal wall, tip of index finger was passed through the incision to reach till the perineal membrane (urogenital diaphragm).

Two minimal (0.4 cm) incisions, *5* cm apart, were made in the abdominal skin just above the superior rim of the pubic bone on either side of midline. Now, the tip of a 18G foley catheter mounted on a guide wire was placed in the bladder to keep the bladder neck away from the needle that is passed by moving the guidewire handle to the same side through which the TVT needle is passed. The tip of needle first crossed skin through the abdominal incision and then perforated the rectus sheath to enter the retropubic space. The needle tip just behind the pubic bone was brought down, guided by the index finger to the vaginal incision. The procedure was then repeated on the other side with a separate needle in same fashion but by directing the guide wire on the opposite side. After this, the guidewire along with the foley catheter was removed and cystoscopy was done to check any bladder injury by the needle. The end of the tape on the two sides were fixed to the eye of two needles and were pulled from the abdominal side so that the two ends of the tape come out through the abdominal incisions.

The tape was adjusted without tension under the urethra after keeping an artery forceps between the mesh and midurethra. The vaginal incision was then closed, after cutting the abdominal ends of the tape in the subcutaneous tissue without any fixation. Abdominal stab incisions were closed by antiseptic adhesive bandages and Foley catheterization was done.

TOT procedure was performed in same fashion as Delorme [8].

On the day of surgery, the following parameters were measured like procedure duration, pain severity after surgery using visual analogue scale at 12 hours and 24 hours. Operating time was calculated from incision start time to closure stop time. Post voidal volume was checked by ultrasonography on the next day of surgery after removal of catheter. If it was found to be more than 100 ml, bladder was recatheterised to be removed after 24 hrs. Post void residual urine was also assessed at 1week, 1 month, 3 months and 6 months of surgery. Post operative overall pain associated with surgery was evaluated on the next day of surgery, at 1 week, 1 month and 3 months by visual analogue pain scoring scale. Time to return to normal activity was evaluated at 1week, 1 month, 3 months and 6 months. At 6 months follow up visit, the surgical result, patient satisfaction and long term complications were also evaluated. Surgical result was evaluated by cough stress test with a comfortably full bladder.

The outcome of surgical treatment was observed as objective and subjective cure rate. Objective cure rate divided into 3 groups, including cured, improved and failed. Patients were considered cured of stress urinary incontinence if they had a negative cough stress test on examination, improved if they had no leakage on cough stress test on examination, but developed occasional urinary leakage during stress. However, this occasional leakage did not influence daily activities or required any further treatment. In patients who did not meet these criteria, treatment were considered failed.

Subjective cure rate was also divided into 3 groups, including cured, improved and failed. Patients were considered cured of stress urinary incontinence if there was negative cough stress test as experienced by patient and no reports of urinary leakage during stress, improved if they had no leakage on the cough stress test as experienced by themselves but developed occasional urinary leakage during stress. However this occasional leakage did not influence daily activities or required any further treatment. In patients who did not meet these criteria treatment were considered failed.

Patients were asked to describe their overall satisfaction with the surgical procedure by showing them visual analogue scale

(Likert 3 point scale) with three possible choices including very satisfied, satisfied and not satisfied. Very satisfied defined as per the image in visual analogue scale which also included patients who had decided to recommend the same procedure to other patients. Satisfied and not satisfied aiso defined as per the image in visual analogue scale.

**Statistical analysis**

Using a 65% objective cure rate for TVT, we required 40 patients per arm to detect a 25% difference in the cure rate by TOT with 80% power and alpha value of 0.05 [13].

Continuous variable were analysed by independent student 't' test or Mann-Whitney U test depending on the data normality. Categorical data were analysed by chi square or Fisher exact test, as appropriate. p value of<0.05 was considered to be statistically significant. Statistical analysis was done by Medcalc version 11.6(Belgium) software.

