

Tension-Free Vaginal Tape Obturator: Midterm Data on an Operative Procedure for the Cure of Female Stress Urinary Incontinence Performed on 100 Patients

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ABSTRACT **Study Objective:** To evaluate the midterm therapeutic results of a minimally invasive anti-incontinence operative procedure, the tension-free vaginal tape (TVT) obturator.

Design: With this prospective, observational, and consecutive patient series, the TVT obturator procedure was performed by the same surgeon on 100 patients. Follow-up lasted 30 to 36 months.

Setting: Operative theaters of Assuta medical centers private hospitals.

Patients: One hundred female patients with urodynamically proven stress urinary incontinence.

Interventions: TVT obturator operations were performed for all patients.

Measurements and Main Results: Demographic and therapeutic aspects of the patient group data were evaluated. Clinical signs for bowel, urethral, or bladder injuries were undetectable with this TVT obturator patient group. Intraoperative bleeding, postoperative field infections, or postoperative pelvic floor relaxations were not noted. The therapeutic failure rate for the TVT obturator procedure was 8.0% (8 of 100 patients) after 1 year, whereas the midterm failure rate was 10.8% (10 of 93 patients). Six of the 10 patients with TVT obturator failure underwent interval TVT operations with satisfactory results. The overall midterm satisfaction rate for this study group of patients was 89.2% (83 of 93 patients), 6 (6.5%) of those patients were improved only, yet still with minimal residual urinary leakage.

Conclusion: Use of the TVT obturator, a midurethral sling, did not involve bladder penetration and was complicated by a low rate of postoperative outlet obstruction. The midterm therapeutic results and the cost-effectiveness of the TVT obturator appear similar to previously reported midurethral sling operations. Long-term comparative data collection is required to enable drawing solid conclusions regarding the appropriate position of this operative technique within the spectrum of antiincontinence operations. *Journal of Minimally Invasive Gynecology* (2008) 15, 92–96 © 2008 AAGL. All rights reserved.

Keywords: Tension-free vaginal tape obturator; Urinary stress incontinence; Midterm follow-up

The tension-free vaginal tape (TVT) procedure is a well-established surgical procedure for the treatment of female stress urinary incontinence. This midurethral polypropylene tape support operation, described in 1996, is accepted worldwide as an easy-to-learn, effective, and safe surgical

technique. Being minimally invasive and providing high success rates coupled with a low complication incidence, it has rapidly become very popular [1–5].

The 5% to 15% occurrence of TVT failure has been reported previously and the preferable therapeutic approach [2,3,5] has been discussed. It has been reported that some typical TVT operative complications are of concern to the operating surgeons. One of these is bladder penetration—a rather frequent complication of little prognostic influence, necessitating intraoperative cystoscopy and occasional TVT needle reinsertion, and an extended postoperative period of bladder catheterization [2,3,5,6]. Another well-known TVT complication is postoperative urinary outlet obstruction,

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Table 1
Demographics (No. = 100)

Median age in yrs, (range)	52.1 (36–77)
Median parity (deliveries), (range)	3.3 (1–8)
Patients with previous USI corrective surgery (%)	6 (6.0)
Patients with a background of chronic illness*	39 (39.0)
Median incontinence period in yrs, (range)	5.1 (0.5–25)

USI = urinary stress incontinence.

* Diabetes mellitus, bronchial asthma, hypertension, venous insufficiency, and hypothyroidism.

which might have a negative influence on patient rehabilitation [2,3,5]. Other TVT-related complications include bowel penetration, intraoperative bleeding, and postoperative infections [2,3,5–10]. The last 3 complications, although rare and probably caused by poor surgical technique, might entail the potential risk of serious harm to health. Against this background, design of a midurethral sling “inside-out” transobturator TVT-like procedure was encouraged, bypassing the retropubic area, which is intimately proximal to the neighboring bladder, bowel, and blood vessels [11]. Instead, the TVT obturator needle route passes through the relatively safe medial compartment of the obturator fossa, 2.5 to 3 cm medially to the obturator vessels and nerve, remote from the pelvic viscera and vessels [11]. The aim of the current analysis was to evaluate the midterm therapeutic results of this minimally invasive antiincontinence operative procedure, the TVT obturator.

