One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur.

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Title page

One-year results of a prospective randomized evaluator blinded multicenter study comparing TVT and TVT-Secur

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Disclosures

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Abstract

Introduction

The aim of this prospective randomized multicenter study was to compare TVT-Secur with retropubic TVT in terms of efficacy and safety.

Methods

We set out to enrol 280 stress-incontinent women with a half-time interim analysis of short term cure and adverse events. The short term results have previously been published. Of the133 randomized women, 125 underwent surgery and 121 (TVT *n*=61, TVT-Secur *n*=60) were available for follow-up one year post surgery.

Results

No significant differences were found between groups regarding demographics or grade of incontinence. One year after surgery, both subjective and objective cure rates were significantly lower for TVT-Secur than for TVT (subjective cure: TVT 98 %, TVT-Secur 80%, $p= 0.03$; objective cure: TVT 94%, TVT-Secur 71% for cough test, $p= 0.01$, TVT 76%, TVT-Secur 58% for pad test, $p= 0.05$). Three major complications occurred in the TVT-Secur group:one tape erosion into the urethra, one tape inadvertently placed into the bladder and one immediate postoperative bleeding due to injury to the corona mortis. No major complications occurred in the TVT group. No significant differences were found between groups regarding peroperative bleeding, hospital stay, urge symptoms, residual urinary volume, subjective bladder emptying problems, postoperative urinary tract infections or minor complications. The TVT-Secur group used more antimuscarin medication after surgery than the TVT group ($p= 0.03$) Median time for surgery was 13 and 22 minutes for TVT-Secur and TVT respectively ($p< 0.0001$).

Conclusion

The TVT-Secur procedure had significantly inferior subjective and objective cure rates compared with the retropubic TVT procedure. Three serious adverse events occurred in the TVT-Secur group. We therefore discourage further use of TVT-Secur.

Summary

In a prospective randomized study, TVT-Secur had significantly inferior one-year subjective and objective cure rates and more serious complications than the retropubic TVT procedure.

Key words

Female stress urinary incontinence, incontinence surgery, objective outcome, subjective outcome, TVT, TVT-Secur.

Introduction

Stress urinary incontinence (SUI) affects up to 40 % of women in the western world and its prevalence is likely to increase as the population ages [1-3]. Women have a 4% risk of needing SUI surgery during their lifetime, with nearly one third of surgeries performed due to recurrence [4]. The Burch colposuspension, once the standard technique, has gradually been set aside for less invasive procedures as retropubic suburethral polypropylene slings placed under the mid-urethra, i.e. the tension-free vaginal tape (TVT®, Gynecare, Ethicon Inc., Somerville, USA) introduced in 1996 [5]. A transobturator passage of the sling was described by Delorme in 2001 [6]. Subsequently, variations of these methods have been introduced. The efficacy of mid-urethral slings (MUS) is at least comparable to that of the Burch colposuspension [7]. A 2009 Cochrane review has shown the retropubic route to be slightly more efficacious than the transobturator route but also associated with more complications [8]. However, a recent large multi center study by Richter et al. found both routes equally successful for treating SUI [9].

A recent review reports a total complication rate of between 4.3% and 75.1% for TVT and between 10.5% and 31.3% for transobturator procedures [10] To reduce the complications associated to the blind passage of the needle, the TVT-Secur (a single incision sling device) was introduced in Europe in 2006.

The aim of the present study (Suburetral Slings in Southern Sweden, SSISS) was to compare the TVT-Secur with the retropubic TVT procedure in terms of efficacy and safety in a prospective, randomized setting. According to study protocol, an interim analysis was planned halfway through the study or in case of serious adverse events. Based on interim analysis of the two months follow-up data and the reported adverse events [11,12], we decided to stop further enrolment. We now present the one-year follow-up data.

Material and Methods

Between 2007-2009 patients with primary SUI or mixed urinary incontinence (MUI) with predominant SUI symptoms were asked to participate in the study. All women underwent a standardized preoperative investigation including a two-day voiding diary, the King's Health questionnaire, a VAS scale regarding bother due to incontinence, a demographic and contraceptive history and a detailed incontinence history. Furthermore a gynecological examination, measurement of residual urine, a cystoscopy, stress-test in upright position and a standardized short term pad-test were performed [13].The inclusion criteria were: history of SUI, wish for surgical treatment, no wish for future pregnancy, age $\geq$ 18 years, $\geq$ 3 mL leakage at a standardized pad-test, cough-synchronous leakage at stress test (up to ten coughs in standing position) the latter two with a bladder volume of 300 mL. The main exclusion criteria were: need for concomitant surgery for genital organ prolapse, regular pelvic floor training begun less than three months before inclusion, previous surgery for urinary incontinence, bladder capacity less than 300 ml, residual urinary volume more than 100 ml and known detrusor instability [11].