**Results**

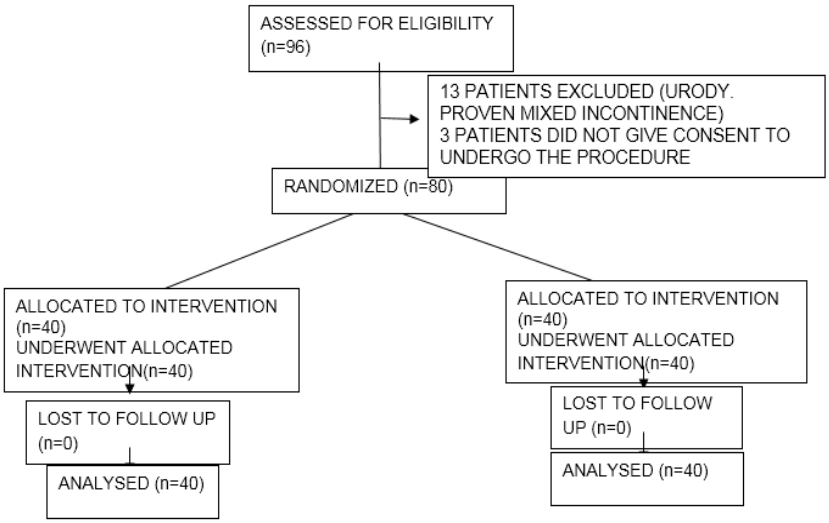


**Fig 1:** Flow diagram of the progress through the phases of a randomized trial.

This study was done on 80 patients with randomized allocation to undergo TVT and TOT procedures as described earlier. All patients were followed for a period of 6 months.

There was no significant difference between the groups for baseline characteristics such as age, parity, BMI, menopausal status, concomitant surgeries and previous surgery for incontinence or prolapse (Table 1). Furthermore, there was no significant difference, with regard to duration, severity of the symptoms and preoperative post void residual urine. All patients had urodynamically proven stress urinary incontinence.

There was no difference between type of anaesthesia given to either group.

The day after surgery, patients were allowed to pass urine after omission of Foley catheter. All patients passed urine normally and none required recatheterisation.

Mean operative time was significantly longer in the TVT group with a mean of 35.9 min as compared to a mean of 26.8 min in TOT group (p value<0.0001) (Table 2). Comparision of post void residual urine by ultrasonography done on the next day of surgery, at 1 week, 1 month, 3 months and 6 months in both groups showed no statistically significant difference. The mean post void residual urine on the next day of surgery was 47.15 cc in TVT patients and 44.7cc in TOT patients respectively which was not statistically significant (p value> 0.05) and that at 6 months were 33.32cc and 32.82 cc in TVT and TOT group of patients which was also not significant (p value>0.05).Similarly, post void residual urine measured at 1 week, 1 month and 3 months were not statistically different in either group of patients.

Only one patient in the TOT group complained of leg pain post operatively at 12 and 24 hours among 40 patients. Overall pain as analyzed by visual analogue scale on the next day of surgery, in patients who underwent concomitant surgery was 5.7cm and 6.3cm in TVT and TOT patients respectively( p value>0.05) and at 3 months, 0.5cm and 0.63cm in TVT and TOT patients respectively( p value>0.05). Overall pain at 1 week and 1 month were aiso similar in either group.

In those patients who did not underwent any concomitant surgery, overall pain scores was comparatively in lower range being 3cm and 2.75 cm on the next day of surgery (p value>0.05) and 0.33cm and 0.25 cm at 3 months(p value>0.05) in TVT and TOT groups respectively. The difference of overall pain as assessed at 1 week and 1 month were also not statistically significant in either groups.

A case of mesh erosion was diagnosed at 6 months of procedure in a patient of the TOT group. There was no major perioperative complication like bladder, bowel or major vascular injury in TVT and TOT group.

Time to return to normal activity were similar in both groups, with a mean of 10.09 days in TVT group and 9.78 days in TOT group (p value>0.05) of patients who underwent concomitant surgery. Those who did not underwent concomitant surgery, returned to normal activity earlier with a mean of 3.33 days and 2.88 days in TVT and TOT group of patients respectively, the difference being not significant (p value>0.05). De novo urinary urgency developed in two (5%) patients in TVT group and one (2.5%) patient in TOT group, the difference being not significant (p value>0.05).

Statistical analysis failed to detect any significant differences between TVT and TOT procedure with regard to objective cure rates at a follow up of 6 months. Thirty four (85%) and Thirty five (87.5%) women were objectively cured in the TVT and TOT groups respectively ($p$>0.05). Six (15%) patients were improved in TVT group and five (12.5%) in TOT group (p value>0.05).

