Original article

TVT-SECUR:
100 teaching operations with a novel anti-incontinence procedure

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Abstract: AIM. To evaluate the technical aspects and training process of the TVT-SECUR – a novel minimally invasive anti-incontinence operative procedure. METHODS. With this prospective, observational and consecutive patient series, the TVT-SECUR operation was taught by one trainer to experienced pelvic floor surgeons on 100 patients with urodynamically proven stress urinary incontinence. Peri-operative data was prospectively collected. RESULTS. The surgical aspects of these 100 patient's parameters were evaluated. No voiding difficulties, significant pain, or any other patient inconvenience was observed post-operatively. The early therapeutic failure rate for the TVT-SECUR procedure was 9.0%. Four patients had vaginal wall penetration with the inserters, requiring withdrawal and re-insertion as well as vaginal wall repair. Three other patients needed trimming of a vaginaly extruded tape segment, done in the office with satisfactory results. Five patients had un-intended tape removal at the time of inserter removal, necessitating the usage of a second TVT-SECUR. No signs for bowel, bladder, or urethral injuries, intra-operative bleeding or post-operative infections were evident. CONCLUSIONS. Use of the TVT-SECUR, a novel mid-urethral sling, seems to be a safe anti-incontinence procedure. Operative complications associated with the TVT, such as bladder penetration and post-operative outlet obstruction as well as the TVT-Obturator complications such as post operative thigh pain and bladder outlet obstruction seem to be reduced with the TVT-SECUR.

Key words: TVT-SECUR; Urinary Stress Incontinence; Training.

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, which is based on a mid-urethral Prolene tape support, is accepted worldwide as an easy-to-learn, effective and safe surgical technique.[1-5] Some typical TVT operative complications of concern to the operating surgeons include: bladder penetration, urinary outlet obstruction, potential bowel penetration, intra-operative bleeding and post-operative infections.[2, 3, 5-9] Against this background, Jean de Leval was encouraged to design a novel mid urethral sling in the form of an "inside-out" trans-obturator TVT-like procedure. In such, the TVT needle bypasses the retropubic 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 was designed to overcome two of the peri-operative complications reported with use of TVT-Obturator: thigh pain and bladder outlet obstruction.[11-12] This was addressed by tailoring the tape to be 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 operative data collected with early training in the first 100 novel, minimally invasive anti-incontinence procedures.

METHODS

Patients suffering from urinary stress incontinence with no intrinsic sphincteric deficiency, 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 from 25/9/2006 to 25/12/2006. One hundred TVT -SECUR training procedures were performed after receiving profound consultation and explanation of the informed consent, highlighting the novelty of the procedure, the lack of experience and the training issues. This operative series of Hammock approach was done at 13 hospitals with one single trainer having previous experience with 35 TVT-SECUR operations. All patients were given one gram of Monocef (Cefonicid, Beecham Healthcare) intravenously, one hour prior to surgery 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 ICS pelvic organ prolapse quantification system (POPQ).[14] Patients presenting with significant pelvic organ prolapse had colporrhaphies (anterior and posterior) with or without implantation of vaginal mesh (Pro-Lift™, Gynecare, Summerville, NJ) implantation for pelvic floor 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] Intra-operative and early post-operative complications within this patient series were recorded. Patients were interviewed and subjected to pelvic examination at the ends of the first and second post-operative months. 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, that affected her quality of life, reported by patient and clinically confirmed. Minimal residual leakage, not deteriorating the patient's quality of life, was mentioned but not regarded as therapeutic failure.

RESULTS

Patient's pre-operative, operative and post-operative details have been tabulated in Tables 1 and 2, respectively. According to the POPQ system,[14] 48 patients (48.0%) had an advanced cystocele (Aa/Ba>+1), 19 (19.0%) had an advanced rectocele (Ap/Bp>+1), 2 (2.0%) had uterine prolapse (C>+1) and 5 (5.0%) had vaginal vault prolapse (C>+1). All patients had the TVT-SECUR as primary anti-incontinence operation. Fifty one patients (51.0%) underwent concomitant operative procedures in addition to the TVT-SECUR: 48 patients

TABLE 1. – *Pre-operative details (No. = 100).*

Cystocele (Aa/Ba>+1)*	48 Pts (48.0%)
Rectocele (Ap/Bp>+1)*	19 Pts (19.0%)
Uterine prolapse (C>+1)*	2 Pts (2.0%)
Vaginal vault prolapse (C>+1)*	5 Pts (5.0%)

(*) In accordance with the POP-Q system.