Consenting women who fulfilled all inclusion criteria were randomized to either retropubic TVT or TVT-Secur in a proportion of 1:1. For randomization an equal proportion of assignments for TVT or TVT-Secur were mixed and placed in opaque envelopes which were then sealed, mixed again, and numbered. They were kept at a central study secretariat which also managed the central study log. Each patient was assigned a research file containing all study protocols, marked with an individual file number. All patients gave their written informed consent and the study was approved by the Regional Institutional Review Board including an approval for all participating centers.

[11].

A restricted number of surgeons (*n*= 6), all with previous experience of at least 100 suburethral sling operations and confident with both retropubic and transobturator techniques, were involved. Pre-study training was supervised by one of the authors and consisted on at least five TVT-Secur procedures [11]. All patients were operated on an ambulatory basis following the standard

techniques for retropubic TVT and TVT-Secur (hammock approach) [11,14,15]. Patients were operated on local anesthesia using a blend of 60 mL 5 % Carbocaine-adrenaline and 60 mL saline solution, combined with intravenous sedation with Fentanyl and Propofol.

Postoperative counselling and the length of the sick-leave were standardized and the same for both groups. Patients were discharged within 12 hours after surgery if they were able to void spontaneously with residual urine of less than 100 mL at one measurement or less than 150 mL at two consecutive measurements. Patients not fulfilling these criteria were discharged with either an indwelling catheter or taught to perform self-catheterization. Residual urine was measured the following day and every second day thereafter until voiding according to the above was achieved.

Follow-up consisted of a standardized telephone interview two months post surgery and an outpatient examination one year post surgery, including pad- and stress test in the same manner as pre surgery. Patients were encouraged to contact the operating center earlier in case of complications. The follow-up was performed by an independent evaluator, usually a continence nurse. The evaluator blinding was achieved by placing the patient's operative file as well as the results of the randomization in a sealed envelope immediately after surgery and by instructing the patient not to reveal the operative technique at any subsequent follow-up.

Database and statistical analysis

According to the power analysis the study was designed to detect a 10 % difference in cure rate at an estimated 85% level of cure and aimed to include 280 patients with an additional 28 patients to compensate for an estimated 10% drop out. An interim analysis of cure and complications was planned after 140 included patients, or earlier if serious adverse events occurred. Initially, we estimated an approximate equal enrolment among the four participating centers and therefore no individual power analysis was undertaken. Two centers were not able to provide sufficient enrolment over time due to change of staff. They were therefore disengaged from further enrolment but continued with follow-up as planned. Thus, the majority of procedures were performed by the remaining two centers.

Data were consecutively entered and stored in a central separate computer based registry (StatView database, SAS Institute Inc., Cary, NC) approved by the Data Registry Board of Skåne University Hospital, Lund. All study files and protocols were collected centrally and data were entered into the database before the operative technique was revealed during analysis.

For the statistical analysis, the χ^2 test, the Wilcoxon's, the Mann-Whitney's or the Kruskall-Wallis' test were used as appropriate. A p-value ≤ 0.05 was considered statistically significant.

Results

A total of 133 women were randomized (retropubic TVT *n*= 69, TVT-Secur *n*= 64) by either of four gynecology departments (A-D) in southern Sweden (A= 71, B= 48, C= 7, D= 7). Of these women, four were excluded due to protocol violations and another four declined surgery after randomization due to personal reasons.

Therefore, 125 women remained and were operated according to the randomization protocol (retropubic TVT *n*=63, TVT-Secur *n*= 62). Demographic data showed no statistical difference between groups regarding age, parity or BMI (Table 1).

All but two patients (*n*= 122) underwent surgery using local anesthesia. Median time from patient's entry to depart from the operating theatre was 58 minutes (range 42-94 minutes) for TVT and 50 minutes (range 27-95 minutes) for TVT-Secur (*p*=0.0001). Median time for surgery (from beginning of administration of local anesthesia to last suture) and including cystoscopy for TVT patients was 22 minutes (range 13-36 minutes) for TVT and 13 minutes (range 7-25 minutes,) for TVT-Secur (*p*< 0.0001). Peroperative bleeding was less than 25mL in 63% and 52% of the patients in the TVT and TVT-Secur groups respectively.(*p*=0.41) .The TVT-Secur sling did not had to be reinserted in any patient and no more than one device was used per procedure. Most patients (78%) were discharged within six hours after surgery, with an almost identical distribution between both groups. One patient in each group was discharged more than 24 hours after surgery (one due to reoperation because of bleeding from the corona mortis (TVT-Secur) and one for social reasons (TVT)).

