Postoperative Complications After Tension-Free Vaginal Tape Versus Transobturator Tape Procedure For Stress Urinary Incontinence

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Citation

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Abstract

ObjectiveTo determine the frequency of post operative complications after tension-free vaginal tape (TVT) compared with the transobturator tape (TOT) procedure in women with stress urinary incontinence (SUI).Study designProspective study of all consecutive women with urodynamically confirmed SUI undergoing anti-incontinence surgery between January 2000 and January 2010. All procedures were performed by experienced urogynaecologists well trained in TVT and TOT surgery. Assessments were carried out at 1, 6, 12 and, 36 months after surgery.ResultsThe study population included 366 women (mean age 59.5 years), 243 in the TVT group and 123 in the TOT group. The groups were similar in terms of demographics, preoperative data, and cure rates. De novo urgency occurred in 13.4% of patients at 6 months after surgery, in 19.3% at 12 months, and in 22.1% at 36 months. De novo urgency was significantly more frequent in the TVT group than in the TOT group at 12 (22.2% vs 11.2%, P = 0.025), 24 (24.8% vs 12.3%, P = 0.033), and 36 (0% vs 24.7%, P = 0.034) months. Cure rates were similar in both groups. The final adjusted cure rate was 87.3% (319/366).ConclusionTreatment of SUI using the TOT procedure was associated with a lower rate of de novo urgency.

INTRODUCTION

Urinary incontinence remains a distressing medical disorder that affects approximately 45% of American women [2] and 35% of European women [3] during their lifetimes. In Tunisia, the prevalence in the general population is approximately 23%. Urinary incontinence is frequently underreported because of the stigma associated with this condition. The most common type of urinary incontinence in women is stress incontinence, defined as the involuntary loss of urine during coughing, sneezing, or physical exertion such as sporting activities or sudden change in position. Urethral hypermobility related to a loss of urethral support – the hammock-like supportive layer described by DeLancey [5] – is putatively associated with most cases of stress urinary incontinence (SUI).

Pelvic floor muscle exercise is the first choice of treatment for SUI and is known to be effective in approximately 50% of cases [6]. Continence surgery is indicated when conservative treatment fails or the patient wants definitive treatment. Tension-free vaginal tape (TVT) is a standard surgical procedure used to treat SUI since 1995 when it was first described by Ulmsten and Petros [7]. This procedure, which involves implantation of a polypropylene tape under the midurethra via a minimal vaginal incision, is one of the most used methods for incontinence surgery. Blind passing of the needle into the retropubic space, however, could cause bladder perforation and injury to the urethra, retropubic organs and blood vessels. To avoid such complications, a new surgical approach using the transobturator tape (TOT) , either from outside to inside or inside to outside, has been developed [8]. The transobturator route enables the paravesical space to be preserved, limiting the risks of vesical, visceral, and vascular injuries. Moreover, the TOT procedure has a lower overall complication rate and no absolute need of postoperative cystoscopy [9] and [10].

The objective of this prospective study was to compare the frequency of post operative complications after TVT and TOT procedures in women with SUI.

MATERIALS AND METHODS

Between January 2000 and January 2010, consecutive women with SUI underwent continence surgery, including the TVT procedure and, since 2005, the TOT procedure.

Only patients with SUI due to urethral hypermobility of longer than one year's duration were eligible. Patients with intrinsic sphincter deficiency, intrinsic urethral sphincter deficiency with urethral hypermobility, mixed incontinence, and occult SUI were excluded from the study. All patients were free of neurological diseases, peripheral neuropathies, metabolic disorders and urinary tract or perineal skin infections. All patients were given an explanation of the surgical procedure and written informed consent was obtained. Approval of the institutional review board for this clinical cohort study was not required.

Preoperative evaluation included detailed history, urogynaecological examination, vaginal echography, cervical cytology, urinalysis and urodynamic studies. Patients with involuntary detrusor contractions or filling defects on urodynamic evaluation were excluded from the study. Signs and symptoms of lower urinary tract dysfunction were recorded. Physical examination included a stress test (cough provocation) and cotton swab test (Q-tip test).

All procedures were performed by experienced urogynaecologists well trained in TVT and TOT surgery. TVT was carried out as previously described [7]. Patients were in general operated on under locoregional anaesthesia – 82.5% (4.4% general anaesthesia and 13.1% local anaesthesia and sedation. The tape was adjusted tension-free. Cystoscopy with a 70° optic with the needle in place was performed to rule out bladder penetration. Since 2005, consecutive patients underwent the TOT procedure as described by de Leval [8]. No cystoscopy was required for the procedure. The commercially available TVT and TOT kits were used (Gynecare®, Johnson & Johnson, Somerville, NJ, USA).

An assessment of perioperative and postoperative complications, such as urinary retention, de novo urgency, voiding difficulties, recurrent infection, persistent pain and vaginal mesh erosion was made for each patient. All patients were asked to visit the clinic at 1, 6 and 12 months after surgery, at which time the surgeon performed a clinical examination to assess proper positioning of the tape and integrity of the vaginal mucosa. Follow-up urodynamic study was not routinely performed but was done if indicated by urinary symptoms. At 6 and 12 months, patients also conducted a self-evaluation of the severity of their symptoms as compared with preoperative symptomatology into four categories: cured, improved, similar and worse (failure). Follow-up checks at 24 and 36 months.

