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# TVT-Obturator: Short-Term Data on an Operative Procedure for the Cure of Female Stress Urinary Incontinence Performed on 300 Patients

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**Abstract**

***Objectives:*** To evaluate the short-term therapeutic results of a novel minimally invasive anti-incontinence operative procedure—the tension-free vaginal tape (TVT)-obturator.

***Methods:*** With this prospective, observational, and consecutive patient series, TVT-obturator surgery was performed, according to de Leval (2003), by the same surgeon on 300 patients with urodynamically proven stress urinary incontinence. Follow-up lasted 4–24 mo.

***Results:*** The demographic and therapeutic aspects of the patient group data were evaluated. The TVT-obturator required neither bladder catheterization nor intraoperative diagnostic cystoscopy. Half of the 18 (6%) patients with postoperative voiding difficulties had postoperative urethral bladder catheterization for 1–4 d, whereas the other 9 patients underwent a tape loosening procedure in theater under anesthesia. The early therapeutic failure rate for the TVT-obturator procedure was 2.7% (8 patients). Six of the latter patients underwent an interval TVT operation with satisfactory results. Neither bowel nor urethral injuries were recorded, and no evidence of bladder penetration was observed. With the TVT-obturator, no intraoperative bleedings, postoperative field infections, or postoperative pelvic floor relaxations were noted.

***Conclusions:*** Use of the TVT-obturator, a novel midurethral sling, seems to reduce the incidence of some of the operative complications associated with the TVT, primarily bladder penetration and postoperative outlet obstruction. The early therapeutic results and the cost-effectiveness of the novel TVT-obturator appear similar to those reported for common TVT surgery. However, long-term comparative data collection will be required to enable drawing solid conclusions regarding the appropriate position of this operative technique within the spectrum of anti-incontinence operations.



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## 1. Introduction

The tension-free vaginal tape (TVT) procedure is a well-established surgical procedure for the treatment of female stress urinary incontinence. The operation, described by Ulmsten in 1996 [1], which is based on a midurethral Prolene tape support, is accepted worldwide as an easy-to-learn, effective and safe surgical technique. Being minimally invasive and providing high success rates at a low complication incidence, it has rapidly become very popular [1–5].

The 5–15% occurrence of TVT failure has been reported previously, and the preferable therapeutic approach [2,3,5,9] 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 re-insertion, as well as an extended postoperative period of bladder catheterization [2,3,5,6]. Another well-known TVT complication is postoperative urinary outlet obstruction, which might have a negative influence on patient rehabilitation [2,3,5,8]. Other TVT-related complications include bowel penetration, intraoperative bleeding, and postoperative infections [2,3,5–9]. The last three complications, although very rare and probably caused by poor surgical technique, might entail the potential risk of serious harm to health.

Against this background, Jean de Leval [11] was encouraged to design a novel midurethral sling "inside-out" trans-obturator TVT-like procedure wherein the TVT needle bypasses the retropubic area, which is intimately proximal to the neighboring bladder, bowel, and blood vessels. Instead, the TVT-obturator needle route passes through the relatively safe medial compartment of the obturator fossa area, 2.5–3 cm medially to the obturator vessels and nerve, remote from the pelvic viscera and vessels. The aim of the current analysis was to evaluate the short-term therapeutic results of this novel, minimally invasive, anti-incontinence operative procedure—the TVT-obturator.

## 2. Methods

Patients suffering from urinary stress incontinence, based on subjective complaints and objective clinical signs and confirmed with urodynamic diagnosis including cystometry, uroflowmetry, and stress test, were prospectively and consecutively referred for corrective surgery. Three hundred TVT-obturator procedures were performed from May 2004 to December 2005. The results on this series of patients, operated on according to de Leval [11] by the same surgeon, are reported here.