Two patients in the TVT group had voiding difficulties (more than 24 hours). Both fulfilled voiding criteria within 48 hours after surgery. Two patients in the TVT-Secur group needed intermittent catheterization for more than 24 hours (two and seven days respectively). No patients experienced permanent obstructed voiding. No tapes had to be loosened or cut postoperatively.

Six minor peroperative complications were reported: two bladder perforations, both with TVT, two accidental perforations of the vaginal wall beside the incision (one with TVT-Secur, and one with TVT), one venous bleeding of about 200 ml with TVT and one bleeding between 100-200 mL with

TVT-Secur, both solved with compression .

Three major complications occurred, all following the TVT-Secur procedure. One patient had an injury of the corona mortis (blood vessel variant, running behind the pubic bone, anastomosing the obturator and external iliac systems), which required immediate surgical re-intervention with evacuation of a one litre retropubic hematoma and vessel ligature [15]. In another patient, tape erosion into the urethra was diagnosed 70 days after surgery. Peroperative cystoscopy was normal in spite of slight hematuria. The patient complained shortly after surgery of intense urgency. After an initial "wait and see" period, the sling, which subsequently had eroded further into the urethra, was removed by uretroscopy 22 months after surgery. Afterwards the patient's SUI recurred. A retropubic TVT procedure was performed after further 4 months. Two months after the second surgery she was satisfied and had no symptoms of SUI or urge.

A third patient presented soon after surgery with recurrent bacteriuria and urgency symptoms. Cystoscopy revealed the distal end of the TVT-Secur sling inside the bladder at one side. The intracystic part of the sling was removed by a combined endoscopic and cystoscopic procedure.

Of 125 patients who underwent surgery, 121 were available for long -term follow-up (TVT *n*=63, TVT-Secur *n*= 62) Although we aimed for follow-up 12 months after surgery, five women (TVT *n*=1, TVT-Secur *n*=4) were evaluated less than six months after surgery due to self-reported complications or early recurrence, and 13 patients (TVT *n*=9, TVT-Secur *n*= 4) were evaluated later than 20 months post surgery due to logistical reasons. Four women were lost to follow-up.

At the postoperative follow-up examination (TVT group median 13 months (range 5-29 months), TVT-Secur group median 12 months (range 1-27 months) *p*=0.20 the subjective cure rate, defined as cured or improved, for stress urinary incontinence symptoms was 98% for TVT and 80% for TVT-Secur,(*p*= 0.03) (Table 2). The objective cure rates were 94% for TVT and 71% for TVT-Secur, *p*=0.01 (no leakage at cough test); and 76% for TVT, 58% for TVT-S, *p*= 0.05 (no leakage at standardized pad-test [13]) (Table 3). Data regarding postoperative urinary tract infections and overactive bladder/de novo urgency are presented in Table 4. No significant differences were found

between the two groups. However, women in the TVT-Secur group used more anticholinergics than those in the TVT group (p=0.03). Neither the residual urinary volume (p=0.13), nor the subjective sensation of incomplete voiding (p=0.41) were statistically different between groups. The overall rate for minor complications (dyspareunia, pain or discomfort, abnormal vaginal discharge) was similar for both groups (TVT= 11%, TVT-Secure 13%, p=0.9) (Table 5). Mesh exposure occurred in five patients, two in the TVT and three in the TVT-Secur group.

Discussion

In our series, the subjective and objective cure of stress urinary incontinence was significantly inferior following TVT-Secur than retropubic TVT when evaluated one year post surgery. This association might have even been stronger with a completed enrolment as originally planned. However, due to the interim analysis of cure and the occurrence of three serious adverse events in the TVT-Secur group [11] we felt compelled to stop the study prematurely.

