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Perioperative Complications and Early Follow-up with 100 TVT-SECUR Procedures

Menahem Neuman, MD

From Research and Development in Urogynecology, Shaare Zedek Medical Center, Jerusalem and Urogynecology, Assuta Medical Centers, Rishon le-Zion and Tel-Aviv, Israel.

ABSTRACT Our objective was to evaluate the complications and early follow-up of the tension-free vaginal tape (TVT)-SECUR, a new minimally invasive anti-incontinence operative procedure. A prospective, observational, and consecutive patient series was conducted. Perioperative and 12-month postoperative data were prospectively collected for the first 50 patients against the next consecutive 50 patients, among which TVT-SECUR specific surgical measurements were adopted (Canadian Task Force classification 2). In private hospital operative theatres, the TVT-SECUR operation was performed. Patients with urodynamically proved stress urinary incontinence were enrolled in this study after detailed informed consent was given. The TVT-SECUR, in the hammock shape to mimic the TVT-obturator placement, yet with no skin incisions, required neither bladder catheterization nor intraoperative diagnostic cystoscopy. The clinical and surgical data of 100 consecutive patients with TVT-SECUR were collected prospectively. Two patients had urinary obstructions and needed surgical tape-tension relief. One patient had a 50 mL paravesical self-remitting hematoma. At the first-month postoperative follow-up appointment, the objective therapeutic failure rate for the TVT-SECUR procedure among the 50 patients was 20.0% (10 patients). But when the tape was placed close to the urethra with no space allowed in between, the failure rate in the second patient group went down to 8.0% (4 patients); yet no further postoperative bladder outlet obstruction was diagnosed. Four (8.0%) patients in the first group had vaginal wall penetration with the inserters, requiring withdrawal, reinsertion, and vaginal wall repair. This was avoided with the second patient group by facilitating the inserters' introduction by widening the submucosal tunnel to 12 mm. Six (12.0%) other patients in the first group needed postoperative trimming of a vaginally extruded tape segment, performed in the office with satisfactory results. This problem was addressed later by making the submucosal dissection deeper to avoid intimate proximity of the tape with the vaginal mucosa. Consequently the tape protrusion rate was reduced to 8% (4 patients). Five (10.0%) patients in the first group had unintended tape removal at the time of inserter removal, necessitating the use of a second TVT-SECUR. This was addressed by meticulous detachment of the inserter before its withdrawal, after which no further unintended tape displacements were recorded. No clinical signs for bowel, bladder, or urethral injuries; intraoperative bleeding; or postoperative infections were evident. Telephone interview at the end of 12 months postoperatively was completed with 44 (88.0%) of the first patient group and 46 (92%) of the second patient group. In all, 39 (88.6%) and 43 (93.5%) of the telephone-interviewed patients of the first and second groups, respectively, reported objective urinary continence. The TVT-SECUR, a new midurethral sling, was associated with early safety and efficacy problems. These were identified and rectified, to make the TVT-SECUR a safe and effective anti-incontinence procedure. Operative complications associated with the TVT, such as bladder penetration and postoperative outlet obstruction, and TVT-obturator complications, such as postoperative thigh pain and bladder outlet obstruction, may be reduced with the TVT-SECUR. The first 100 operations' cumulative data analysis yielded some insights, including the necessity of meticulous and proper dissection before placement of the tape and the need for applying minimal extra tension to the tape. However, long-term comparative data collection will be required to draw solid conclusions regarding the appropriate position of this operative technique within the spectrum of anti-incontinence operations. Journal of Minimally Invasive Gynecology (2008) 15, 480–484 © 2008 AAGL. All rights reserved.

Keywords: TVT-SECUR; Urinary stress incontinence; Minimally invasive operation

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Corresponding author: Menahem Neuman, MD, Research and Development in Urogynecology, Shaare Zedek Medical Center, 7 Te'ena Street, Carmei-Yosef, 99797, Israel.