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS for Windows. Categorical variables are expressed as numbers and percentages. Outcome of the TVT and TOT procedures was analysed in terms of cure at 6, 12, 24 and 36 months. Differences between the TVT and TOT groups were analysed with the chi-square (□2) test. Statistical significance was set at $P < 0.05$.

RESULTS

The study population included 366 women with a mean age of 59.5 years (range 31–85 years). The mean parity was 3 and only 0.9% (n = 3) were nulliparous. A total of 243 patients had the TVT procedure and 123 had the TOT procedure. The groups were similar in terms of demographics, parity and history of previous anti-incontinence surgical operations. The number of hysterectomies, however, was greater among patients treated with the TVT procedure. The majority of patients in both study groups were operated on under spinal anaesthesia. Salient characteristics of the study population are shown in Table 1.

Figure 1

Table 1. Patient demographics and perioperative data.

	‹TVT› (n = 243)	‹TOT› (n = 123)	P value
Age, years, mean (range)	60.5 (32 – 84)	57.7 (35 – 85)	NS
Vaginal deliveries	3	3	NS
Previous anti-incontinence procedures	4 (1.6)	3 (2.4)	NS
Hysterectomy	86 (47.9)	37 (30.1)	0.039
Anterior colpoplasty	123 (50.6)	50 (40.6)	NS
Posterior colpoplasty	36 (14.8)	11 (8.9)	NS
Spinal anaesthesia	184 (75.7)	104 (84.5)	NS

Percentages in parenthesis unless otherwise stated.

Intraoperative and postoperative complications are shown in Table 2. Bladder perforation occurred in 15 patients in the TVT group and in none in the TOT group ($P = 0.005$). Postoperatively, urinary infection and chronic pain were significantly more frequent in women undergoing the TOT procedure ($P = 0.01$).

Figure 2

Table 2. Complications of the TVT and TOT procedures in 366 patients.

Complications	‹TVT› (n = 243)	‹TOT› (n = 123)	P value
Intraoperative			
Bladder perforation	15 (6.2)	0	0.005
Vessel injury	4 (1.6)	0	NS
Anaesthetic complication	0	1 (0.8)	NS
Postoperative			
Urinary retention	32 (13.2)	9 (7.3)	NS
Urinary infection	1 (0.4)	6 (4.9)	0.011
Chronic pain	1 (0.4)	6 (4.9)	0.011
Mesh extrusion	10 (4.1)	7 (5.7)	NS

Percentages in parenthesis

Drop-outs at follow-up were 0% at 6 months, 5.1% (n = 17) at 12 months, 6% (n = 18) at 24 months and 10.4% (n = 25) at 36 months, without differences between the TVT and TOT procedures.

At 6 months after surgery, de novo urgency occurred in 13.4% of patients without statistically significant differences between the TVT and TOT procedures (13.6% vs 13.0%). At 12 and 24 months, the overall rates of de novo urgency were 19.3% and 22.1%, respectively. At 36 months, the overall rate of 23.2% was similar to 22.1% at 24 months. De novo urgency, however, was significantly less frequent among women undergoing the TOT procedure than the TVT procedure at 12 (11.2% vs 22.2%, P = 0.025), 24 months (24.8% vs 12.3%, P = 0.033) and 36 months (0% vs 24.7%, P = 0.034) (see Table 3).

Figure 3

Table 3. post operative complications in women undergoing the TVT and TOT procedures.

Follow-up	All patients (n = 366)	‹TVT› (n = 243)	‹TOT› (n = 123)	P value
6 months	49/366 (13.4)	33/243 (13.6)	16/123 (13.0)	0.879
12 months	64/332 (19.3)	54/243 (22.2)	10/89 (11.2)	0.025
24 months	67/298 (22.1)	60/241 (24.8)	7/57 (12.3)	0.033
36 months	56/241 (23.2)	56/227 (24.7%)	0/14 (0)	0.034

Percentages in parenthesis.

Cure rates were similar in both study groups (Table 4). The final adjusted cure rate was 87.3% (319/366).

Figure 4

Table 4. Cure rates in women undergoing the TVT and TOT procedures.

Follow-up	All patients (n = 366)	‹TVT› (n = 243)	‹TOT› (n = 123)	P value
6 months	342/366 (93.4)	229/243 (94.2)	113/123 (91.9)	NS
12 months	305/332 (91.9)	222/243 (91.4)	83/89 (93.3)	NS
24 months	269/298 (90.3)	214/241 (88.8)	55/57 (96.5)	NS
35 months	213/241 (88.4)	199/227 (87.7)	14/14 (100)	NS

Percentages in parenthesis.