We do not believe that the difference in cure rate, in particular the proportion of uncured and early recurrencies patients in the TVT-Secur group, can be explained by insufficient surgical skills, as the basics of both procedures are similar. Participating surgeons had broad experience in sling surgery, having performed at least 100 procedures each. Moreover, pre-study training was supervised by one of the authors and aimed to standardize operative technique before enrolling patients into the study. Different surgical approaches may be more or less "forgiving" and technique deviations may result in more or less serious adverse events. Increased knowledge of possible differences between methods concerning this matter is one of the reasons for performing this clinical study. Most uncured women in the TVT-Secur group reported either a very short, or no postoperative effect on their incontinence symptoms, suggesting an insufficient anchoring of the sling. Moreover, our results correspond with previous both randomized and non-randomized publications evaluating the efficacy of TVT-Secur. Most of them report lower cure rates for TVT-Secur than for retropubic TVT, with rates between 67-80% [16-33].

Possible causes for the seemingly inferior results of the TVT-Secur have previously been investigated. Two studies on cadavers have been performed. One showed an anatomically incorrect position of the TVT-Secur sling in most of the cases, regardless of the surgeon's previous experience [34]. The second showed that the hole in the obturator membrane tended to widen when the inserter was twisted, thus hampering the fixation of the distal fleece part of the sling [35]. Martan et al. evaluated 85 SUI patients using perineal ultrasound one week and three months after a TVT-Secur procedure. They concluded that decreased restriction of the mid-urethral mobility three months after

surgery was a possible cause for the lower cure rate following TVT-Secur [26].

A weakness in our study is the fact that some of the women were not assessed postoperatively as originally planned. 11% of our patients were examined later than 20 months postoperatively instead of after 12 months. However, we do not believe this delay to be a major bias, as all these women belonged to the cured group (regardless the device used on them) and the result of the assessment would have been the same had we had the chance to examine/interview them as it was intended. Five women were examined much earlier than 12 months post surgery. Four belonged to the TVT-Secur group and presented with either serious complications and/or an early recurrence that demanded reoperation.

A potential weakness of our study is that we chose not to contemplate the use of validated questionnaires on urinary incontinence, pelvic floor dysfunction, quality of life or sexual function for post-operative assessment. However, this would have been a main drawback only if the two studied methods had turned out to be equally effective in terms of objective cure of stress incontinence. As TVT-Secure was associated with both a significantly lower objective cure rate and three rare serious complications, we do not believe that additional information provided by those questionnaires would have changed the conclusion of this study.

The main reason, as stated by the manufacturer, for developing TVT-Secur was to further reduce the complications of traditional retropubic or transobturator slings. In our series three major complications occurred in the TVT-Secur group, and other authors have reported bladder perforation, bleeding from the corona mortis, severe bleeding from the internal obturator muscle, injury of the internal pudendal artery and even male dyspareunia [12, 36-39]. Our results indicate that despite the manufacturer’s recommendation not to perform a urethrocystoscopy following an obturator membrane-anchored TVT-Secur procedure, peroperative bladder and urethral perforation should be ruled out. The fact that one TVT-Secur sling inadvertently perforated the bladder, in spite of performing a lateral (hammock) anchoring (as prescribed by study protocol) indicates that there is no absolute difference between retropubic and obturator anchoring. Therefore, we believe

urethrocystoscopy should be routinely performed following placement of TVT-Secur slings regardless of anchoring method of choice.

Even minor complications, such as mesh exposure and not self-limiting dyspareunia, seem to be more common for TVT-Secur [40-41]. In our series, the occurrence of dyspareunia was low and not significantly different between groups.

In our study, mean time for surgery was nine minutes shorter for the TVT-Secur compared with retropubic TVT. We do not believe this compensates for the lower cure rate and complication pattern of the TVT-Secur.

Sick-leave was prescribed solely based on the patient's occupation. This study indicates that the TVT-Secur procedure may provide weaker anchoring or/and need a longer healing time. Should this demand a longer sick-leave in order to achieve similar cure rates to those of retropubic TVT, we believe this disadvantage, by itself, is enough to disqualify TVT-Secur.

Conclusion

The main arguments for choosing TVT-Secur over TVT (less complications and no need for urethrocystoscopy) are not supported by our data, and would only be valid in a non-inferiority situation when compared with TVT.

In our study, the subjective cure rate for TVT-Secur was significantly lower than for retropubic TVT one-year post surgery. This confirms our previous short-term results. Therefore, there is no reason for choosing TVT-Secur over TVT, and we think it is important to discourage its further use.

The traditional retropubic and transobturator approaches are well studied, easy to perform, proven to be safe and have excellent cure rates. Therefore, we believe that suburethral (mini-) slings with alternative anchoring techniques should not be introduced to the market without solid evidence ensuring they bring an actual benefit to the patient.

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Table 1: Demographic characteristics of patients randomized to retropubic TVT or TVT-Secur.

