

Adjustment of tension applied in transobturator tapes in females with intrinsic sphincteric deficiency: Two centers' prospective, comparative, randomized surgical trial

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Abstract

Objectives: Stress incontinence is the most common type of urinary incontinence in females. Recently, the gold standard treatment is mid-urethral tapes, however their efficacy is questioned in intrinsic sphincter deficiency (ISD). In our study, we try to adjust the tension applied during transobturator tapes (TOT) to evaluate its effectiveness in ISD, in order to prevent obstruction or failure and persistence of stress urinary incontinence.

Materials and Methods: This study was prospectively conducted on eighty female patients having ISD, presenting at the Urology Departments in Alexandria and Minia University Hospitals. The patients were randomly assigned to two groups, with Group I including forty patients, who underwent TOT using tension-free technique, and Group II including forty patients using our new tension adjustment technique under saddle anesthesia. Patients filled the International Continence Questionnaire and Urinary Distress Inventory and did pressure flow study pre- and postoperatively. Postoperatively, the patients filled Patient Global Impression of Improvement and underwent translabial ultrasound (U/S) to estimate the distance between the tape and the urethra.

Results: In Group I, 70% of the patients were cured with mean Valsalva leak point pressure (VLPP) of 51.43 ± 3.39 preoperatively, 20% were not improved, and 10% were improved with a mean VLPP of 44.5 ± 3.54 preoperatively, which increased to 86 ± 4.24 postoperatively. In Group II, 95% of the patients were cured with a mean VLPP of $50.74 \text{ cmH}_2\text{O} \pm 6.56$ preoperatively and 5% improved but not cured with a mean VLPP of $31 \text{ cmH}_2\text{O}$ preoperatively, which increased to $127 \text{ cmH}_2\text{O}$ at a bladder capacity of 400 ml. All patients in both groups underwent translabial U/S 6 months postoperatively. The distance between the mid-tape and the outer urethra measured by translabial US showed no significant difference between the two studied groups.

Conclusion: Performing TOT using our tensioned proposed technique in ISD seems to be effective and with low morbidity. Intraoperative adjustment of tension using Valsalva maneuver under saddle anesthesia gives better outcomes than the conventional tension-free technique. The concept of tension-free vaginal tape should be challenged.

Keywords: Adjustment, intrinsic sphincter deficiency, stress incontinence, transobturator tape

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INTRODUCTION

The most common subtype of urinary incontinence in females is stress urinary incontinence (SUI). Evidence from published data show that 50% of incontinent females will manifest with genuine SUI, with an additional 30% of them experiencing mixed urinary incontinence (MUI).^[1]

SUI is classified into two main subtypes: urethral hypermobility which is mainly due to weakness of the supporting tissues of the urethra, or intrinsic sphincter deficiency (ISD) due to defective urethral sphincter mechanism.^[2]

Transvaginal tapes (TVT) and transobturator tape (TOT) are currently considered the gold standard treatment modality of SUI.^[3] These tapes are supposed to be placed in a tension-free manner. Recent reports noted the long-term effectiveness of the TOT procedure, with success rate of 80%–95%. Although the initial cure rate of TOT was high, it appeared to be decreased over time.^[4-6]

Ideally, the tape should be placed with a proper tension at an ideal distance from the urethra described as tension free which was described as a “Metzenbaum scissor,” equivalent to a distance of 3–5 mm (mm).^[7]

One of the complications for mid-urethral tapes is diminished urine flow after the tape. This is thought to be caused by urethral obstruction due to increased tension of tape on the urethra.^[8] Urinary retention has been reported in 0%–5% of patients undergoing the mid-urethral tapes.^[9] On the contrary, persistent SUI postoperatively may be caused by loose tape due to inadequate tension applied to the mid-urethra.^[10]

In our study, we try to adjust or standardize the tension applied during TOT procedures to evaluate its effectiveness for the treatment of females with ISD, in order to prevent obstruction caused by increased tension of the tape, or failure and persistence of SUI due to loose tape.

MATERIALS AND METHODS

Institutional review board approval was obtained at the Faculties of Medicine of Alexandria and Minia Universities. This study was prospectively conducted on eighty consecutive female patients having ISD, presenting at the Urology Department, Alexandria Main University Hospital, and at the Urology Department, Minia University Hospital, from January 2017 till July 2019, as shown in the consort diagram [Figure 1].