(48.0%) had anterior and 19 (19.0%) had posterior colporrhaphies, Eleven patients (11.0%) had anterior ProLift, 2 (2.0%) had posterior ProLift and 5 (5.0%) had total ProLift™ operation (Gynecare) for the support of the vaginal walls and apex. No hysterectomies where performed with this patient's series. The 82 trainees where experienced pelvic floor staff surgeons, 28 (34.1%) of them where Urologists and 54 (65.9%) Gynecologists, each performed one or two operations. The mode of anesthesia was subject to patient's request, resulting in general in 52 (52.0%) operations, regional in 11 operations and local in 37 (37%) operations. No anesthetic mode appeared to be superior in terms of facilitating the procedure or the recovery.

The TVT-SECUR patients were followed up for period of 2 to 5 months. Therapeutic failure, meaning sustained urinary stress incontinence, was diagnosed in 7 out of the first 35 patients (20.0%). Seven (20.0%) other patients reported residuals non-significant post operative leakage, not influencing quality of life and hence not regarded as therapeutic failures. Acknowledging these figures, the mesh tension was subsequently minimally increased with the last 65 patients and a further two failure patients (3%) were observed. In total 9 patients (9%) failed. No clinical signs for operative bleeding, bladder or intestinal penetration, post-operative infection, bladder over activity or outlet obstruction were observed. Four patients (4.0) had vaginal wall penetration with the inserters, requiring withdrawal and re-insertion as well as vaginal wall repair. This was avoided later by making the preliminary sub-mucosal tunnel as wide as 12 mm to permit the device to slip in smoothly. With such, no further vaginal penetrations were noted. Three other patients (3.0%) presented with vaginal tape extrusion, this was easily resected in office and no morbid sequela was recorded. After incorporating suburethral dissection to the procedural steps and allowing the tape to sink away from the vaginal mucosa – no more mesh extrusion occurred. Five patients had un-intended tape removal at the time of inserter removal, necessitating the usage of a second TVT-SECUR. This was addressed by proper inserter separation from the tape prior to its withdrawal, and with such, no further unintended tape displacements were recorded. One patient had to be taken back to theater for evacuation of an early post operative para-vesical hematoma of 50 ml. Hematocrit level was not altered and neither blood transfusion nor bleeding control measures were required. All the above mentioned complications, other than the one case of hemorrhage and one case of vaginal tape extrusion, occurred with the first 42 patients.

TABLE 2. – *Operative and post-operative patient's details (No. = 100).*

Anesthesia: general /regional/local (Pts)	52(52.0%)/11(11.0%)/37(37.0)
Concomitant corrective operations (Pts)	
Colporrhaphy: Anterior / Posterior	48 (48.0%) / 19 (19.0%)
Vaginal Mesh:	
ProLift - anterior/posterior/total	11 (11.0%) / 2 (2.0%)/5(5.0)
Un-intended tape removal (Pts)	5 (5.0%)
Vaginal wall penetration (Pts)	4 (4.0%)
Post-operative vaginal tape protrusion (Pts)	3 (3.0%)
Post operative para-vesical hematoma (Pts)	1 (1.0%)
Early therapeutic failure (Pts)	9 (9.0%)
Residual non significant urinary leakage (Pts)	7 (7.0%)
Clinical signs for post-operative bleeding, bladder penetration, bowel and/or urethral injury, post-operative outlet obstruction or infection (Pts)	0 (0.0%)