COMMENTS

In this clinical series of 366 women with SUI undergoing anti-incontinence operations, the TVT procedure was associated with a higher incidence of de post operative complications at 12 and 24 months after surgery than the TOT procedure. The differences between both techniques were 11% and 12.5% at 12 and 24 months, respectively. The difference of 24.7% in favour of the TOT procedure at 36 months should, however, be interpreted taking into account that only 14 patients with a full follow-up time of 36 months after TOT were entered into the study.

Women in both study groups were comparable in terms of age, parity or history of previous anti-incontinence procedures. TVT and TOT procedures were performed by the same experienced surgical team and using similar types of anaesthesia. Moreover, the length of stay and days with

urinary catheter left in the bladder were also similar. In our study, like others [9] and [10] both techniques appear to be equally effective in the surgical treatment of SUI. Cure rates at 12 months were 91.4% for the TVT procedure compared with 93.3% for the TOT procedure. At 24 months, cure rates were slightly lower for the TVT procedure than the TOT procedure (88.8% vs 96.5%) but differences were not statistically significant.

The use of a TVT device has for a few years been the operation most often performed to treat female urinary incontinence. One of the most frequent complications of this surgery is bladder perforation. To prevent this, Dargent et al. [12] used the method initially suggested by Delorme [13], in which the two ends of the sling were passed through the obturator membrane and the muscles which cover it, circumventing the ischiopubic bone with the Emmet needle introduced from outside to inside. No bladder perforation was noted among the first 71 operated patients. Moreover, routine cystoscopy is not needed with the TOT procedure. Prospective studies have confirmed the effectiveness of the transobturator tape [9] and [10].

Although postoperative acute urinary infections occurred in 4.8% in women in the TVT group and in 0.4% in the TOT group, recurrent urinary tract infection at follow-up was similar (5.7% in the TOT group vs 4.5% in the TVT group). On the other hand, because treatment of acute urinary tract infection with fosfomycin is highly effective, the occurrence of acute cystitis was considered a minor postoperative complication. The management of recurrent episodes of urinary tract infection is difficult, however, and may require long-term antibiotics or even reoperation. Urinary retention was similar in both procedures, as reported in the literature [10]. One woman in the TVT group complained of chronic postoperative pain in the retropubic space and six patients in the TOT group of persistent inguinal pain. In the study of Collinet et al. [14] of 984 women with SUI treated with the TOT procedure, residual pain was recorded in 2.7% of cases.

De novo urgency is one of the complications less frequently described in the literature as a primary endpoint, although rates varying between 5.9% and 25% have been observed in different studies in which the TVT technique was used [11], [15], [16], [17] and [18]. In one study of 108 women who underwent the TOT procedure, the incidence of de novo urgency was 14.8% [19]. In a meta-analysis of randomised controlled trials that compared the effectiveness of TOT and TVT for the treatment of SUI [20], de novo frequency and urgency symptoms were equivalent (odds ratio 0.89, 95% confidence interval [CI] 0.54–1.86). In a more recent meta-analysis carried out by the same authors, in which 31 randomised controlled trials were analysed with a total study population of 4796 women, de novo urgency was also equivalent for direct comparisons between TVT and TOT (odds ratio 0.87, 95% CI 0.50–1.51) [21]. In the present study, de novo urgency was significantly more common after the TVT procedure (22.2%) than the TOT procedure (11.2%) and differences were already noticeable at one year after surgery. The origin of de novo urgency and its mechanisms are unclear. On the other hand, discrepancies in the rate of de novo urgency reported in the literature may be explained by the fact that the de novo urgency diagnosis has no reliable objective diagnostic criteria. In our study, risk factors for de novo urgency were not assessed. In the study of Holmgren et al. [11], risk factors for the occurrence of de novo urgency after the TVT procedure included older age, parity, and history of caesarean section and history of recurrent urinary infections.

Women in the TVT group showed a higher number of concomitant hysterectomies than those in the TOT group but differences in the occurrence of de novo urgency according to the presence or absence of associated hysterectomy were not observed. Differences in the time at which the TVT and TOT techniques were introduced (the TOT technique was used since 2005) are the reason for a higher number of patients treated with the TVT procedure and a longer follow-up in this group. Moreover, the present findings should be interpreted taking into account that patients were not assigned at random to the surgical procedure. Quality of life related to de novo urgency was not examined in our study. This complication, however, is one of the most important factors associated with patients' satisfaction with the outcome of anti-incontinence repair procedures [16] and [18] and also with their quality of life. In our study, patients assessed the severity of symptoms into the four categories of cured, improved, similar and failure. The fact that de novo urgency was selected as the primary endpoint of the study adds strength to our findings as this complication is rarely reported when TVT and TOT procedures are compared.

CONCLUSION

In summary, in the present clinical series of 366 patients with SUI undergoing continence surgery, the TOT procedure was associated with a lower rate of post operative complication at 12, 24 and 36 months after surgery. Full

follow-up time of 36 months, however, was available for only 14 patients after TOT. In this respect, the rate of late complications, in particular the incidence of post operative complications, should be evaluated in a larger series with a follow-up of 5 years or more. This calls for further studies to assess long-term complications associated with the TVT and TOT procedures for the treatment of SUI.

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