Methods

Patients with urinary stress incontinence, based on subjective symptoms and objective clinical signs and confirmed with urodynamic diagnosis including cystometry, uroflowmetry, and stress test, were prospectively and consecutively referred for corrective surgery. In all, 100 TVT obturator (Gynecare, Somerville, NJ) procedures were performed from May through November 2004 by the same surgeon and reported earlier as part of a larger group of patients with a short follow-up period [10,11]. The data on this series of patients are reported here. All patients were given 1 g of Monocef (cefonicid; Beecham Healthcare, Glasgow, UK) intravenously, 1 hour before surgery [12] and were subjected to an iodine antiseptic prophylactic vaginal wash before commencement of the operation. The mode of anesthesia depended on patient request. The bladder was not emptied before surgery. A foley catheter was placed for the operation, and no diagnostic cystoscopy was performed after. Pelvic floor relaxation was recorded in accordance with the International Continence Society pelvic organ prolapse quantification system [13], and patients with other significant features of pelvic organ prolapse quantification system had colporrhaphies (anterior and posterior) and vaginal hysterectomies as indicated, concomitant with the antiincontinence surgery. Operative bleeding was managed

with surgical hemostasis via the vaginal approach [14]. Intraoperative and postoperative complications within this patient series were prospectively recorded. Postoperative residual urinary volume was assessed by ultrasonography 4 to 6 hours after surgery and an indwelling urethral catheter was placed for 24 hours if more than 150 mL. Patients were interviewed and subjected to pelvic examination at the first, sixth, twelfth, and thirteenth to thirty-sixth postoperative months. A systematic and validated questionnaire, identical to the 1 used before operation, was used for the postoperative interview. Subjective patient questionnaire reports regarding urgency, frequency, stress, and urge incontinence for urine and feces; sexual function impairments; voiding habits; pelvic pain; and bulging were prospectively collected and recorded. The clinical findings on physical pelvic examinations regarding urine and feces leakage, along with relaxation and prolapse of pelvic floor and organs were also prospectively collected according to the ICS standards terminology [13]. Operative failure diagnosis was based on patient reports and confirmed by a clinical stress test. The operative failure was objectively proved in repeated urodynamic studies. Data analysis was performed with software (SAS V9.1; SAS Institute, Cary, NC). Data are presented in the form of descriptive statistics. Categorical variables are depicted by a count and percentage and continuous variables are represented by median and range because the data are not normally distributed.

Results

Patient demographics, and preoperative, operative, and postoperative details have been tabulated in Tables 1, 2, and 3, respectively. According to the pelvic organ prolapse quantification system [13], 31 (31.0%) patients had advanced cystocele (Aa/Ba > +1), 49 (49.0%) had advanced rectocele (Ap/Bp > +1), 6 (6.0%) had uterine prolapse (C > +1), and 3 (3.0%) had vaginal vault prolapse (D > +1). Six (6.0%) patients had TVT obturator as a nonprimary anti-incontinence operation. Furthermore, nearly a third of the study population had severe chronic illnesses such as bronchial asthma, hypertension, venous insufficiency, and hypothyroidism. The outcome of this surgical technique in

Table 2
Preoperative details (No. = 100)

Details	No. of patients (%)
Subjective OAB symptoms	37 (37.0)
Objective OAB	30
Cystocele (Aa/Ba > +1)*	31 (31.0)
Rectocele (Ap/Bp > +1)*	49 (49.0)
Uterine prolapse (C > +1)*	6 (6.0)
Vaginal vault prolapse (D > +1)*	3 (3.0)

OAB = overactive bladder.

* In accordance with the pelvic organ prolapse quantification system.

Table 3
Operative and postoperative patient details (No. = 100)

Details	No. (%)
Anesthesia: general/regional	82 (82.0)/18 (18.0)
Concomitant corrective operations	65 (65.0)
Colporrhaphy: anterior, posterior, or both	51 (51.0)
Hysterectomy: vaginal/abdominal	6 (6.0)/3 (3.0)
Vaginal mesh: posterior IVS/Apogee	3 (3.0)/2 (2.0)
Median follow-up period in mo (range)	33.2 (30–36)
Early postoperative pain (VAS 0–10)	
0–3	74 (74.0)
4–6	23 (23.0)
7–10	6 (6.0)
Postoperative voiding difficulties	4 (4.0)
Urethral catheterization (1–4 days)	3 (3.0)
Operative tape loosening	1 (1.0)
Vaginal tape protrusion	1 (1.0)
Dyspareunia	1 (1.0)
Postoperative OAB subjective symptoms	13 (13.0)
De novo OAB subjective symptoms	0 (0.0)
Therapeutic failure	10/93 (10.8)
1-yr Therapeutic failure	8/100 (8.0)
Midterm (30–36 mo) therapeutic failure	2/93 (2.2)
Interval TVT operation	6/100 (6.0)
Patients highly satisfied (>8 VAS)	10/93 (10.8)
1-yr Satisfaction	92/100 (92.0)
Midterm (30–36 mo) satisfaction	83/93 (89.2)
Bladder penetration, bowel and/or urethral injury, intraoperative bleeding > 200 L, postoperative infection, or pelvic floor relaxation	0 (0.0)

OAB = overactive bladder; TVT = tension-free transvaginal tape; VAS = visual analog scale.

patients with these severe chronic illnesses was not different from that in the other patients enrolled in the study.