All patients were given 1 g of monocef (Cefonicid, Beecham Healthcare) intravenously, 1 h prior to surgery [10] and were subjected to an iodine antiseptic prophylactic vaginal wash prior to commencement of the operation. The mode of anesthesia depended on patient request. No Foley catheter was placed and no diagnostic cystoscopy was performed. Pelvic floor relaxation was recorded in accordance with the International Continence Society (ICS) pelvic organ prolapse quantification system (POPQ) [12]. Patients presenting with other significant features of POPQ had colporrhaphies (anterior and posterior) and vaginal hysterectomies as indicated, concomitant with the anti-incontinence surgery. Operative bleeding was managed with surgical hemostasis via the vaginal approach [13].

Intraoperative and postoperative complications within this patient series were prospectively recorded. Patients were interviewed and subjected to pelvic examination during the first, sixth, and twelfth postoperative months. A systematic and validated questionnaire, identical to the one used prior to operation, was used for the postoperative interview. Subjective patient questionnaire reports regarding urgency, frequency, stress and urge incontinence for urine and faeces, sexual function impairments, voiding habits, pelvic pain, and bulging were prospectively collected and recorded. The clinical findings on physical pelvic examinations regarding urine and faeces leakage, and relaxation and prolapse of the pelvic floor and organs were also prospectively collected according to the ICS standards terminology [12]. Operative failure diagnosis was based on patient reports and confirmed by a clinical stress test. The operative failure was objectively proven in repeated urodynamic studies.

Data analysis was performed with SAS version 9.1 (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 the mean, SD, and range.

## 3. Results

Patient demographics and operative, preoperative, and postoperative details have been tabulated in Tables 1–3, respectively. According to the POPQ system [12], 167 (55.7%) patients had advanced cystocele (Aa/Ba $>$ +1), 115 (38.3%) had advanced rectocele (Ap/Bp $>$ +1), 29 (9.7%) had uterine prolapse (C $>$ +1), and 11 (3.7%) had vaginal vault prolapse (D $>$ +1). Fifteen (5.0%) patients had the TVT-obturator as a nonprimary anti-incontinence operation. Furthermore, nearly a third of the study population were suffering from severe chronic illnesses such as bronchial asthma, hypertension, venous insufficiency, and hypothyroidism. The outcome of this surgical technique in patients suffering from these severe chronic illnesses did not differ from that found in the other patients enrolled in the study.

**Table 1 – Demographics (no. = 300)**

| | |
|---|---|
| Age (yr) (mean ± SD [range]) | 55.0 ± 10.8 (29–83) |
| Parity (deliveries) (mean ± SD [range]) | 3.1 ± 1.4 (1–10) |
| Previous USI corrective surgery | 15 pts (5.0%) |
| Background chronic illness* | 104 pts (34.7%) |
| Incontinence period (yr) (mean ± SD [range]) | 4.6 ± 4.2 (0.3–31) |

USI: Urinary stress incontinence.
* Diabetes mellitus, bronchial asthma, hypertension, venous insufficiency, and hypothyroidism.

**Table 2 – Preoperative details (no. = 300)**

| | |
|---|---|
| OAB symptoms | |
| Objective symptoms | 92 pts (30.7%) |
| Subjective symptoms | 86 pts (28.7%) |
| Cystocele (Aa/Ba > +1)* | 133 pts (44.3%) |
| Rectocele (Ap/Bp > +1)* | 115 pts (38.3%) |
| Uterine prolapse (C > +1)* | 29 pts (9.7%) |
| Vaginal vault prolapse (D > +1)* | 11 pts (3.7%) |

OAB: Overactive bladder; POP-Q: pelvic organ prolapse quantification system.
* In accordance with the POP-Q system.

Subjective urgency and frequency rate was 30.7%, and urodynamic objective detrusor overactivity was diagnosed by cystometry in 28.7% of this patient study group. The mean patient-reported preoperative urinary incontinence period was calculated at 4.6 y. Two hundred thirteen (71.0%) patients underwent concomitant operative procedures in addition to the TVT-obturator: 190 (63.3%) had anterior and/or posterior colporrhaphies, 28 (9.3%) had vaginal hysterectomies, and 18 (6.0%) had abdominal hysterectomies. Eleven (3.7%) patients had Posterior IVS (Tyco) and two (0.6%) had Apogee (AMS) for the support of the vaginal vault. The TVT-obturator patients were followed up for a mean period of 1.2 y (4–24 mo); 168 patients had more that 12 mo of follow-up. No patients were lost to follow-up.