E-mail: mneuman@netvision.net.il

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The tension-free vaginal tape (TVT) procedure is a well-established surgical procedure for the treatment of female stress urinary incontinence. The operation, described in 1996, which is based on a midurethral poly-propylene tape support, is accepted worldwide as an easy-to-learn, effective, and safe surgical technique [1–5]. However, typical TVT operative complications of concern to the operating surgeons include: bladder penetration, urinary outlet obstruction, potential bowel penetration, intraoperative bleeding, and postoperative infections [2,3,5–9]. Against this background, Delorme was encouraged to design a novel midurethral sling in the form of a transobturator TVT-like procedure. In such, the TVT needle bypasses the retro pubic area, which is in intimate proximity with the bladder, bowel, and blood vessels, by making the needle route pass through the relatively safe medial compartment of the obturator fossa area, remote from the pelvic viscera and vessels [10]. The TVT-obturator was shown to be a safe and easily performed minimally invasive anti-incontinence procedure [11,12]. The novel TVT-SECUR (Gynecare, Somerville, NJ) was designed to overcome 2 of the perioperative complications reported with use of the TVT-obturator: thigh pain and bladder outlet obstruction [11,12]. This was addressed by tailoring the tape to only 8 cm long and anchoring the tape edges into the internal obturator muscle, rather than passing it through the obturator foramen, muscles, and membrane. The initial pull-out force of the tape and further tissue ingrowth were studied in the sheep model, revealing satisfactory figures [13]. The aim of the current analysis was to evaluate the early training operative data collected with the first 100 novel, minimally invasive anti-incontinence procedures.

Methods

In all, 100 consecutive patients with urinary stress incontinence with no intrinsic sphincteric deficiency, based on subjective symptoms and objective clinical signs, confirmed with urodynamic diagnosis including cystometry, uroflowmetry, and stress test, were prospectively and consecutively referred for hammock shape TVT-SECUR. All patients received a thorough consultation and explanation emphasizing the novelty of the procedure and the lack of experience, before giving informed consent. All patients were given 1 g of Monocef (Cefonicid; Beecham Healthcare, Glasgow, UK) intravenously 1 hour before surgery and were subjected to an iodine antiseptic prophylactic vaginal wash before 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 [14]. Patients with significant vaginal wall relaxation had colporrhaphies concomitant with the anti-incontinence surgery. Hysterectomies were not performed with this series. Operative bleeding was managed with hemostatic suture placement via vaginal approach [15]. Intraoperative and early postoperative complications within this patient series were recorded prospectively. Patients were interviewed, asked to respond to urogynecology (UDI6) and quality-of-life (QoL) (IIQ7) questionnaires [16], and had a pelvic examination at the end of the first postoperative month. Telephone interview was conducted for the UDI6 and IIQ7 questionnaire replay at 12 postoperative months and the unsatisfied patients were asked to make a personal appointment. The clinical findings regarding urine and feces leakage and prolapse were also collected according to the ICS standards terminology [14]. Therapeutic failure was defined as persistent urinary stress incontinence affecting QoL, both reported by the patient and clinically confirmed. Minimal residual leakage, not deteriorating the patient's QoL, was mentioned but not regarded as therapeutic failure. After completion of the first 50 operations the accumulated data were analyzed, revealing increased failure and complication rates. Hence, the surgical steps altered respectively: with the second 50 patients the tunnels were made wider, deeper, and shorter; the inserters were separated properly from the tapes before withdrawal; and space was avoided between the tape and urethra. The two patient groups' data were compared. All statistical analyses were performed with software (SPSS 10.1.4; SPSS Inc., Chicago, IL). The *t* test was used for quantitative variance analysis, whereas the Fisher exact test and the χ^2 test were used for categorical variance. All statistical tests were evaluated at the $p = .05$ level of significance.

Results

A total of 100 hammock-shaped TVT-SECUR operations were performed from September 9, 2006, through December 25, 2006, for the treatment of urodynamic urinary stress incontinence. Patients' preoperative, operative, and postoperative details were tabulated in Tables 1, 2, and 3, respectively. According to the pelvic organ prolapse quantification [14], 56 (56.0%) patients had an advanced cystocele (Aa/Ba $> +1$), 22 (22.0%) had an advanced rectocele (Ap/Bp $> +1$), 4 (4.0%) had uterine prolapse (C $> +1$), and 3 (3.0%) had vaginal vault prolapse (C $> +1$). All patients underwent the TVT-SECUR operation for treatment of incontinence. In all, 36 (72.0%) and 43 (86%) patients of the first and second groups, respectively, underwent concomitant operative procedures in addition to the TVT-SECUR: 71 patients had anterior and/or 22 posterior colporrhaphies; and 8 (8.0%) patients had anterior and/or ProLift (Gynecare) operation

Table 1
Preoperative details (N = 100)

Preoperative data	First 50 patients	Second 50 patients	Statistical significance
Age, yrs (mean, SD)	53.3 (9.2)	55.4 (9.7)	p =.26
Parity (mean, SD)	3.0 (1.0)	2.8 (1.1)	p =.61
OAB	9 (18.0%)	5 (10.0%)	p =.41
Previous anti-incontinence surgery	8 (16.0%)	3 (6.0%)	p =.10

OAB = overactive bladder.