Subjective urgency and frequency rate was 37.0% and urodynamic objective detrusor overactivity was diagnosed by cystometry in 81.1% of this patient study group. The mean patient-reported preoperative urinary incontinence period was calculated at 5.1 years. In all, 82 (82%) patients elected to have general anesthesia whereas the rest (18%) had regional anesthesia. A total of 65 (65.0%) patients underwent concomitant operative procedures in addition to the TVT obturator: 51 (51.0%) had anterior and/or posterior colporrhaphies, 6 (6.0%) had vaginal hysterectomies, and 3 (3.0%) had abdominal hysterectomies. Three (3.0%) patients had posterior IVS (Tyco Healthcare, Hampshire, UK) and 2 (2.0%) had Apogee (American Medical Systems, Minnetonka, MN) for the support of vaginal vault. The patients with TVT obturator were followed for 30 to 36 months. Seven (7.0%) patients were lost to follow-up. Therapeutic failure, meaning sustained urinary stress incontinence, was diagnosed in 10 (10.8%) of the 93 patients at the midterm evaluation point; in 8 of them (8 of 100 patients, 8%) this was diagnosed within the first 12 months after surgery (Fig. 1) and 4 of them had TVT obturator only. Six (6.0%) patients reported persistence of residual leakage at stress of minimal degree, with no real impact on quality of

daily life. Of the 10 patients with TVT obturator failure, 6 were cured later by classic TVT [15]. Of 37 patients, 24 (64.9%) with symptomatic preoperative bladder overactivity reported no urgency, frequency, or urge incontinence after surgery. Four (4.0%) patients had postoperative bladder outlet obstruction with residual postmicturition volume of more than 150 mL, 3 of whom recovered by repeated urethral catheterizations for 1 to 7 days whereas 1 required tape tension loosening in the operating department. Two (2.0%) patients had postoperative urinary tract infection and 1 (1.0%) had vaginal protrusion of a 5-mm segment of the tape, which was resected successfully at the outpatient clinic while continence was maintained. In all, 74 (74.0%) patients reported postoperative pain level of 0 to 3 (by a visual analog scale of 0–10), 23 (23.0%) had pain at the level of 4 to 6, and the rest (3.0%) had severe pain at the level of 7 to 10. No operative-related pain was evident beyond the first postoperative week. No intraoperative bleeding, bladder or intestinal penetration, postoperative relaxation of the pelvic floor, de novo bladder overactivity symptoms, or postoperative field infection was reported. One (1.0%) patient had postoperative dyspareunia as a result of posterior migration of the tape, which was palpated close to the anterior vaginal fornix, away from the original placement. This was resolved after cutting the tape at the medial line under anesthesia. Continence was not lost by this additional procedure. Of the patients, 92% (92 of 100) reported high satisfaction (>8 visual analog scale) with the overall operative results whereas 89.2% (83 of 93) reported this at the conclusion of the study, based on a score of 8 or more on an analog visual satisfaction scale, ranging from 0 to 10. The success rate and postoperative complications of the surgical procedure were statistically independent from the patient's age, incontinence period, or perioperative pain level, despite the wide variation of these 2 parameters in the population under study. Within the subgroup of persistent postoperative bladder overactivity symptoms, the high satisfaction rate reduced to 75.0% (9 of 12 patients) for the patients available for end point follow-up.

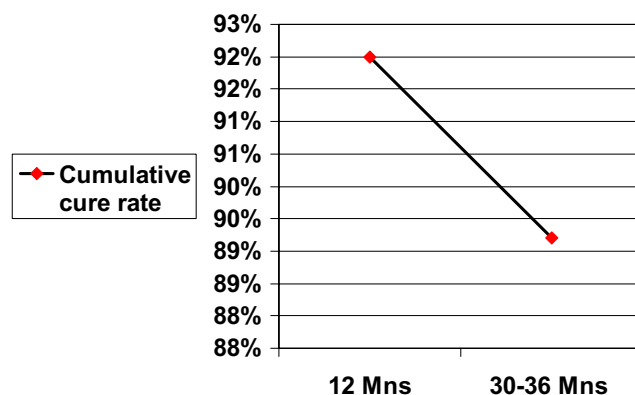


Fig. 1. Life table plot of urinary stress incontinence cure rate 12 to 36 months (Mns) after tension-free transvaginal tape obturator operation.