The patients were randomly assigned using closed envelope technique to two groups:

- Group I: Forty female patients with ISD who underwent TOT (DynaMesh[®]) using the conventional tension-free technique (defined as the distance between TOT and urethra as a visible distance of few millimeters by using Metzenbaum scissor)
- Group II: Forty female patients with ISD. The procedure was performed under saddle spinal anesthesia, to make the patient bear down and cough intraoperatively. They underwent new tension adjustment technique (once the tape is passed bilaterally through the obturator foramina, the bladder is filled with 200 ml of saline, the catheter is withdrawn, and the patient is asked to bear down to demonstrate the leakage). Further pulling of the tape from both ends by hands to increase the tension till no leakage occurs with bearing down.

Inclusion criteria included female patients more than 18 years old, those with ISD (Valsalva leak point pressure [VLPP] <60 cmH₂O by filling cystometry), and females with MUI with predominant SUI.

Virgin females; females less than 18 years old; those with neurogenic bladder, diabetes, (postvoid residual [PVR]) urine >100 ml; females with uterine or cervical malignancy; and those with vaginal bleeding and pelvic inflammatory diseases were excluded from the study.

Each patient was subjected to the following:

Preoperatively

1. Informed consent signed by the patient explaining possible outcomes and possible complications of the procedure
2. Thorough history taking regarding the age, parity status, menstrual history, medical history, and previous surgical history
3. Complete physical examination, including neurological and urogynecological examination
4. Stress test with half-filled bladder at 200–250 ml in semi-setting and standing positions.
 - a. Symptom-specific Questionnaires, such as International Continence Questionnaire and Urinary Distress Inventory (UDI-6)
 - b. Free uroflowmetry and pressure flow study (PFS)
 - c. Ultrasound (U/S) abdomen and pelvis with PVR estimation.

Postoperative follow-up included the following:

- All patients were checked for spontaneous voiding and PVR should be <100 ml before discharging the next day of surgery.

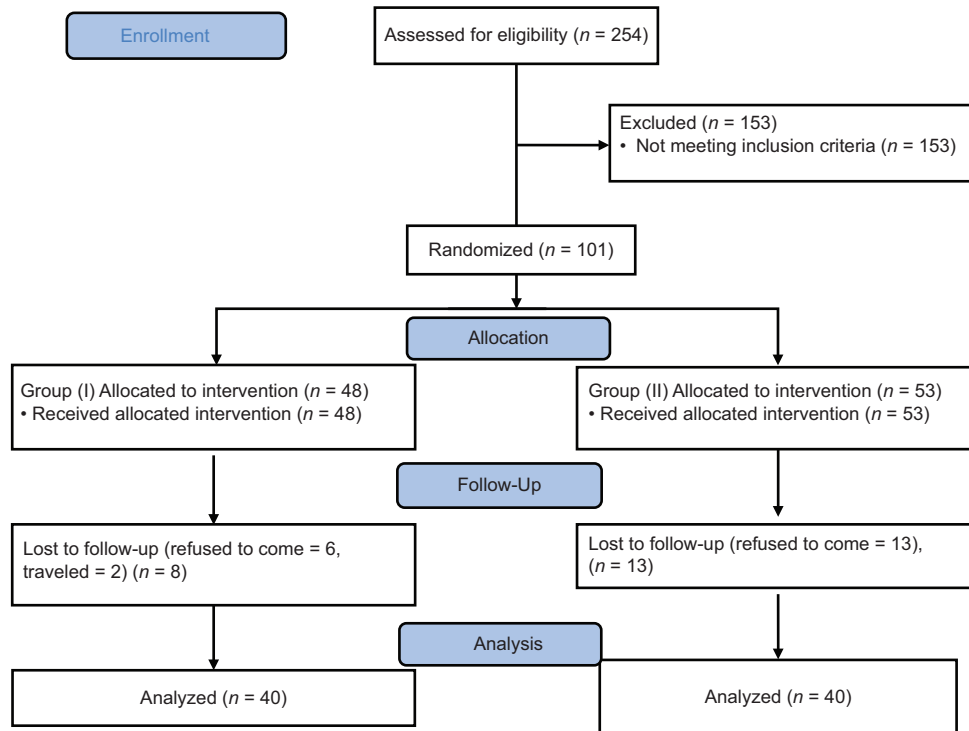


Figure 1: CONSORT flow diagram

- After 6 months:
 - Patient satisfaction, by Patient Global Impression of Improvement (PGI-I)^[11]
 - Stress test with half-filled bladder in semi-setting and standing positions
 - Symptom-specific questionnaire: ICIQ-SF^[12] and UDI-6^[13]
 - Free uroflowmetry and PFS
 - U/S abdomen and pelvis with PVR estimation
 - Translabial U/S to estimate the distance in millimeters between the center of the placed tape and the inner muscular coat of the urethra sparing the urethral mucosa and correlate it with clinical findings. The U/S was performed in the lithotomy position with filled bladder using a vaginal 4–9 MHz probe (Ultrasound Machine GE Voluson 730 PRO, USA). They were performed by the same radiologist who is experienced in urogynecological imaging.

