Impact of transobturator vaginal tape on female stress urinary incontinence and sexual function

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Abstract  
Objective: To evaluate the effect of vaginal transobturator tape (TOT) on female stress urinary incontinence (SUI) and sexual function.

Patients and methods: In all, 145 patients with SUI underwent TOT repair using the ‘outside-in’ technique. All patients had been sexually active in the previous 6 months. Patients were evaluated by history, routine laboratory investigations, cough stress test, abdominopelvic ultrasonography, and full urodynamic studies. The preoperative data assessed included: age, parity, body mass index, menopausal status, and Stamey grade of SUI. The intraoperative data assessed included: operative time, blood loss, and hospital stay; intra- and postoperative complications were also assessed. At 2 weeks after discharge, patients were followed-up with a routine examination and cough stress test. After 6 months’ patients were assessed by urodynamic studies, maximum urinary flow rate, post-void residual urine volume. The following questionnaires were completed before and at 6 months after TOT insertion: International Consultation of Incontinence Questionnaire-Short Form (ICIQ-SF), Urogenital Distress Inventory-Short Form (UDI-6), and Female Sexual Function Index (FSFI).

Results: All sociodemographic data of the 145 patients were collected. According to ICIQ-SF scores, 122 patients were cured, 19 had improved, and four failed. There
were significant improvements in the UDI-6 and FSFI scores, indicating that the women had significant improvement in their sexual life. There were six cases of urinary tract infection, five cases had a fever, and eight patients complained of groin or thigh pain postoperatively.

**Conclusions:** Correction of SUI using TOT appears to have a positive effect on female sexual function.

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**Introduction**

Urinary incontinence (UI) is a common problem affecting women and 25–45% of adult women have UI, with ~50% of them having stress UI (SUI) [1]. UI frequently negatively impacts on the sexual function of the patients whatever the type of UI [2]. This may be explained by various reasons, e.g. diminished libido, dyspareunia, recurrent dermatitis, and it may also affect lubrication and orgasm [3]. Additionally, urine leakage during intercourse indirectly diminishes sexual function [4].

Over many years, various procedures have been introduced for the treatment of SUI, with modifications to minimise associated morbidity [5]. Transobturator tape (TOT) ‘outside–in’ or (TVT-O) ‘inside–out’ became popular procedures, focusing on managing the UI regardless of its effect on female sexual function [6]. Different views have been reported on the issue of SUI surgery on the sexual function of the women [7]. In literature, the effect of surgery varies between improvement, no change, or even deterioration of female sexual function [8].

TOT, using synthetic tape, for the repair of SUI is a procedure that has become controversial, especially with respect to its effect female sexual function. Some report that it worsens sexual function due to narrowing of the vagina, increases pain and dyspareunia, and also partners can feel the tape during intercourse [9,10]. Others report that it improves sexual function, as it is considered a minimally invasive procedure that stops urine leakage during intercourse, decreases dermatitis, and thus increases sexual desire [11].

There is still a paucity of data on the role of TOT and its effect on female sexual function [3]. Thus, in the present study we evaluated the TOT procedure for the treatment of SUI and its effect on female sexual function.

**Patient and methods**

In all, 145 female patients with SUI were included in this prospective study after approval of the local ethics committee, from April 2013 to April 2015. All the included patients had SUI and were sexually active in the 6 months before TOT insertion. Women with detrusor overactivity; mixed UI, in which urgency was predominant; Grade 3 or 4 pelvic organ prolapse; previous UI or prolapse surgery; neurological disorders; active vaginal infection; female genital system malignancy; and previous pelvic irradiation were excluded from the study.

Preoperatively the patients were routinely evaluated with a medical and surgical history, physical and neurological examination, routine laboratory investigations, abdominopelvic ultrasonography (for exclusion of any other pathology), cough stress test with the bladder semi-full, and full urodynamic studies [flowmetry, cystometry, Valsalva leak-point pressure (VLPP)]. Grading and severity of SUI was assessed according to Stamey grading system [12]. Patients were evaluated before and at 6 months after TOT insertion using the following questionnaires: the Arabic versions of the International Consultation Of Incontinence Questionnaire-Short Form (ICIQ-SF) [13]; Urogenital Distress Inventory-Short Form (UDI-6) [14,15]; and the Female Sexual Function Index questionnaire (FSFI) [16] to evaluate sexual activity, the score is obtained from six domains and the final score calculated by multiplying the sum by the domains, a score of <26 is considered as impaired sexual function [17]. Also, the Patient Perception of Intensity of Urgency Scale (PPIUS) [18] was used.

