

A short-term follow-up comparison of two trans-obturator tape procedures

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Abstract The objective of the study was to compare the clinical outcomes at the short-term follow-ups of two novel transobturator mid-urethral sling procedures – the trans-obturator tape (TOT) procedure and the tension-free vaginal tape (TVT)-obturator procedure. The study cohort consisted two groups of 40 women with urodynamically proven stress urinary incontinence (SUI). The patients in one group underwent the TOT procedure, performed according to Delorme (Prog Urol 11:1306–1313, 2001); those in the second group underwent the TVT-obturator operation, performed according to de Leval (Eur Urol 44:724–730, 2003). Intra-operative diagnostic cystoscopy was not performed with either the TVT-obturator or the TOT procedures. The average follow-up was 12 months. The two patient groups were similar in terms of demographic and therapeutic criteria, except for patient age, which was significantly younger in the TVT-obturator group. Previously reported TVT-related operative complications, such

as bladder penetration, intra-operative bleeding, field infection and post-operative pelvic floor relaxation, were not observed in patients of either group. Bowel and urethral injuries were also not recorded. The therapeutic failure rates were 10% for the TOT procedure and 5% for the TVT-obturator procedure. Urinary frequency and urgency post-operatively were reported in 25% of the TOT patients and 19% of the TVT-obturator patients, pelvic or vaginal pain affected 10% of the TOT and 5% of the TVT-obturator patients, while post-operative voiding difficulty was experienced by 12.5% of the TOT and 7.5% of the TVT-obturator patients. None of the above-mentioned differences between the two patient groups were of statistical significance. The TVT-obturator and TOT procedures, both minimally invasive, novel, mid-urethral sling procedures, seem to be safe, easy-to-perform and effective in treating female SUI. The patients of both study groups suffered less intra- and post-operative surgical complications than previously been reported in connection with the TVT operation. The TVT-obturator patients had fewer therapeutic failures, less post-operative urinary frequency and urgency, less pelvic pain and less voiding difficulty. All of these findings, however, had no statistical significance; consequently, long-term comparative data collection will be required before solid conclusions can be drawn on the superiority of either of these two operative techniques.

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Introduction

The tension-free vaginal tape (TVT) procedure, first described by Ulmsten et al. in 1996 and based on mid-urethral prolene tape support, is a surgical procedure used

for treating female stress urinary incontinence (SUI) [1–6]. Although the procedure is well-established, a number of complications are associated with the TVT operative approach that have drawn the concern of surgeons. These include bladder penetration [2, 3, 6] and post-operative urinary outlet obstruction [2, 3, 6, 8, 10] as well as bowel penetration, intra-operative bleeding, and post-operative infection [2, 3, 6–9]. The latter three complications entail the potential risk of severely harming the health of the patient. Against this background, de Leval [11] and Delorme [12] designed novel transobturator mid-urethral sling procedures. Jean de Leval described the TVT-obturator as follows: "while the TVT needle passes through the retropubic area, which is proximal to the neighboring bladder, bowel and blood vessels, the newly reported TVT-Obturator needle route runs through the relatively safe medial compartment of the obturator fossa area" [11]. Delorme developed the transobturator tape (TOT) procedure, in which a skin incision is made at the genitofemoral fold at the level of the clitoris and the tape is inserted through the obturator foramen underneath the urethra. The vaginal wall is then re-approximated with a running Vicryl 2/0 suture [12].

This study reported here was designed to compare surgeons' learning curves for these two TOT procedures.

Methods

Patients suffering from SUI, diagnosed both clinically and urodynamically, were referred for corrective surgery. The first author performed the TVT-obturator procedures, and the last author performed the TOT procedures. The second and third authors compared the patients' series for these two different types of procedures. Data were collected by

telephone interview based on the Urinary Distress Index (UDI-6) validated questionnaire. The TVT-obturator operations were carried out according to de Leval [11] and the TOT procedure was according to Delorme [12]. All of the operated patients were given 1 g Monocef (Cefonicid; Beecham Healthcare) intravenously 1 h prior to surgery [13] and had an iodine antiseptic prophylactic vaginal wash before commencement of surgery. The mode of anesthesia depended on the patient's request. Diagnostic cystoscopy was not carried out in either patient group. Therapeutic failures were confirmed by repeat urodynamic studies and treated successfully by TVT. Patients with early post-operative partial outlet obstruction were treated with bladder catheterization for up to 2 weeks [8]. All statistical analyses were performed with SPSS ver.10.1.4 (SPSS, Chicago, Ill.). The *t*-test was used for quantitative variance analysis, while the Fisher's exact test and the chi-square test were used for categorical variance. All statistical tests were evaluated at the $P=0.05$ level of significance.