Cure was defined as negative stress test postoperatively (half-filled bladder), and no demonstration of leakage during UDS (no VLPP). Improvement was defined as negative or positive stress test postoperatively, and increased VLPP postoperatively on UDS.

Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0 (IBM Corp, Armonk,

NY, USA) Qualitative data were described using number and percent. The Kolmogorov–Smirnov test was used to verify the normality of distribution. Quantitative data were described using range (minimum and maximum), mean, standard deviation, and median. Significance of the obtained results was judged at the 5% level.

The used tests were

1. Chi-square test or categorical variables: to compare between groups
2. Fisher's exact or Monte Carlo correction: correction for Chi-square when >20% of the cells have expected count <5
3. Student t-test: For normally distributed quantitative variables, to compare between the two studied groups
4. Paired *t*-test: For normally distributed quantitative variables, to compare between two periods (pre and post)
5. Mann–Whitney test: for abnormally distributed quantitative variables, to compare between the two studied groups
6. Wilcoxon signed-rank test: for abnormally distributed quantitative variables, to compare between two periods (pre and post).

Sample size was calculated using G* Power software version 3.1.9.4 and with test family (t-tests), type of power analysis (computed required sample size given, power and effect

size), input parameters, effect size = 0.64, error = 0.05, power (1 - 0.8 and with assuming allocation ratio N1/N2 = 1) resulting output parameters were sample size for each group forty patients. This yielded a total sample size of eighty patients.

RESULTS

Eighty female patients were included in our trial. They were divided into two groups:

- Group I: Forty female patients, who were treated using conventional technique
- Group II: Forty female patients, who were treated using our proposed technique.

The mean gravidity of Group I was 4.60 ± 1.73 with a range of 3–8, whereas the mean parity was 3.60 ± 1.93 with a range of 2 to 7 deliveries. Twenty-two patients in this group were premenopausal, and three patients underwent abdominal hysterectomy.

The mean gravidity of Group II was 4.50 ± 2.06 with a range of 2–9, whereas the mean parity was 3.60 ± 1.50 with a range of 2–7 deliveries. Fifteen patients were premenopausal, and two patients in this group underwent abdominal hysterectomy as shown in Table 1.

Thirty patients in Group I complained of coital urinary incontinence preoperatively, with only eight patients still complaining postoperatively. In Group II, 22 patients complained of coital urinary incontinence, and they were all cured of it postoperatively [Table 2].

All patients in both groups underwent pressure-flow study preoperatively and 6 months postoperatively.

Table 3 shows the results of PFS in both groups.

Twenty patients from Group I had detrusor overactivity (DO), which persisted in 16 patients postoperatively. In Group II, twenty patients had DO, which remained in 14 of them postoperatively.

In Group I, 28 patients (70%) were cured with a mean VLPP of 51.43 ± 3.39 preoperatively, 8 patients (20%) were not improved with a mean VLPP of 36.5 ± 7.05 preoperatively and 43.25 ± 5.74 postoperatively, and four patients (10%) were improved but not cured with a mean VLPP of 44.5 ± 3.54 preoperatively, which increased to 86 ± 4.24 postoperatively.

In Group II, 38 patients (95%) were cured with a mean VLPP of $50.74 \text{ cmH}_2\text{O} \pm 6.56$ preoperatively and two

patients (5%) improved but not cured with a mean VLPP of $31 \text{ cmH}_2\text{O}$ preoperatively, which increased to $127 \text{ cmH}_2\text{O}$ at a bladder capacity of 400 ml.

All patients in both groups underwent translabial U/S 6 months postoperatively. The distance between the mid-tape and the outer urethra measured by trans-labial US showed no significant difference between the two studied groups, with the mean distance in Group I of $0.41 \text{ cm} \pm 0.09$ and $0.37 \text{ cm} \pm 0.08$ in Group II [Figure 2].