**Procedure**

For the TOT procedure a transobturator mid-urethral sling system (Johnson & Johnson Co., New Brunswick, NJ, USA) was used. Under spinal or general anaesthesia (when there was contraindication to spinal anaesthesia) patients were positioned in dorsal lithotomy, a urethral catheter was inserted and then a 1.5-cm vertical incision in the anterior vaginal wall 1 cm below the external meats was made. Then, the left and right lateral vaginal walls were dissected until the level of the obturator membrane, with another two right and left incisions were made in the inguinal crease at level of the clitoris.
The needle is passed in (out–in technique) until it penetrates the obturator membrane and is received on the index finger at the vaginal incision, the tape is hung on it, and then the needle pulled out through inguinal incision with the tape. The steps are then repeated again on the other side. The tape is adjusted to be tension free. Finally, the vaginal and groin incisions are closed with 2/0 sutures and a vaginal pack is left with the urethral catheter in situ for 24 h. At discharge patients received appropriate antibiotic, NSAIDs, vaginal antiseptic, and the patients were asked to avoid sexual intercourse for 1 month.

Follow-up

Intraoperative data assessed included: operative time, blood loss, and hospital stay; intra- and postoperative complications were also assessed. Patients were asked to attend after 2 weeks from discharge for a routine follow-up examination and cough stress test. After 6 months’ patients were assessed by urodynamic studies, maximum urinary flow rate ($Q_{\text{max}}$), post-void residual urine volume (PVR), ICIQ-SF questionnaire, UDI-6 questionnaire, the FSFI questionnaire.

Statistical analysis

The collected data were tabulated and analysed using the Statistical Package for the Social Sciences (SPSS® version 16; SPSS Inc., Chicago, IL, USA). Categorical data are presented as numbers and percentages, whilst quantitative data are expressed as means ± standard deviations (SDs) and ranges. The chi-squared test was used to analyse categorical variables. Quantitative data were tested for normality using the Kolmogorov–Smirnov test, if shown to be non-parametric, the Wilcoxon test was used to test the differences between matched variables, whilst the Mann–Whitney $U$-test was used to analyse differences between two independent groups. A two-sided $P \leq 0.05$ was considered to indicate statistical significance.

Results

This study included 145 female patients. Table 1 shows the sociodemographic data of the included patients. All the preoperative and urodynamic data of the patients are reported in Table 2; all patients had a positive cough stress test, whilst 55 patients (37.9%) had mild urge symptoms according to their PPIUS score. Table 3 shows that there was no significant intraoperative blood loss, at a mean (SD) of 72.5 (30.2) mL; with no need for blood transfusion in any case. The mean (SD, range) operative time (calculated from start of surgery with anaesthesia time not included) was 21 (3.6, 14–26) min and the postoperative hospitalisation ranged from 18 to 36 h. During the operation, there were no urethral or bladder injuries. Postoperatively six patients had UTIs treated with appropriate antibiotics, five patients had a fever treated by combining antibiotics with antipyretics, and eight patients complained of groin or thigh pain that improved on NSAIDs and analgesics. According to PPIUS score, 44 patients still had mild urge symptoms and 32 of them improved with anticholinergic drugs. One patient had urinary retention, which was treated by insertion of a urethral catheter.

Table 1 Patients’ sociodemographic characteristics.

| Variable                     | Value   |
|------------------------------|---------|
| Number of patients           | 145     |
| Mean (SD, range)             |         |
| Age, years                   | 47.0 (7.8, 35–62) |
| Body mass index, kg/m$^2$    | 26.4 (3.2, 20–33) |
| Parity, n                    | 3.6 (1.5, 1–6) |
| Mode of delivery             |         |
| Normal vaginal delivery      | 4.1 (1.1, 1–6) |
| Caesarean section            | 2.5 (0.6, 1–4) |
| Menopausal status            |         |
| Pre-menopausal               | 82 (56.6) |
| Menopausal                   | 63 (43.4) |
| Past medical history         |         |
| Negative                     | 119 (82.1) |
| Hormonal therapy             | 14 (9.7) |
| Prior hysterectomy           | 12 (8.3) |

Table 2 Preoperative data of the 145 patients studied.