Therapeutic failure, meaning sustained urinary stress incontinence, was diagnosed in eight (2.7%) patients, four of them among the group having more than 12 mo of follow-up (2.4%) and two (2.3%) of them among the TVT-obturator–only patients. Of the eight TVT-obturator failure patients, six were cured after retreatement by TVT [14]. No intraoperative bleeding, bladder or intestinal penetration, postoperative relaxation of the pelvic floor, or postoperative field infection was reported. Early postoperative partial outlet obstruction, defined as post micturition bladder urine content of 150 ml or more, was treated with repeated bladder catheterization for up to 4 d (nine [3.0%] patients), whereas complete obstruction needed tape resection (nine [3.0%] patients) [8]. Four (1.3%) patients suffered postoperative dyspareunia attributable to posterior migration of the tape, which was palpated close to the anterior vaginal fornix, away from the original placement. This complication was resolved after cutting the tape at the medial line in theater under anesthesia. Continence was not lost by this

**Table 3 – Details of operative and postoperative patients (no. = 300)**

| | |
|---|---|
| Anesthesia: general/regional (pts) | 245 (82.0%)/55 (18.0%) |
| Concomitant corrective operations (pts) | 213 (71.0%) |
| Colporrhaphy: anterior/posterior | 137 (45.7%)/89 (29.7%) |
| Hysterectomy: vaginal/abdominal | 28 (9.3%)/18 (6.0%) |
| Vaginal mesh: PIVS/Apogee | 11 (3.7%)/2 (0.6%) |
| Bladder penetration, bowel and/or urethral injury, intraoperative bleeding >200 ml, postoperative infection, or pelvic floor relaxation | 0 pts (0.0%) |
| Vaginal tape protrusion | 2 pts (0.7%) |
| Dyspareunia | 4 pts (1.3%) |
| Total early therapeutic failure | 8 pts (2.7%) |
| Early therapeutic failure within the subgroup of > 12 mo of follow-up (168 pts) | 4 pts (2.4%) |
| Early therapeutic failure within the subgroup of TVT-obturator only (87 pts) | 2 pts (2.3%) |
| Interval TVT operation | 6 pts (2.0%) |
| Postoperative voiding difficulties (>24 h) | 18 pts (6.0%) |
| Urethral catheterization (1–4 d) | 9 pts (3.0%) |
| Operative tape loosening | 9 pts (3.0%) |
| Postoperative OAB subjective symptoms | 43 pts (14.3%) |
| De novo OAB subjective symptoms | 10 pts (3.3%) |
| Follow-up period (yr) (mean ± SD [range]) | 1.2 ± 0.5 (0.3–2.0) |

OAB: overactive bladder; TVT: tension-free vaginal tape.

additive procedure. Two (0.7%) patients had vaginal tape protrusion, which was repaired in theater under anesthesia simply by covering the protrusion again with surrounding vaginal mucosa. In total, 23 (7.7%) patients required reoperation with 8 needing another anti-incontinence operation and 15 needing relatively minor corrective day-care procedures. Forty-three (14.3%) patients reported postoperative symptoms of bladder overactivity, 10 (3.3%) as de novo occurrence and the remainder as a long-lasting problem. The success rate and postoperative complications of the surgical procedure were statistically independent from the patient's age or incontinence period, despite the wide variation of these two parameters in the population under study.