Table 2
Operative patient details (N = 100)

Operative data	First 50 patients	Second 50 patients	Statistical significance
Anesthesia: G/R	41 (82%)/9 (18%)	44 (88.0%)/6 (12%)	p = .11
Concomitant corrective operations: colporrhaphy or vaginal mesh	36 (72.0%)	43 (86.0%)	p = .09

G = general; R = regional.

for the support of the uterus, vaginal walls, and apex. No hysterectomies where performed with this patient series. The mode of anesthesia was subject to patient request, resulting in general anesthesia for 86 (86.0%) patients and in regional anesthesia for 14 (14.0%) patients. No anesthetic mode appeared to be superior in terms of facilitating the procedure or the recovery. The patients with TVT-SECUR were followed up for a period of 12 months. Ten (10.0%) of them were lost. Within the first 50 patients, first-month therapeutic failure (objective sustained urinary stress incontinence) was diagnosed in 10 (20.0%) patients. Three (6.0%) other patients reported residual postoperative leakage, not influencing QoL and, hence, not regarded as therapeutic failures. As a result of these figures, the tape was placed close to the urethra, permitting no space in between with the last 50 patients and consequently the objective failure rate was reduced to 4 (8.0%) patients at 1 month postoperatively. Neither operative bleeding nor clinical signs for bladder or intestinal penetration, postoperative infection, bladder overactivity, or outlet obstruction were evident. Four (8.0%) patients in the first group had vaginal wall penetration with the inserters, requiring withdrawal, reinsertion, and vaginal wall repair. This was avoided later by making the preliminary submucosal tunnel as wide as 12 mm to permit the device to slip in smoothly.

Table 3
Complications and postoperative patient details (N = 100)

Postoperative data	First 50 patients	Last 50 patients	Statistical significance
Total operative complications	32 (64%)	13 (26%)	p = .05
Complications: first vs second group:			
Tape removal (5/0)			
Vaginal wall penetration (4/0)			
Vaginal tape protrusion (6/4)			
Uterine prolapse (1/0)			
Bladder outlet obstruction (1/1)			
OAB (14/7)			
Dyspareunia (0/1)			
Paravesical hematoma (1/0)			
First-month therapeutic failure	10 (20.0%)	4 (8.0%)	p = .14
Clinical signs for postoperative bleeding, bladder penetration, bowel and/or urethral injury, postoperative outlet obstruction, or infection	0 (0.0%)	0 (0.0%)	

OAB = overactive bladder.

Following on this, no further vaginal penetrations were noted. Five (10.0%) other first-group patients had vaginal tape extrusion, which was easily resected in office and no morbid sequela was recorded. No mesh extrusion occurred since incorporating suburethral dissection to the procedural steps. Five (10.0%) patients in the first group had unintended tape removal at the time of inserter removal, necessitating the use of a second TVT-SECUR. This was addressed by proper inserter separation from the tape before its withdrawal and, consequently, no further unintended tape displacements were recorded. One patient had a self-resumed postoperative paravesical hematoma of 50 mL. Hematocrit level was not altered and neither blood transfusion nor bleeding control measures were required. No patient described the subjective operation-related pain level as higher than minimal. At 12 months' follow-up, an attempt to interview by telephone or e-mail was carried out. In all, 44 and 46 patients of both groups replayed the UDI6 and IIQ7 questionnaires and reported 88.6% and 93.5% continence, respectively. Bladder overactivity symptoms such as frequency, urgency, and urge incontinence were evident with 18% and 10% of the first and second patient groups before surgery. This was increased to 28% and 20% of the first and second patient groups after operation. No other pelvic floor–related QoL impairments were recorded. Return to normal daily activity occurred within 4 days with 80% of the patients (range 1–10 days). The patients were instructed to avoid sexual intercourse for 6 weeks after surgery.