| Variable                     | Value   |
|------------------------------|---------|
| N (%)                        |         |
| Urgency                      |         |
| No                           | 90 (62.1) |
| Mild                         | 55 (37.9) |
| Stamey grade                 |         |
| I                            | 12 (8.3) |
| II                           | 114 (78.6) |
| III                          | 19 (13.1) |
| Cough test                   |         |
| Negative                     | 0       |
| Positive                     | 145 (100) |
| PVR, mL, mean (SD, range)    | 28.4 (7.5, 20–45) |
| VLPP, cmH$_2$O, n (%)        |         |
| > 90                         | 22 (15.2) |
| 60–90                        | 104 (71.7) |
| < 60                         | 19 (13.1) |
| $Q_{\text{max}}$, mL/s, mean (SD, range) | 23.4 (2.26, 15–25) |
| ICIQ-SF score, mean (SD, range) | 14.8 (4.5, 6–21) |
| N (%)                        |         |
| Slight                       | 0       |
| Moderate                     | 42 (29.0) |
| Severe                       | 64 (44.1) |
| Very severe                  | 39 (26.9) |
for 10 days. Also, two patients had mesh erosion, one of them improved with local oestrogen cream and the other required trimming of the mesh edges mucosal covering and re-suturing.

According to ICIQ-SF score, 122 patients were cured (score = 0), 19 improved (score/C20 12), and four failed. This was confirmed by the cough stress test, which was negative in 141 patients and positive in the remaining four postoperatively (Table 3). In repeated urodynamic studies, there was no significant difference in the PVR, at a mean (SD) preoperatively of 28.4 (7.5) vs 29.8 (3.25) mL postoperatively; or $Q_{\text{max}}$, at a mean (SD) preoperatively of 23.4 (2.26) vs 22.9 (2.86) mL/s postoperatively.

Table 4 shows the changes in the UDI-6 questionnaire before and 6 months after TOT insertion, with significant improvement in questions three and four, and in the total score. Previous studies have also reported significant improvements in UDI-6 scores after TOT insertion in sexually active patients, from a mean (SD) of 7.07 (2.9) to 2.8 (2.11) in 28 patients [28] and from 8.12 (2.58) to 6.03 (3.18) in 57 patients [3].

There are several factors associated with anti-incontinence operations that may impact on sexual function, e.g. impaired vaginal elasticity, scarring, fibrosis, and impaired nerve function [9]. Dyspareunia may occur after anti-incontinence surgery due to distortion of the urethro-vaginal space by the tape and decreased sensation and innervation to the anterior vaginal wall that may affect sexual function [23,29]. Also, distortion of the clitoris during the operation due to its close anatomical relation to the distal urethra can affect innervations, particularly the dorsal nerve, which may result in a decrease in its parasympathetic vasodilator 

Discussion

Despite its popularity for the treatment of female SUI, TOT still provokes controversy in its effect on female sexual function; some authors advocate a positive effect, whilst others do not [19]. This conflict encouraged us to evaluate TOT as a treatment for female SUI and its effect on female sexual function.

According to our patients’ ICIQ-SF results the cure rate was 84.1% and 13.1% improved, a success rate in agreement with previous publications [20–23]. Dwyer and Riss [24] reported a cure rate of 85% in 1225 patients over 10 years, with 94% of these patients indicating that they would recommend the operation to someone else. The present study reported no cases of urethral or bladder injury and there was no need for blood transfusion. This is better than other reports in which there have been cases of urethral injury during dissection and/or cases of bladder injury [22,25–28], which may have been due to initial experiences with the technique. Narin et al. [28] also reported in their TOT series no cases of blood transfusion.

In the present study, there was a significant improvement in UDI-6 questionnaire scores, which decreased at 6 months postoperatively, especially for questions three and four about SUI and urine leakage. This is better than other reports in which there have been cases of urethral injury during dissection and/or cases of bladder injury [22,25–28], which may have been due to initial experiences with the technique. Narin et al. [28] also reported in their TOT series no cases of blood transfusion.
effect, thus interfering with sexual arousal leading to FSD [30]. Sentilhes et al. [1] noticed that anti-incontinence surgery improved urine leakage during intercourse, which can occur with deep penetration and clitoral stimulation that increases abdominal pressure, thus women who have urine leakage during intercourse have a greater chance of improved sexual function and overall sexual satisfaction after a sling operation [6,31].

In our present study, we found a significant improvement in all domains of the FSFI questionnaire and in the total score, thus the number of patients with FSD decreased postoperatively, which concurs with previous studies [18,21,28,32,33]. Elzevier et al. [10] found an improvement in the score in his study comparing TVT and TOT, Kuhn et al. [34] reported improvement in all domains of the score except for orgasm, and Brubaker et al. [35] reported improvement after various types of anti-incontinence operations.