**Table 1:** Baseline characteristics of both groups

| | TVT group(n=40) | TOT group (n=40) | p value |
|---|---|---|---|
| 1. AGE Yrs (MEAN±SD ) | 43.6± 6.73 | 42.15±6.33 | 0.32* |
| 2. Bmi Kg/M$^2$ (%) | | | |
| <19.99 | 2(5%) | 3(7.5%) | >0.05# |
| 20-24.99 | 6(15%) | 4(10%) | 0.73# |
| 25-29.99 | 23(57.5%) | 26(65%) | 0.64# |
| >30 | 9(22.5%) | 7(17.5%) | 0.77# |
| 3. Education (%) | | | |
| Graduate | 5(12.5%) | 4(10%) | >0.05# |
| Sec Level | 8(20%) | 10(25%) | 0.79# |
| Primarylevel | 23(57.5%) | 21(52.5%) | 0.82# |
| Uneducated | 4(10%) | 5(12.5%) | >0.05# |
| 4. Occupation (%) | | | |
| Heavy Work | 9(22.5%) | 10(25%) | >0.05# |
| Moderate Work | 27(67.5%) | 26(65%) | >0.05# |
| Light Work | 4(10%) | 4(10%) | 0.7# |
| 5. Religion (%) | | | |
| Hindu | 18(45%) | 19(47.5%) | >0.05# |
| Muslim | 22(55%) | 21(52.5%) | >0.05# |
| 6. Parity (%) | | | |
| Nulliparous | 2(5%) | 3(7.5%) | >0.05# |
| Multiparous | 38(95%) | 37(92.5%) | >0.05# |
| 7. Menopausal Status (%) | | | |
| Perimenopausal | 17(42.5%) | 19(47.5%) | 0.82# |
| Postmenopausal | 23(57.5%) | 21(52.5%) | 0.82# |
| 8. Previous Surgeries (%) | | | |
| Incontinence | 0% | 0% | |
| Hysterectomy | 1(2.5%) | 0% | >0.05# |
| 9. Pre-Op Clinical Parameter | | | |
| SYMP DURN Mths (MEAN±SD) | 10.85±7.11 | 13.33±8.94 | 0.19* |
| Prolapse,Popq Stage1(%) | 25(62.5%) | 27(67.5%) | 0.81# |
| PVRU Cc (MEAN±SD) | 56.98±8.23 | 57.95±6.16 | 0.55* |
| 10. Concomitant | | | |
| Surgery (%) | 34(85%) | 32(80%) | 0.76# |

*student unpaired t test
# chi square test

**Table 2**: Comparision of perioperative outcomes and postoperative complications in patients with tvt and tot

| | TVT (n=40) | TOT(n=40) | p value |
|---|---|---|---|
| Operative Time Mins (Mean±SD) PVRU cc (MEAN±SD) | 35.9±4.45 | 26.88±1.65 | <0.0001* |
| On next day of surgery | 47.15±6 | 44.7±5.33 | 0.06* |
| At 1 week | 43.12±5.07 | 41.18±4.48 | 0.07* |
| At 1 month | 39.05±5.86 | 37.25±3.90 | 0.1* |
| At 3 months | 35.22±5.32 | 33.45±4.18 | 0.1* |
| At 6 months | 33.32±5.49 | 30.82±4.11 | 0.45 * |
| LEG PAIN (%) | | | |
| AT 12 hrs | 0% | 1(2.5%) | >0.05# |
| At 24 hrs | 0% | 1(2.5%) | >0.05# |
| Overall Pain With Concomtant Surgery cm (MEAN±SD) | | | |
| On the next day of surgery | 5.7±1.57 | 6.31±1.62 | >0.05* |
| At 1 week | 2.7±0.97 | 3.44±1.16 | >0.05* |
| At 1 month | 0.94±1.01 | 1.44±1.05 | >0.05* |
| At 3 months | 0.5±0.92 | 0.63±0.94 | >0.05* |
| Overall Pain Without Concomtant Surgery cm (MEAN±SD) | | | |
| On the next day of surgery | 3±1.09 | 2.75±1.04 | >0.05* |
| At 1 week | 1.33±1.03 | 1.5±0.92 | >0.05* |
| At 1 month | 0.67±1.03 | 0.5±0.92 | >0.05* |
| At 3 months | 0.33±0.82 | 0.25±0.7 | >0.05* |
| Injuries (%) | 0% | 0% | |
| Mesh Erosion (%) | 0% | 1(2.5%) | >0.05# |
| Time To Return To Normal Activity Days (MEAN±SD) | | | |
| With concomitant surgeries | 10.09±2.19 | 9.78±3.78 | >0.05* |
| Without concomitant surgeries | 3.33±0.51 | 2.88±0.83 | >0.05* |
| De Novo Urgency (%) | 2(5%) | 1(2.5%) | >0.05# |