Discussion

The TVT procedure has become very popular ever since it was first described in 1996. Common complications in previously performed surgeries for the treatment of stress urinary incontinence, such as intraoperative blood loss, pelvic and abdominal organ injury, postoperative de novo detrusor instability, dyspareunia, and urethral erosion, are rare in the TVT era [1–5]. Prospective randomized multicentric studies comparing TVT and the former gold standard Burch colposuspension indicated similar therapeutic impact for both [16,17]. However, TVT was associated with a higher intraoperative complication rate whereas colposuspension was associated with a higher postoperative complication rate and a longer recovery period [16–19]. The previously reported TVT-related complications include bladder penetration, intraoperative bleeding, postoperative field infection, and bowel injury [1–3,5]. Because surgical procedures are more likely to cure stress urinary incontinence rather than nonsurgical procedures [20], the TVT procedure was adapted to avoid the aforementioned complications. This operation provides midurethral support for the treatment of female urinary stress incontinence, while not encroaching on the bladder, the femoral blood vessels, or the bowel. This is achieved by exploiting the obturator fossa as a route for the polypropylene tape, replacing the retropubic space. The midterm data presented herein are in agreement with the earlier reported efficacy of the TVT obturator regarding early cure and intraoperative and early postoperative complication rates [18]. Therapeutic failure rate at 30 to 36 months postoperatively was 10.8% for this patient study group, not much different from the 8.0% failure rate at 12 months of follow-up and similar to the failure rate with the TVT obturator only subgroup (7.0%). Bladder penetration, previously reported in relation to “outside-in” transobturator designed midurethral tape procedures [21,22], was never described in association with an “inside-out” transobturator procedure. In this group of patients, no common intraoperative clinical signs for bladder penetration, such as urinary leakage through surgical abdominal or vaginal cuts, were noted. Although bladder perforation could not be ruled out by diagnostic cystoscopy, the absence of any indicative signs, also in our series of patients, provides additional support to the idea that the TVT obturator does not cause bladder penetration.

Intraoperative bleeding, postoperative field infection, and voiding difficulties also seem to occur less with the TVT obturator than previously reported for TVT [2,3,5,8,10,13,16–19]. However, the latter observation might, in part, be explainable by the relatively short follow-up period for the only recently introduced TVT obturator procedure, the relatively small study sample size, and the accumulated surgical experience with midurethral sling placement during the time since TVT was launched. Only 13 (13.0%) patients required minimal invasive reoperation: 10 (10.0%) of them needed a repeated antiincontinence

operation and 3 needed corrective day-care procedures. The latter were performed to cure outlet urinary obstruction resulting from extended tape tension (1 patient, 1.0%), dyspareunia caused by posterior migrated tapes (1 patient, 1.0%), and vaginal protrusion (1 patient, 1.0%). These figures resemble those previously reported for the TVT procedure [1–6]. In all, 37 (37.0%) patients reported symptoms of bladder overactivity before surgery, in 81.1% of them this was accompanied by cystometric diagnosis of detrusor overactivity. Thirteen (35.1%) of them continued having the same problem postoperatively. This improvement might be explained by pelvic floor damage repair. No de novo occurrence of bladder overactivity symptoms was recorded with this patient group. The 1 year and study end point high over all patients’ satisfaction rates, and the relatively low operative pain score encourage electing the TVT obturator for the treatment of female urinary stress incontinence.

In summary, the TVT obturator procedure appears to be relatively easy to perform and relatively trouble-free for both surgeons and patients. The experienced surgeon might consider abandoning urethral catheterization and diagnostic cystoscopy during surgery [23]. The potential superiority of the TVT obturator relative to the globally known TVT, as indicated by the data presented here and suggested previously [23–27], should be further confirmed by additional randomized prospective longitudinal comparative studies.

Conclusion

The herein presented midterm data further support the notion that the TVT obturator procedure, a midurethral sling operation for the treatment of female stress urinary incontinence, seems to be effective and safe. Intraoperative diagnostic cystoscopy and bladder catheterization might not be mandatory for the experienced surgeon performing this operation. The TVT obturator procedure is associated with a relatively low rate of minor complications, both intraoperatively and postoperatively, in comparison with other modalities of antiincontinence operation. These included a lower incidence of operative bleedings, postoperative field infections, and voiding difficulties. The data reported here show that the TVT obturator–related cure of urinary stress incontinence persists with time, being similar for 30 to 36 months as for 1 year after operation. Nevertheless, randomized controlled trials and long-term follow-up are needed before the question of which of these 2 surgical antiincontinence techniques are preferred can be answered.

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