Other studies have reported mixed effects of TOT on female sexual function [36]. Abdel-Fattah et al. [37] found that 50% of patients had no change in sexual function, 34% improved, whilst 14% deteriorated, but the study was limited as it did not focus on sexual function. Others have reported deterioration in female sexual function after TOT insertion, with a high rate of dyspareunia probably due to vaginal narrowing as the inside-out technique (TVT-O) was used, which utilises more vaginal tissue [38,39].

This divergence in views on anti-incontinence surgery and its effect on female sexual function may be due to the variety in age, neurological and anatomical factors, hormonal state, and pelvic floor prolapse of the patients [18], also the success of the operation itself in inhibiting leakage during intercourse will enhance wellbeing and thus increase libido [40,41].

There has been a perception that the menopausal state augmented personal distress and thus contributed to deterioration in female sexual function [32], but in our present study there was no significant difference in pre- and postmenopausal women pre- and postoperatively. A study by Berra et al. [42] also did not find that menopausal status impacted on female sexual function.

Limitations of the present study include being a single arm and single product study.

**Conclusions**

The TOT procedure has high efficacy in managing SUI with a low complication rate. Also, regarding the effect of TOT on the FSFI score, all domains of the questionnaire in pre- and postmenopausal women were improved, with no significant effect of the menopausal state on the score.

### Table 5

| FSFI domain | Premenopausal (N = 82) | Postmenopausal (N = 63) | Preoperative, mean (SD, range) | Postoperative, mean (SD, range) | P* | P* | P* |
|-------------|-----------------------|-------------------------|--------------------------------|--------------------------------|----|----|----|
| Desire      | 2.91 (0.73, 1.8–4.8)  | 3.45 (0.72, 2.4–4.8)    | <0.001                         | 3.04 (0.84, 1.8–4.8)            | 3.32 (0.76, 2.4–4.8) | <0.001 | 0.41 | 0.25 |
| Arousal     | 3.46 (0.59, 2.1–5.4)  | 4.20 (0.66, 2.7–5.7)    | <0.001                         | 3.25 (0.78, 0–5.4)              | 4.04 (0.75, 2.7–5.7) | <0.001 | 0.21 | 0.07 |
| Lubrication | 4.32 (0.54, 3–5.7)    | 4.58 (0.55, 3.3–5.7)    | <0.001                         | 4.13 (0.80, 0–5.7)              | 4.41 (0.54, 3.0–5.7) | <0.001 | 0.17 | 0.063 |
| Orgasm      | 3.95 (0.85, 2–5.2)    | 4.17 (0.51, 3.2–5.2)    | <0.001                         | 3.85 (0.71, 0–5.2)              | 4.11 (0.51, 3.2–5.2) | <0.001 | 0.53 | 0.43 |
| Satisfaction| 4.56 (0.61, 3.2–5.6) | 4.78 (0.56, 3.6–6.0)    | <0.001                         | 4.64 (0.83, 0–6.0)              | 4.84 (0.61, 3.0–6.0) | 0.004 | 0.38 | 0.53 |
| Pain        | 4.07 (0.68, 2–5.6)    | 5.05 (0.55, 3.2–6.0)    | <0.001                         | 3.89 (0.89, 0–5.6)              | 4.92 (0.67, 3.2–6.0) | <0.001 | 0.32 | 0.299 |
| Total FSFI  | 23.30 (1.74, 18.6–27) | 26.28 (1.39, 22.7–29.1) | <0.001                         | 22.83 (3.03, 30–27)             | 25.78 (1.74, 19.9–28.8) | <0.001 | 0.43 | 0.11 |

* P, Wilcoxon, pre vs postoperative.
† P, Mann–Whitney U-test comparing preoperative data between the pre- and postmenopausal groups.
‡ P, Mann–Whitney U-test comparing postoperative data between the pre- and postmenopausal groups.

### Table 6

| Variable          | Premenopausal, n (%) | Postmenopausal, n (%) | χ² (preoperative), P | χ² (postoperative), P |
|-------------------|----------------------|-----------------------|---------------------|-----------------------|
| FSD               | 70 (85.4)            | 40 (48.8)             | 0.39, 0.53 (NS)     | 0.47, 0.12 (NS)       |
| No FSD            | 12 (14.6)            | 42 (51.2)             | 13.4, <0.001        | 12.8, <0.001          |

χ² (preoperative) → compares preoperative data among pre- and postmenopausal groups.
χ² (postoperative) → compares postoperative data among pre- and postmenopausal groups.
NS, not significant.
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Conflict of interest

None.

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