*student unpaired t test
# chi square test

Also, there was no significant differences between TVT and TOT procedure with regard to subjective cure rates at a follow up of 6 months (Table 3). Thirty two (80%) and thirty four (85%) women were subjectively cured in the TVT and TOT groups respectively ($p$>0.05). Eight (20%) patients were improved in TVT group and six (12.5%) in TOT group (p value>0.05).

Regarding satisfaction scoring, thirty (75%) and thirty one (77.5%) women expressed to be very satisfied in the TVT and TOT groups respectively ($p$>0.05). Ten (25%) and eight (20%) patients were satisfied in the TVT and TOT groups respectively ($p$>0.05). One (2.5%) was not satisfied in TOT group ($p$>0.05).

**Table 3**: Surgical result in patients of tvt and tot

| | TVT (n=40) | TOT (n=40) | p value |
|---|---|---|---|
| Objective Cure Rate (%) | | | |
| Cured | 34(85%) | 35(87.5%) | >0.05# |
| Improved | 6(15%) | 5(12.5%) | >0.05# |
| Failed | 0% | 0% | |
| Subjective Cure Rate (%) | | | |
| Cured | 32(80%) | 34(85%) | >0.05# |
| Improved | 8(20%) | 6(15%) | >0.05# |
| Failed | 0% | 0% | |
| Level Of Satisfaction (%) | | | |
| Very satisfied | 30(75%) | 31(77.5%) | >0.05# |
| Satisfied | 10(25%) | 8(20%) | >0.05# |
| Not satisfied | 0% | 1(2.5%) | 0.78 # |

# chi square test

## Discussion

In our study, we found both TVT and TOT procedures for surgical treatment of stress urinary incontinence to be equally efficacious and safe. The objective and subjective cure rates of TVT and TOT were comparable (85% vs 87.5% and 80% vs 85% respectively), the difference being not statistically significant. Also, the risk of complications were minimal in either operations.

Various studies as performed by Ulmsten *et al*. [5], Nilsson *et al*. [14], Debodinance *et al*. [15] reported an incidence between 0.8% to 21% of bladder perforation, stating it to be the most common complication occurring during TVT procedure. In our study, we did not observe any case of bladder, bowel or vascular injury during TVT or TOT procedure.

TOT is the same in concept as TVT but it differs from TVT in that, rather than passing through the retropubic space, sling materials are drawn through the obturator foramina. The theoretical advantage of TVT-O is that the retropubic space is not violated and, therefore, the risk of bladder, bowel or major vascular injury is absent [16, 17]. But on the other hand, Pushkar *et al*. [18] stated that TOT procedures are associated with higher incidence of vaginal lacerations than retropubic procedures and it is possible that this may be responsible for the slightly higher incidence of mesh erosion in the transobturator approach.

We found only one case of mesh erosion in the TOT group at the follow up of 6 months. Latthe *et al*. [10] had observed vaginal tape erosion rates to be 2.2% in TVT and 3.6% in TOT procedures. The mean time for the onset of erosion after sling insertion was 11.2 months [19]. Another potential advantage of TOT is the sling orientation, similar to a natural hammock shape, which may result in a lower incidence of retention and/or de novo urgency. It is generally accepted that suburethral insertion of the tape has an obstructive effect, which increases urethral resistance and, therefore, may affect voiding function [16, 17].

Klutke *et al*. [20], Jaquetin *et al*. [21], Karram *et al*. [22] noted transient urinary retention ranging from 2.3% to 27% after TVT insertion. de Tayrac *et al*. [4] did not find any difference in bladder outlet obstruction in two groups though moderate to severe obstruction occurred in 11.1% versus 17.3% in the TOT and TVT group respectively.