	TVT group	TVT-Secur group	
	Mean (range)	Mean (range)	*p*-value
Age (years)	48 (33-78)	47 (33-84)	0.65
Parity (*n*)	2 (2-5)	2 (0-8)	0.97
Body Mass Index (Kg/m^2)	24.6 (18.8-36)	25.4 (20.3-42.1)	0.18
Duration (years)	9 (1-45)	6.5 (1-40)	0.08
Number of leakage episodes/day (*n*)	3 (0-9)	3 (0-16)	0.57
	n (%)	*n* (%)	*p*-value
Hormonal status premenopausal postmenopausal postmenopausal + HT Missing information	 39 (63) 16 (26) 6 (10) 1 (1)	 42 (69) 13 (21) 6 (10) 0	0.70
Bother due to incontinence* mild moderate severe Missing information	 2 (3) 34 (55) 23 (37) 3 (5)	 1 (2) 27 (44) 28 (46) 5 (8)	0.63
Preoperative urge no urge mild severe Missing information	 36 (58) 23 (37) 3 (5) 0	 38 (62) 19 (31) 3 (5) 1 (2)	0.81
Incontinence grade▪ I II III Missing information	 16 (26) 39 (61) 8 (13) 0	 14 (23) 42 (69) 4 (6) 1 (2)	0.47

¤ HT: Hormonal therapy

* Patient's own assessment prior to hospital visit

▪ According to Ingelman-Sundberg criteria

Table 2: Subjective cure of stress urinary incontinence symptoms at long term follow-up in patients randomized to retropubic TVT or TVT-Secur (χ^2 test).

Subjective outcome¤	TVT *n*= 61 *n* (%)	TVT-Secur *n*= 60 *n* (%)	
Cured	47 (77)	28 (47)	*p*= 0.03*
Improved	13 (21)	20 (33)	
Slightly improved	0 (0)	5 (8)	
Unchanged	0 (0)	1 (2)	
Worsened	0 (0)	1 (2)	
Early recurrence	1 (2)	3 (5)	

TVT: tension-free vaginal tape

*Cured + improved compared to all others

¤ Defined as

Cured: No experience of stress urinary incontinence (SUI) symptoms.

Improved: Significant reduction in, but still experience of, SUI symptoms.

Slightly improved: Minor reduction of SUI symptoms .

Worsened: More SUI symptoms than before surgery

Table 3: Objective cure of stress incontinence symptoms at long term follow-up in patients randomized to retropubic TVT or TVT-Secur (χ^2 test).

Objective outcome *n*	TVT *n* (%)	TVT-Secur *n* (%)
No leakage at cough-synchronous test *n*=59 *	56 (94)	40 (71) *p*=0.01
No leakage at standardized pad-test *n*=56 §	43 (76)	53 (58) *p*=0.05

* Missing information on four patients

§ Missing information on six patients

Table 4: Urge symptoms and incidence of postoperative cystitis at long term follow-up following retropubic TVT or TVT-Secur

Urge symptoms	TVT *n*= 61 *n* (%)	TVT-Secur *n*= 60 *n* (%)	*p*= 0.45*
No symptoms before/after	34 (56)	31 (52)	(missing information on 4 patients)
De novo, mild	6 (10)	2 (3)	
De novo, moderate	3 (5)	2 (3)	
De novo, severe	1 (2)	3 (5)	
Unchanged	7 (11)	8 (14)	
Improved	7 (11)	12 (20)	
Cured	3 (5)	2 (3)	
Incidence of cystitis	TVT *n*= 60 *n* (%)	TVT *n*= 60 *n* (%)	*p*= 0.48
None	49 (82)	46 (77)	(missing information on 5 patients)
1-2 episodes	10 (16)	9 (15)	
3-4 episodes	1 (2)	2 (3)	
> 4 episodes	0	2 (3)	
pyelonefritis	0	1 (2)	

TVT: tension free vaginal tape

- De novo urgency compared to all others

Table 5: Minor complications and mesh exposure at long term follow-up in patients randomized to retropubic TVT or TVT-Secur

Complication*	TVT *n*= 60 *n* (%)	TVT-Secure *n*= 55 *n* (%)	
None	53 (89)	48 (87)	*p*=0.93
Pain	3 (5)	2 (3)	
Dyspareunia	2 (3)	3 (5)	
Abnormal vaginal discharge	0	0	
Mesh exposure¤	2 (3)	3 (5)	

Missing information on six patients

*Assessed by a YES/NO question

¤ Assessed by gynecological examination