## 4. Discussion

The TVT procedure has become very popular ever since Ulmsten first described it in 1996 [1]. 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 demonstrated similar therapeutic impact for both [15,16]. 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 [15–18]. The previously reported TVT-related complications include bladder penetration, intraoperative bleeding, postoperative field infection, and bowel injury [1–3,5]. Since surgical procedures are more likely to cure stress urinary incontinence rather than non-surgical procedures [19], de Leval adapted the TVT procedure to avoid the aforementioned complications. His novel type of surgery enables midurethral support for the treatment of female urinary stress incontinence, while not encroaching on the bladder, the femoral blood vessels, or the bowel. This outcome is achieved by exploiting the obturator fossa as a route for the Prolene tape, replacing the retropubic space. The short-term data presented herein is in agreement with the earlier reported efficacy of the TVT-obturator regarding early cure as well as intraoperative and early postoperative complication rates [17]. Early therapeutic failure rate was 2.7% for this patient study group; this rate was not much different in the more than 12 mo of follow-up (2.4%) or in the TVT-obturator–only (2.3%) subgroups. Bladder penetration, previously reported in relation to ''outside-in'' transobturator-designed midurethral tape procedures, [20,21] was never described in association with an ''inside-out'' transobturator procedure. In our 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, as also seen 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 [2,3,5,8,10,13,15–18]. 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, as well as the accumulated surgical experience with midurethral sling placement during the time since TVT was launched. Only 23 (7.7%) patients required reoperation: 8 (2.7%) of them needed a repeat anti-incontinence operation and 15 needed relatively minor corrective day-care procedures. The latter were performed to cure outlet urinary obstruction resulting from extended tape tension (nine [3%] patients), dyspareunia caused by posterior migrated tapes (four [1.3%] patients), and vaginal protrusion (2 [0.7%] patients). These figures resemble those previously reported for the TVT procedure [1–6]. Eighty-six (28.7%) patients reported symptoms of bladder overactivity, accompanied by cystometric diagnosis of detrusor overactivity prior to surgery, whereas only 33 (11%) of them suffered from the same problem postsurgery. This improvement might be explained by the thorough pelvic floor damage repair. The de novo occurrence of symptoms of bladder overactivity in the case of 10 (3.3%) patients could neither be predicted preoperatively nor explained by any particular event that occurred during surgery.

In summary, the TVT-obturator procedure appears to be easier and more trouble-free for both surgeons and patients, and might not require urethral catheterization or diagnostic cystoscopy during surgery [22]. The potential superiority of the TVT-obturator relative to the globally known TVT, as indicated by the data presented here and suggested by others [23–26], should be further confirmed by additional randomized, prospective, longitudinal, comparative studies.

## 5. Conclusions

Our data further support the notion that the TVT-obturator procedure, a novel 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 with this newly introduced surgical approach. The TVT-obturator procedure was associated with fewer complications, both intraoperatively and postoperatively, than previously reported for the TVT procedure. These complications included a lower incidence of operative bleedings, postoperative field infections, and voiding difficulties. Nevertheless, randomized controlled trials and long-term follow-up are needed before the question of which of these two surgical anti-incontinence techniques are preferred can be answered.

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**Editorial Comment**

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Urinary incontinence has a high prevalence among women [1] and the overall costs involved in treating patients have been increasing [2]. Investigators have therefore been seeking novel and more efficient therapeutic procedures. One of these, which is described in the present article, is the tension-free vaginal tape (TVT)-obturator, a modification of the more widely used TVT surgical method. These are first results from a comparatively short follow-up, and yet they are encouraging because the procedure seems to be safer and to have fewer complications than the method on which it is based.

The study, however, has other limitations. Because it investigates a relatively new surgical technique, a larger population of properly selected patients could not be enrolled in the study. For example, about 70% of the patients had to be submitted to other surgical treatments in addition to the TVT-obturator, and about 35% suffered from various and previous chronic illnesses. Also, the ages of the patients and their periods of urinary incontinence varied widely.

These facts notwithstanding, the author reported that the outcome of the surgical technique was affected neither by these illnesses nor by the patient's age and incontinence period. So this is an additional advantageous feature of the TVT-obturator technique, and the author should have commented more at length on that. For example, the extracellular matrix of supportive structures of pelvic organs and of the urinary tract may undergo remodeling and have less tensile strength as a result of age or variations in female sex hormones, which may in turn underlie disorders such as prolapse and stress urinary incontinence itself [3]. Indeed, urinary incontinence does occur more frequently in older women [4], and one would expect the efficiency of the TVT-obturator technique to diminish with age.

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