There was no case of urinary retention observed in our study in both patient groups as none in either group required recatheterisation after omission of foley catheter on the next post-operative day.

We did not notice any significant difference in post-void residual urine as quantitated by ultrasonography on the next day of surgery, at 1 week, 1 month, 3 months and 6 months following surgery.

We observed two (5%) cases of de novo urinary urgency in TVT group and one (2.5%) case in TOT group. Wang *et al*. [23] had noted 9(5.8%) and 6 (4.1%) patients in their follow up complaining of de novo urgency in TVT and TOT group respectively. Also Lee *et al*. [24] observed 4(6.6%) cases of de novo urgency in TOT group and none in TVT group in post operative period.

In a study performed by Latthe *et al*. [10], leg/groin pain was experienced more in TOT group than in TVT group (OR 9.34).

Leg/groin pain was experienced by 26.4% of women in the TOT group but by only 1 (1.7%) in the TVT group by Teo *et al*. [13]. Groin pain was also more commonly reported in the TVT-O group by Laurikainen *et al*. [25] (1.5 vs 16%, $p$<0.001) and it seemed to last longer.

In our study one case of leg pain in TOT group presenting at 12 and 24 hours of operative procedure. The pain did not persisted long as seen during follow up period, patient had no groin pain at 1 week, 1 month and 3 months of operative procedure.

Also, overall pain as assessed by visual analogue pain scoring system on the next day of surgery, at 1 week, 1 month and at 3 months were not different significantly in TVT and in TOT group. As obvious, overall pain in patients who underwent concomitant surgery was significantly more in either group as compared to those patients who did not underwent concomitant surgeries.

We observed significant difference between the operative time of two procedures, the operative time during TVT procedure being longer than TOT procedure. The difference may be due to use of cystoscopy during TVT procedure.

Zullo *et al*. [26] and Wang *et al*. [23] stated in the study that the difference of operative time may result largely from the cystoscopy procedure carried out in the TVT group. Teo *et al*. [13] noted similar operative time with a median of 20 mins and 22

mins in TVT group and TOT group but this study included the use of cystoscopy during both procedures.

In our study, the time to return to normal activity was similar in both groups, though it was more in patients who also underwent concomitant surgeries like vaginal hysterectomy, laparoscopic assisted vaginal hysterectomy, anterior colporrhaphy and posterior colpo-perineorrhaphy.

Lee *et al*. [24] found a mean of 5.2 days and 4.9 days time to return to normal activity in his study.

Lee *et al*. [24] observed a cure rate of 86.3% in each group at the end of one year. Teo *et al*. [13] noted similar cure rates at 6 months follow up in both groups.

Liapis *et al*. [27] found a subjective cure rate of 74.6% in TVT group and 73.9% in TOT group and objective cure rate of 90% and 89% in TVT and TOT respectively.

In our study subjective cure rates were 85% in TVT group and 87.5% in TOT group, the difference being not significant statistically.

15% patients in TVT group and 12.5 % in TOT group were improved in our study.

One of the limitation of our study was that the follow up period was short i.e. 6months. Second limitation, in our study was that, about 80-85 % of patients had undergone the surgery for SUI along with a concomitant surgery for other pathology associated, so the outcome measures like time to return to normal activity and post operative pain got affected due to the concomitant surgery. The number of patients who have undergone only TVT or TOT is less (15% vs 20%).

The strength of our study was that we have done TVT by outside in method which is not widely practiced. The inside out method of TVT is widely practiced and has sufficient literature about the method regarding cure and complications.

We have found this (outside in TVT) method to be effective and safe.

In our study, another strength was that no case was lost to follow up. As because all the patients in our study had pre-operative urodynamic study to confirm the diagnosis of stress urinary incontinence and to rule out urge incontinence, so the result of our study is not generalisable in a population where urodynamic study is not done (either due to non availability of urodynamic study or where clinical examination is the only mode of diagnosis).

We may plan in future the same study with bigger sample size, as the difference in the objective and subjective cure rates of TVT vs TOT is very small.

To get a statistically significant difference in the outcome and even complications, the study must have a bigger sample size.

**Disclosure:** The authors declare no conflicts of interest.

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