DISCUSSION

The TVT procedure has become very popular ever since it was first described by Ulmsten in 1996. Common complications in previously performed surgeries for the treatment of stress urinary incontinence, 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 multicenter studies, comparing TVT to the former gold standard Burch colposuspension, demonstrated similar therapeutic impact for both. However, TVT was associated with a higher intra-operative complication rate while colposuspension was associated with a higher post-operative complication rate and a longer recovery period.[16-17] The previously reported TVT-related complications included bladder penetration, intra-operative bleeding, post-operative infection and vessel and bowel injuries.[1-3, 5-8] Since surgical procedures are more likely to cure stress urinary incontinence rather than non-surgical procedures,[18] de Leval adapted the TVT-Obturator procedure to avoid the aforementioned complications. His novel type of surgery enables mid urethral 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 retropubic space. The reported data regarding efficacy of the TVT-Obturator in terms of cure as well as intra-operative and early post-operative complication rates is encouraging.[11-12] Bladder penetration, previously reported in relation to "outside-in" trans-obturator designed mid urethral tape procedures,[19-20] has not been described in association with an "inside-out" trans-obturator procedure. Though 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, intra-operative bleeding, post-operative infection and voiding difficulties also seem to occur less with the TVT-Obturator than previously reported for TVT.[2, 3, 5, 8, 11-12, 15-17] However, the TVT-Obturator is not free of operative complications: thigh-pain is reported to interfere with patient satisfaction, operative infections and post-operative bladder outlet obstruction still occur as well as occasional operative hemorrhage.

The TVT-SECUR was designed to minimize the operative procedure as much as possible in order to reduce those undesired complications.[21] 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 sub-mid-urethral 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 as well as diagnostic cystoscopy for recognition of possible bladder penetration. As the main possible advantage of the TVT-SECUR is minimalisation of the procedure and its side-effects, the simpler "ham-

mock" approach was elected for this patient's series. The 100 teaching operations reported herein served for training TVT-SECUR to experienced pelvic floor surgeons. It was obvious that the first trainee's tended to use their previous knowledge and experience gained with the former mid-urethral slings to the performance of this newly developed surgical device. Given that the new laser cut tape and novel inserters are different than the former equipment, one could understand the trainer's early learning curve difficulties. Laser cutting of the Secur tape is thought to greatly diminish the fraying previously seen with the mechanically cut tape. The elasticity of the laser cut mesh is, however, the same as the mechanically cut mesh within the physiologic range of forces applied to a mid-urethral tape. However, it does not "rope out" and remains flat under the urethra. The extra tension applied to the TVT and TVT-Obturator tapes during removal of the covering plastic sleeves, does not occur with the TVT-SECUR. Hence, some extra tension needs to be applied to the TVT-SECUR compared to the TVT in order to achieve the desired therapeutic result. Even doing so, no clinical signs for post-operative bladder outlet obstruction were observed. To accommodate the flatter, wider tape under the urethra that laser cutting produced, further mucosal undermining was done in order to permit the tape to sink deeper, away from the vaginal mucosa. The inserters, being more than twice as wide as TVT and TVT-Obturator needles, necessitate wider tunnels; 12 mm at least, in order to permit smooth passage of the tape and inserter and avoid gathering of vaginal skin which might 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 initial pull out force might be impaired. The unique locking mechanism, attaching the tape to the inserter, should be unlocked properly and detached gently, to avoid unwanted tape removal with withdrawal of the inserter. Doing these simple surgical steps the author was able to lead the trainees toward successful completion of the operation.

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. Paying respect to the above mentioned procedural specific surgical steps might shorten the TVT-SECUR learning curve. The novel TVT-SECUR's actual place among TVT and TVT-related procedures can only be determined with randomized prospective longitudinal comparisons.

CONCLUSIONS

The data presented here supports the notion that the TVT-SECUR, a novel mid-urethral sling operation for the treatment of female stress urinary incontinence, seems to be safe and easy to perform. Intra-operative 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 intra-operatively and post-operatively, than previously reported for the TVT and TVT-related procedures. One should respect 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 required to clarify the relative places of the different mid-urethral tape anti-incontinence techniques.

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