Discussion

The TVT procedure has become very popular ever since it was first described in 1996. Common complications with 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 multicenter studies, comparing TVT to the former gold standard Burch colposuspension, revealed similar therapeutic impact for both. 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 [17,18]. The previously reported TVT-related complications included bladder penetration, intraoperative bleeding, postoperative infection, and vessel and bowel injuries [1–3,5–8]. Because surgical procedures are more likely to cure stress urinary incontinence than nonsurgical procedures [19], Delorme adapted the TVT-obturator 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 is achieved by exploiting the obturator fossa as a route for the Prolene tape, replacing the retro pubic space. The reported data regarding efficacy of the TVT-obturator in terms of

cure along with intraoperative and early postoperative complication rates are encouraging [11,12]. Bladder penetration, previously reported in relation to outside-in transobturator-designed midurethral tape procedures [20,21], was not described in association with an inside-out transobturator procedure. Although bladder perforation could not be ruled out as diagnostic cystoscopy is not routinely performed, the absence of any indicative signs provides additional support to the idea that the TVT-obturator does not cause bladder penetration. Therapeutic failure, intraoperative bleeding, and postoperative voiding difficulties also seem to occur less with the TVT-obturator than previously reported for TVT [2,3,5,8,11,12,15,17,18]. However, the TVT-obturator is not free of operative complications: thigh pain is reported to interfere with patient satisfaction; operative infections and postoperative bladder outlet obstructions still occur as does occasional operative hemorrhage. The TVT-SECUR was designed to minimize the operative procedure as much as possible to reduce these undesired complications [22,23]. This new device is composed of an 8-cm long laser-cut polypropylene mesh and is introduced to the internal obturator muscle (hammock position) by a metallic inserter, while no exit skin cuts are needed. This approach imitates the submidurethral support provided with the TVT-obturator, yet imitating the TVT is possible as well, by introducing the TVT-SECUR arms retropubically rather than to the obturator area. This ''U'' position approach necessitates urethral catheterization and diagnostic cystoscopy for recognition of possible bladder penetration. As the main possible advantage of the TVT-SECUR is minimalization of the procedure and reduction of its side effects, the simpler hammock approach was elected for this patient series. The TVT-SECUR midurethral sling operations for the cure of urodynamic urinary stress incontinence reported herein, performed according to the above-suggested specific guidelines, seems to be both safe and effective. This is evident when comparing the first and second study group's early operative-related complications. No space should be permitted in between the urethra and the TVT-SECUR, differing from the TVT, to achieve the desired therapeutic result. The inserters, being more than twice as wide as TVT and TVT-obturator needles, necessitate wider tunnels, 12 mm at least, to permit smooth passage of the tape and inserter and to avoid gathering of vaginal skin, which may lead to vaginal wall penetration. The tunnel depth should not go beyond the bone edge to avoid damaging the tissue meant to hold the coated tape edge; otherwise the tape initial pull-out force might be impaired. The locking mechanism, attaching the tape to the inserter, should be separated properly and detached gently, to avoid unwanted tape removal with withdrawal of the inserter. Adoption of these simple surgical steps leads to improvement of the operative results. Postoperative improvement with bladder overactivity symptoms was earlier noticed with TVT and TVT-obturator, yet was poorly understood. The integral theory provides an unproved explanation, saying the well-supported bladder is related to less spontaneous detrusor baroreceptors activity. No explanation existed for the nonsignificant increase in bladder overactivity symptoms such as frequency, urgency, and urge incontinence, which were evident with both patient groups after surgery. The UDI6 and IIQ7 questionnaires comparative data statistical analysis revealed no statistical significance.

In summary, the TVT-SECUR procedure appears to be potentially easier to perform and relatively trouble free for both surgeons and patients and might not require urethral catheterization or diagnostic cystoscopy during surgery. Taking into account the above-mentioned procedural specific surgical steps might shorten the TVT-SECUR learning curve. The TVT-SECUR caries the potential of being performed under local anesthesia at an outpatient service setting, yet the novel TVT-SECUR's actual place among TVT and TVT-related procedures should be determined with randomized prospective longitudinal comparisons.

Conclusion

These data support the notion that the TVT-SECUR, a new midurethral sling operation for the treatment of female stress urinary incontinence, was associated with mild early safety and efficacy problems. These problems were identified and rectified, making the TVT-SECUR a safe, effective and easy-to-perform operation. Intraoperative diagnostic cystoscopy and bladder catheterization might not be mandatory for an experienced surgeon when using the hammock approach. The TVT-SECUR procedure might be associated with fewer complications, both intraoperatively and postoperatively, than previously reported for the TVT and TVT-related procedures. One should honor the above-mentioned special features of this novel procedure to ensure simplicity, safety, and security. Randomized comparative controlled trials and long-term follow-ups are still needed to clarify the relative places of the different midurethral tape anti-incontinence techniques.

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