Patients in both groups underwent ICIQ-UI SF and UDI-6 questionnaires preoperatively and 6 months postoperatively. The total scores of ICIQ-SF and UDI-6 showed statistically significant improvement postoperatively in both groups ($P < 0.001$). The improvement was markedly statistically significant in Group II ($P = 0.024$). The mean PGI incontinence questionnaire in Group I was 1.85 ± 1.27 and in Group II, it was 1.15 ± 0.37 , and the improvement was statistically significant in Group II ($P = 0.027$).

DISCUSSION

TVT was first described by Ulmsten and Petros.^[14] It has a cure rate of 74%–86% in women with ISD, but it has significant intraoperative complications with considerable morbidity.^[15]

In 2001, Delorme described TOT. This procedure provides more anatomical position of the tape and less complications.^[16] It showed long-term success rate of 80%–95% in women with SUI.^[3]

Mesh use in the vagina has been questioned a lot recently. In April 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of cystocele to stop selling and distributing their products immediately. The

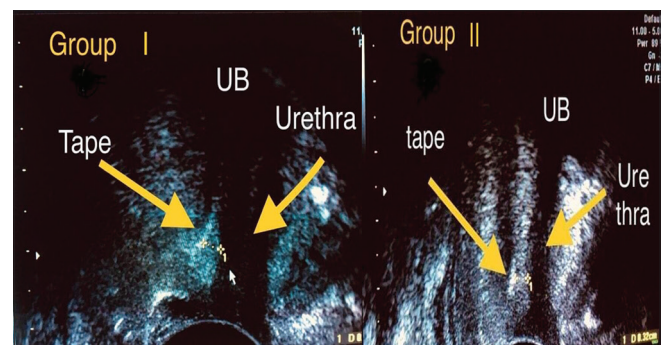


Figure 2: (Left): Translabial ultrasound image showing the distance between the mid-tape and the outer muscular layer of the urethra after the conventional technique. (Right) Translabial ultrasound image showing the distance between the mid-tape and the outer muscular layer of the urethra after our proposed technique

Table 1: The demographic characteristics of both groups

| | Group I (n=40), n (%) | Group II (n=40), n (%) | Test of significant | P |
|--------------------------|-----------------------|------------------------|---------------------|---------------------|
| Marital status | | | | |
| Married | 19 (95.0) | 19 (95.0) | $\chi^2=0.00$ | 1.000 ^{FE} |
| Widow | 1 (5.0) | 1 (5.0) | | |
| Age (years) | | | | |
| Minimum-maximum | 32.0-60.0 | 34.0-70.0 | $t=1.196$ | 0.240 |
| Mean±SD | 49.20±6.54 | 52.30±9.57 | | |
| Median | 50.0 | 52.50 | | |
| Weight (kg) | | | | |
| Minimum-maximum | 63.0-101.0 | 66.0-105.0 | $t=0.043$ | 0.966 |
| Mean±SD | 82.60±11.03 | 82.75±10.85 | | |
| Median | 82.0 | 80.0 | | |
| Height (cm) | | | | |
| Minimum-maximum | 158.0-178.0 | 157.0-172.0 | $t=1.224$ | 0.229 |
| Mean±SD | 166.9±5.94 | 165.0±3.94 | | |
| Median | 166.0 | 165.0 | | |
| BMI (kg/m ²) | | | | |
| Minimum-maximum | 24.51-37.55 | 25.78-37.65 | $t=0.617$ | 0.541 |
| Mean±SD | 29.66±3.82 | 30.38±3.52 | | |
| Median | 29.18 | 30.84 | | |

χ^2 : Chi-square test, FE: Fisher's exact, t : Student's t -test, U: Mann-Whitney test, P: P value for comparing between the two groups, Group I: Conventional technique, Group II: New technique, BMI: Body mass index, SD: Standard deviation

Table 2: The comparison between the two studied groups according to coital urinary incontinence

| Coital urinary incontinence | Group I (n=20), n (%) | Group II (n=20), n (%) | χ^2 | P |
|-----------------------------|-----------------------|------------------------|----------|---------------------|
| Preoperative | 30 (75.0) | 22 (55.0) | 1.758 | 0.185 |
| CI insertion | 24 (60.0) | 18 (45.0) | 0.902 | 0.342 |
| CI orgasm | 18 (45.0) | 14 (35.0) | 0.417 | 0.519 |
| Postoperative | 8 (20.0) | 0 (0.0) | 4.444 | 0.106 ^{FE} |
| CI insertion | 8 (20.0) | 0 (0.0) | 4.444 | 0.106 ^{FE} |
| CI orgasm | 6 (15.0) | 0 (0.0) | 3.243 | 0.231 ^{FE} |
| Percentage of improvement | 73.3 | 100 | 3.467 | 0.113 ^{FE} |