Results

The demographic and operative data of the patients in both study groups are presented in Table 1. Patients presenting with other significant features of pelvic floor relaxation had anterior and posterior colporrhaphy or vaginal hysterectomies concomitant with the anti-incontinence surgery. No statistically significant differences in demographic and operative data were found when comparing those two groups, with the exception that the patients in TVT-obturator groups were younger (average: 52 vs. 62 years). The patients were followed-up for an average period of 12 months (range: 5–19 months). Previously reported TVT-related operative complications, such as bladder penetration,

Table 1 Patient demographics (NS not significant)

	TOT group	TVT- obturator group	Statistical significance (<i>P</i> value)
Age (years; average and range)	62.5	52.8	0.001
Previous anti-incontinence surgery (<i>n</i> and %)	4 (10%)	1 (2.5%)	0.36 (NS)
Previous hysterectomy (<i>n</i> and %)	4 (10%)	2 (5%)	0.396 (NS)
Cystocele grade 2 and 3	19	18	0.81 (NS)
Rectocele grade 2 and 3	4	6	0.45 (NS)
Additional operations (No. and %)	21 (52.5%)	22 (55%)	0.823 (NS)
A. Colporrhaphy	17	15	
P. Colporrhaphy	2	3	
A. and P. Colporrhaphy	2	3	
Vaginal hysterectomy		1	
Background diseases ^a (<i>n</i> and %)	17 (42.5%)	13 (32.5%)	0.356 (NS)

TOT, Transobturator tape; TVT-obturator, tension-free vaginal tape-obturator

^a Bronchial asthma, hypertension, diabetes, among others

intra-operative bleeding, field infection, and post-operative pelvic floor relaxation, were not noted any patients; bowel and urethral injuries were also not recorded. Post-operative complications within these two patient series were recorded and are presented in Table 2. Tape loosening or removal was not required. The therapeutic failure rates were 10% for the TOT and 5% for the TVT-obturator. Urinary frequency and urgency post-operatively was reported in 25% of the TOT and 19% of the TVT-obturator patients, pelvic or vaginal pain affected 10% of the TOT and 5% of the TVT-obturator patients, and post-operative voiding difficulty was experienced by 12.5% of the TOT and 7.5% of the TVT-obturator patients. None of these differences between the two patient groups were statistically significant.

Discussion

Since being described by Ulmsten et al. in 1996 [1], the TVT procedure has become very popular. Common complications of former operations for the treatment of SUI, such as intra-operative blood loss, pelvic and abdominal organ injury, post-operative de-novo Detrusor instability, dyspareunia, and urethral erosion, are rare in the TVT era [1–5]. Prospective randomized multi-center studies that have compared TVT and the former gold standard, the Burch colposuspension, have demonstrated a similar therapeutic impact for both. However, TVT had a higher intra-operative complication rate, while colposuspension had a higher post-operative complication rate and a longer recovery period [14–19]. Among the well-documented typical TVT complications are bladder penetration, intra-operative bleeding, post-operative field infection, and bowel injury [1–3, 5]. De Leval [11] and Delorme [12] described novel TVT-related procedures that enable mid-urethral support for the treatment of female SUI without coming into the vicinity of the bladder, the femoral

blood vessels, or the bowel. This is achieved by using the obturator fossa, rather than the retropubic space, as a route for the prolene tape. The results of our comparative study are in line with the previously reported efficacy of the TOT and the TVT-obturator procedures in terms of cure and early and late post-operative complication rates [20]. The short-term results for TOT and TVT-obturator surgery include fewer cases of bladder penetration, intra-operative bleeding, and post-operative field infection in comparison to the TVT approach. The therapeutic failure rates, post-operative urinary frequency and urgency, pelvic or vaginal pain, and voiding difficulty that our patients encountered were all slightly more common in patients who underwent the TOT procedure than in those having the TVT-obturator procedure, but those findings had no statistical significance. None of these differences between the two patient groups were of statistical significance. This lack of significant difference between the outcome measures of the two patient groups may be partially due to the relatively short follow-up period for the recently launched TOT and TVT-obturator procedures as well as to the accumulated surgical experience with mid-urethral sling placement following the learning curve period for TVT. However, our study was a short-term one with a subjective nature. A long-term follow-up for objectively measured large-scale studies will be required before solid conclusions can be drawn with regard to advocating TOT placement as the procedure of choice for the treatment of female SUI.

Conclusion

The TOT and TVT-obturator procedures, two novel mid-urethral sling operations for the treatment of female SUI, seem to be effective, easy-to-learn, and safe procedures. Intra-operative diagnostic cystoscopy for ruling out bladder

Table 2 Post-operative variables (NS not significant)

Post-operative variables	TOT group (n = 40)	TVT-obturator group (n = 40)	Statistical significance (P value)
Urgency ^a	9 (25%)	7 (19.4%)	0.153 (NS)
Frequency ^a	9 (25%)	7 (19.4%)	0.428 (NS)
UDI-6 (Pts/level)	5/3, 2/2, 2/1	4/3, 3/2	
Urge incontinence ^a	2 (5%)	3 (7.5%)	0.778 (NS)
UDI-6 (Pts / level)	6/3, 3/2	5/3, 2/2	
Stress incontinence ^a	4 (10%)	2 (5%)	0.115 (NS)
UDI-6 (Pts/level)	3/1, 1/2	1/3, 1/2	
Voiding difficulty ^a	5 (12.5%)	3 (7.5%)	0.891 (NS)
UDI-6 (Pts/level)	3/3, 2/2	2/3, 1/2	
Pelvic pain	2 (5%)	0 (0%)	NS
UDI-6 (Pts/level)	1/3, 1/2		0.262 (NS)
Vaginal pain	2(5%)	2 (5%)	0.494 (NS)

^a According to the International Classification for Standards (ICS) committee guidelines

penetration is not required with these surgical approaches. The short-term follow-up results of the present study for TOT and TVT-obturator are comparable: both the TOT and TVT-obturator procedures resulted in fewer intra-operative and post-operative complications than the TVT. Further follow-up is required for the transobturator operation before it can be recommended as primary care of female SUI.

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