χ^2 : Chi-square test, FE: Fisher's exact, P: P value for comparing between the two groups, Group I: Conventional technique, Group II: New technique, CI: Coital urinary incontinence

agency had reclassified them into class III (high risk) in 2016.^[16] This led many countries to stop using any synthetic meshes in the vagina, including tapes. However, concerning mid-urethral tapes, FDA recommendation was only to submit a voluntary report about any problems experienced with synthetic slings through Medwatch, the FDA Safety Information and Adverse Event Reporting program. The current knitted polypropylene tape was not recalled by the FDA and was found to be safe and effective.

Ford and Ogah^[17] reviewed 55 studies comparing retropubic and TOTs in the treatment of SUI or MUI with associated ISD. Subjective cure was 85.5% for TVT group and 75.4% for TOT group. Objective cure assessed by urodynamics showed no significant difference in both groups (76% for TVT and 69% for TOT).

Gungorduk *et al.*^[18] also compared the effect of TVT and TOT in the treatment of ISD. The overall cure rate was 93.3% and 82.5% for TVT and TOT consecutively after 1 year, which decreased to 78.3% and 52.5% after 4 years for TVT and TOT, respectively. Popovic *et al.*^[19] evaluated the TOT efficacy in the treatment of ISD and

reported 70% cure rate after short-term follow-up of 6–12 months.

The previously mentioned studies were in concordance with our results in the conventional tension-free technique arm (Group I). Nearly 70% of the patients were cured objectively (no leak), and only 10% were improved but not cured. Persistent incontinence was found in 20% of the patients.

The main aim of treatment of females with ISD is to restore continence without creating obstructive complications, using a simple minimally invasive procedure with low morbidity and complication rate.

Women with ISD have more severe incontinence than women with SUI and urethral hypermobility.^[20] Tape location and tension are among the most important investigated factors that may affect surgical outcome of mid-urethral slings.^[21,22]

Borazjani *et al.*^[23] evaluated the views of the surgeons on sling tensioning during surgery for female SUI using

Table 3: The results of pressure flow study in both groups

| | | Group I (n=40) | Group II (n=40) | Test of significant | P |
|------------|-----------------|----------------|-----------------|---------------------|--------|
| VV | Preoperative | | | | |
| | Minimum-maximum | 300.0-480.0 | 300.0-480.0 | t=0.211 | 0.834 |
| | Mean±SD | 358.2±46.05 | 361.2±43.83 | | |
| | Median | 347.5 | 347.5 | | |
| | Postoperative | | | | |
| | Minimum-maximum | 240.0-450.0 | 300.0-500.0 | t=0.792 | 0.443 |
| | Mean±SD | 330.40±52.9 | 366.0±44.63 | | |
| | Median | 319.50 | 358.0 | | |
| | P ₁ | 0.436 | 0.123 | | |
| Qmax | Preoperative | | | | |
| | Minimum-maximum | 20.0-29.0 | 20.0-30.0 | t=0.710 | 0.482 |
| | Mean±SD | 24.95±2.39 | 24.4±2.50 | | |
| | Median | 25.0 | 24.0 | | |
| | Postoperative | | | | |
| | Minimum-maximum | 20.0-29.0 | 20.0-28.0 | t=1.965 | 0.057 |
| | Mean±SD | 24.70±2.62 | 23.10±2.53 | | |
| | Median | 24.50 | 23.0 | | |
| | P ₁ | 0.716 | <0.001* | | |
| P det/Qmax | Preoperative | | | | |
| | Minimum-maximum | 7.0-13.0 | 7.0-15.0 | U=129.5 | 0.055 |
| | Mean±SD | 9.90±1.74 | 11.5±2.70 | | |
| | Median | 10.0 | 11.50 | | |
| | Postoperative | | | | |
| | Minimum-maximum | 5.0-14.0 | 10-18.0 | U=79.50* | 0.001* |
| | Mean±SD | 10.50±2.40 | 13.95±2.87 | | |
| | Median | 11.0 | 13.0 | | |
| | P ₁ | 0.330 | 0.007* | | |
| PVR | Preoperative | | | | |
| | Minimum-maximum | 0.0-20.0 | 0.0-20.0 | U=199.0 | 0.978 |
| | Mean±SD | 10.20±7.52 | 11.30±4.12 | | |
| | Median | 11.50 | 11.0 | | |
| | Postoperative | | | | |
| | Minimum-maximum | 0.0-30.0 | 0.0-20.0 | U=184.50 | 0.669 |
| | Mean±SD | 10.85±9.42 | 12.50±5.18 | | |
| | Median | 12.50 | 13.0 | | |
| | P ₁ | 0.776 | 0.218 | | |

*Statistically significant at $P \leq 0.05$. t: Student's t-test, P: P value for comparing between the two groups, Group I: Conventional technique, Group II: New technique, VV: Voided volume, PVR: Postvoid residual, SD: Standard deviation, Q_{max}: Maximum flow rate

an internet-based survey including 596 urologists and gynecologists from 56 different countries. Over 80% of the respondent surgeons believed that the sling tensioning is important or very important. The results showed a wide degree of variation among surgeons with regard to the surgical techniques used. Surgeons used different intraoperative tension evaluation methods, where 15.6% of surgeons performed intraoperative cough tests, 7.8% performed cystoscopic evaluation of urethral coaptation, and 1.9% used Q-tip tests. Nearly 63% of the surgeons placed tension on TVT and TOT slings in a similar manner, 26.2% placed more tension on TOT, and 10.4% placed more tension on TVT.

Ulmsten *et al.*^[5] described their tension-free technique by placing a 16 Fr Foley catheter in the urethra and placing a Metzenbaum scissor between the urethra and tape. This accounts for a distance of about 3–5 mm between the tape and the urethra. Delorme defined the distance between TOT and urethra as a “visible

distance of few millimeters,” without defining any technique.^[16]

Ludwig *et al.*^[24] described TOT 8/4 technique aiming to standardize the surgical procedure of TOT location and tension. They placed Hegar size 8 in urethra and a Hegar size 4 between the tape and urethra to standardize the distance between the tape and urethra within the range of 3.1–4.9 mm in 83% of the cases. The cure rate was comparable for both arms: 82% for TOT 8/4 and 83% for conventional tension-free technique. No obstruction was found in the TOT 8/4 arm.

Kang *et al.*^[24] tried to adjust the tape stress in accordance with cough test during TVT. They compared a group of women who underwent TVT procedure with cough test intraoperatively with another group who did not had cough test. They found a success rate of 92.6% in the cough test group and 93.1 in the noncough test group. They also found that adjusting the tape tension with cough

test during TVT increased the risk of postoperative urine retention as there were 11 cases in the obstruction zone in the cough test group and only 3 cases in noncough test group. In our study, we adjusted the tension intraoperatively using bearing down or Valsalva maneuver under saddle anesthesia, which enables the patients to bear down during the procedure. The Valsalva maneuver is more accurate than cough test as during coughing, reflex contraction of the urethral sphincter occurs to prevent leakage, therefore more tension will be applied theoretically to prevent leakage intraoperatively, and this will account for more obstruction postoperatively.

Lazarou *et al.*^[25] studied the effect of intraoperative Crede's maneuver (CM) after filling the bladder with 300 ml saline to adjust the tape tension during TOT procedure for females with SUI. The cure rate was 79.65% in the CM group and 77.67% in the traditional group. Each group included about 14% of females with ISD, and the cure rate for ISD patients was 85% for the CM group and 81.8% for the traditional method group. The main limitation in this study was that they failed to standardize the pressure applied on the bladder during the CM.

Maroto *et al.*,^[26] studied the transobturator adjustable tape that permits postoperative adjustment of tension in women with SUI. They reported 90% objective cure rate.

Flock *et al.*^[27] evaluated the shape and the position of TVT in female patients with urodynamically proven SUI. The mean distance between the tape and the hypochoic center of the urethra was 4.6 ± 1.5 mm, and they determined that a distance <3 mm would increase the PVR urine.

In our study, patients in both groups underwent translabial U/S 6 months postoperatively. The tapes were located at the mid-urethra. The distance between the mid-tape and the outer urethra measured by trans-labial U/S was comparable with that of the prementioned studies and showed no significant difference between the two studied groups, with mean distance in Group I of $0.41 \text{ cm} \pm 0.09$ and $0.37 \text{ cm} \pm 0.08$ in Group II.

Kociszewski *et al.*,^[28] studied the sonographic tape characteristics and outcomes after TVT. They studied the tape position in relation to the urethra and dynamic changes in TVT shape at rest and during straining using US. They found that the median tape–urethra–lumen distance was 3.8 mm at rest. Tape placement in the upper or lower part of the urethra was associated with a higher failure rate. They found a significant increase in postoperative

complications if the tapes were placed <3 mm from the urethra ($P < 0.0001$).

In our study, we were able to standardize neither the ideal distance between the tape and the urethra nor the ideal degree of tension applied, but we believe that they are important factors affecting the surgical outcome, especially in ISD. More cases and long-term follow-up are recommended to study the relation between tape and urethra and its effect on the outcome of tape surgeries. Although we could not standardize a distance between tape and urethra, using our proposed tension-applied technique, we did not experience any case of post-TOT obstruction, with high cure rate.

Our pressure flow results showed no objective bladder outlet obstruction (BOO), when defined according to Chassagne *et al.*^[29] They proposed cutoff values to define BOO as $Q_{\max} < 15$ ml/s and $P_{\det}@Q_{\max} > 20$ cmH₂O, yielding a sensitivity of 74.3% and a specificity of 91.1%. According to $P_{\det}@Q_{\max}$, there was no significant difference in Group I after TOT, as it increased from 9.90 ± 1.74 cmH₂O preoperatively to 10.50 ± 2.40 cmH₂O. While there was a statistically significant increase in Group II ($P = 0.007$), as it increased from 11.5 ± 2.70 cmH₂O preoperatively to 13.95 ± 2.87 cmH₂O postoperatively, with a statistically significant difference between the two groups postoperatively ($P = 0.001$). Again, these values lie within the normal range, which is again attributed to the small cohort size.

The strengths of our study

Same questionnaires were used in our study preoperatively and postoperatively, and this gives more exact information about changes in SUI. The PFS were also performed by the same urologist pre- and postoperatively in each center. Tapes were all inserted by the same surgeon in each center. No patients were lost to follow-up because of the prospective nature and rather short follow-up period, which enabled the collection of the data directly, thus enhancing the validity of the study. In addition, the supervisor who was responsible for the follow-up assessment was blinded to the patient baseline data to eliminate any possible bias in the study.

Limitations of the study

The small sample size and short follow-up period are the major limitations of this study. Although we were unable to standardize a distance between the tape and the urethra, using our proposed new technique, we did not experience a single case of post-TOT obstruction.

CONCLUSION

Performing TOT using our tensioned proposed technique in females with ISD seems to be effective with low morbidity. It is a reasonable solution for the treatment of ISD. Intraoperative adjustment of tension using Valsalva maneuver under saddle spinal anesthesia gives better outcomes than the conventional tension-free technique in ISD. The concept of tension-free vaginal tape should be challenged.

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Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Minassian VA, Drutz HP, Al-Badr A. Urinary incontinence as a worldwide problem. *Int J Gynaecol Obstet* 2003;82:327-38.
- Osman NI, Li Marzi V, Cornu JN, Drake MJ. Evaluation and classification of stress urinary incontinence: Current concepts and future directions. *Eur Urol Focus* 2016;2:238-44.
- Costantini E, Kocjancic E, Lazzeri M, Giannantoni A, Zucchi A, Carbone A, et al. Long-term efficacy of the trans-obturator and retropubic mid-urethral slings for stress urinary incontinence: Update from a randomized clinical trial. *World J Urol* 2016;34:585-93.
- Jun T, Yoon HS, Kim HS, Lee JW, Bae J, Lee HW. Recurrence rate of stress urinary incontinence in females with initial cure after transobturator tape procedure at 3-year follow-up. *Investig Clin Urol* 2017;58:54-60.
- Ulmsten L, Johnson HP, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1996;7:81-6.
- Davila GW, Johnson JD, Serels S. Multicenter experience with the Monarc transobturator sling system to treat stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;17:460-5.
- Kociszewski J, Rautenberg O, Kolben S, Eberhard J, Hilgers R, Viereck V. Tape functionality: Position, change in shape, and outcome after TVT procedure – Mid-term results. *Int Urogynecol J* 2010;21:795-800.
- Ludwig S, Stumm M, Mallmann P, Jager W. TOT 8/4: A way to standardize the surgical procedure of a transobturator tape. *Biomed Res Int* 2016;2016:4941304.
- Sweeney DD, Leng WW. Treatment of postoperative voiding dysfunction following incontinence surgery. *Curr Urol Rep* 2005;6:365-70.
- Lee KS, Han DH, Choi YS, Yum SH, Song SH, Doo CK, et al. A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year followup. *J Urol* 2007;177:214-8.
- Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: The Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. *Neurourol Urodyn* 1995;14:131-9.
- Abrams P, Andersson K, Brubaker L, Cardozo L. Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse and faecal incontinence. *Int Consult Incontinence* 2005;17:1589-630.
- Mellier G, Mistrangelo E, Gery L, Philippe C, Patrice M. Tension-free obturator tape (Monarc Subfascial Hammock) in patients with or without associated procedures. *Int Urogynecol J Pelvic Floor Dysfunct* 2007;18:165-72.
- Ulmsten U, Petros P. Intravaginal slingplasty (IVS): An ambulatory surgical procedure for treatment of female urinary incontinence. *Scand J Urol Nephrol* 1995;29:75-82.
- Kim HG, Park HK, Paick SH, Choi WS. Comparison of effectiveness between tension-free vaginal tape (TVT) and Trans-Obturator Tape (TOT) in patients with stress urinary incontinence and intrinsic sphincter deficiency. *PLoS One* 2016;11:e0156306.
- Delorme E. Transobturator urethral suspension: Mini-invasive procedure in the treatment of stress urinary incontinence in women. *Prog Urol* 2001;11:1306-13.
- Ford AA, Ogah JA. Retropubic or transobturator mid-urethral slings for intrinsic sphincter deficiency-related stress urinary incontinence in women: A systematic review and meta-analysis. *Int Urogynecol J* 2016;27:19-28.
- Gungorduk K, Celebi I, Ark C, Celikkol O, Yildirim G. Which type of mid-urethral sling procedure should be chosen for treatment of stress urinary incontinence with intrinsic sphincter deficiency? Tension-free vaginal tape or transobturator tape. *Acta Obstet Gynecol Scand* 2009;88:920-6.
- Popovic I, de Tayrac R, Demaria F, Foulot H, Poncet C, Madelenat P. Efficiency of the transobturator suburethral tape in the treatment of 61 patients presenting intrinsic sphincter deficiency. *Gynecol Obstet Fertil* 2007;35:1204-8.
- Schierlitz L, Dwyer PL, Rosamilia A, Murray C, Thomas E, De Souza A, et al. Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: A randomized controlled trial. *Obstet Gynecol* 2008;112:1253-61.
- Najjari L, Stickeler E, Kupec T, Gräf CM, Meinhold-Heerlein I, Goecke TW. Tomographic ultrasound imaging to control the placement of tension-free transobturator tape in female urinary stress incontinence. *Biomed Res Int* 2016;2016:1-6.
- Chantarasorn V, Shek KL, Dietz HP. Sonographic appearance of transobturator slings: Implications for function and dysfunction. *Int Urogynecol J* 2011;22:493-8.
- Borazjani A, Pizarro-Berdichevsky J, Li J, Goldman HB. Surgeons' views on sling tensioning during surgery for female stress urinary incontinence. *Int Urogynecol J* 2017;28:1489-95.
- Kang J, Gou X, Zhao QH, He WY, Xiao MZ, Wang M, et al. Cough test during tension-free vaginal tape procedure in preventing postoperative urinary retention. *Adv Urol* 2013;2013:797854.
- Lazarou G, Miller C, Gupta N, Islam S, Vetere P. Intraoperative Crede maneuver for tape adjustment during transobturator sling placement: Does it improve continence? *Female Pelvic Med Reconstr Surg* 2013;19:369-73.
- Maroto JR, Gorraiz MO, Bueno JJ, Pérez LG, Bru JJ, Chaparro LP. Transobturator adjustable tape (IOA) permits to correct postoperatively the tension applied in stress incontinence surgery. *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:797-805.
- Flock F, Kohorst F, Kreienberg R, Reich A. Ultrasound assessment of tension-free vaginal tape (TVT). *Ultraschall Med* 2011;32 Suppl 1:S35-40.
- Kociszewski J, Rautenberg O, Perucchini D, Eberhard J, Geissbühler V, Hilgers R, et al. Tape functionality: Sonographic tape characteristics and outcome after TVT incontinence surgery. *Neurourol Urodyn* 2008;27:485-90.
- Chassagne S, Bernier PA, Haab F, Roehrborn CG, Reisch JS, Zimmern PE. Proposed cutoff values to define bladder outlet obstruction in women. *Urology* 1998;51:408-11.