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Mid-term follow-up of the TVT-Secur® midurethral sling for primary stress incontinence

Johannes Angleitner-Flotzinger [a], Thomas Aigmueller [b,*]

[a] Department of Gynecology, Krankenhaus der Barmherzigen Schwestern, Linz, Austria
[b] Department of Obstetrics & Gynecology, Medical University of Graz, Austria

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ABSTRACT

Objective: The TVT-Secur® was introduced in 2006 as a less invasive alternative to retropubic and transobturator suburethral slings. This retrospective cohort study evaluated objective and subjective results in a series of 158 consecutive patients as well as complications and the reoperation rate after TVT-Secur procedure.
Study design: Between November 2006 and June 2010 a total of 158 patients underwent a TVT-Secur procedure at a single institution. All patients underwent preoperative urodynamic testing. All patients were invited for follow-up including physical examination, urodynamic studies and subjective evaluation.
Results: A total of 96 patients (61%) were available for follow-up with a mean follow-up of 29.8 months (range 5–50, median 30). At follow-up, eight (8%) of 96 patients had reoperations for stress incontinence. There were no reoperations for bleeding/hematoma, tape erosions or obstructed micturition and there were no tape erosions or exposures. 29 patients (30%) had a negative cough stress test and 44 patients (46%) subjectively considered themselves "cured". Nine of 43 patients (21%) without urgency symptoms preoperatively developed de novo urgency; 24 of 35 patients (69%) with preoperative urgency complaints were free of urgency symptoms.
Conclusion: At 2.4 years, the TVT-Secur appears to have a low adverse events profile but inferior results compared with traditional midurethral slings.

Introduction

In 1996 Ulmsten et al. described transvaginal retropubic placement of a suburethral polypropylene sling for the treatment for stress urinary incontinence (SUI) [1]. This procedure soon was made commercially available and became a standard for the surgical treatment of SUI. Since 1996 the complication rates of alloplastic tapes placed vaginally have been well defined [2–5]. With the aim of simplifying tape placement and reducing the amount of inserted alloplastic material and complications a number of variations on the retropubic approach were developed. These include transobturator tapes and, more recently, so-called minitapes or single-incision slings. The latter are placed vaginally but have no external incisions. The TVT-Secur [6], introduced in 2006, is one such system. Initial reports on the TVT-Secur system were largely favorable [7–16], the short-term results of minislings were promising: in a systematic review the 12-month outcome after TVT-Secur showed an objective cure rate of 76% and a subjective cure rate of 76% [17]. In the interim, although TVT-Secur has been taken off the market, two randomized trials have been published [18,19]. However, few long-term data are available [20,21].

The aim of the present retrospective cohort study was to evaluate objective and subjective cure rates in a series of 158 consecutive patients after TVT-Secur placement at a single institution. We also evaluated reoperations, changes in urge symptoms, dyspareunia, overall satisfaction, and risk factors for treatment failure.

Materials and methods

Between November 2006 and June 2010 all patients who underwent surgical treatment for urodynamic stress urinary incontinence at the Department of Gynecology at the Krankenhaus

* Corresponding author at: Department of Obstetrics & Gynecology, Medical University of Graz, Auenbruggerplatz 14, 8036 Graz, Austria.
Tel.: +43 316 385 81440; fax: +43 31638513061.
E-mail addresses: thomas.aigmueller@medunigraz.at, aigmueller@gmail.com (T. Aigmueller).

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der Barmherzigen Schwestern Linz, Austria were treated with TVT-Secur (Gynecare, Ethicon) placement. Included were all patients with persisting stress urinary incontinence or mixed urinary incontinence after pelvic floor muscle training. Patients with recurrent stress incontinence after sling procedures and patients with predominant urge symptoms were excluded from treatment with TVT-Secur. For patients meeting the inclusion and exclusion criteria, no other surgeries for treatment of stress urinary incontinence were performed during that period. Preoperative assessment included demographic data, condition-specific history, preoperative urge symptoms, physical investigation and urodynamics including cough stress test. Informed consent was obtained from all patients. During the study period we did not perform other surgical methods to treat stress urinary incontinence except for TVT-Secur treatment failures.

TVT-Secur tapes were placed in the so-called hammock position according to the manufacturer's instructions [22] using general anesthesia. The tapes were placed suburethrally without tension but in close contact to the urethra. Cystoscopy was not performed. All patients had single-dose antibiotic prophylaxis. A transurethral catheter was placed and removed 3 h after surgery. Vaginal packing was not performed. Residual urine volume was measured on the day of surgery and on day 1 after surgery, discharge was routinely planned for day 1.

Between October 2010 and March 2011 all patients were contacted for a follow-up visit. Follow-up examination included overall and condition-specific history, evaluation of reoperations, urge symptoms and dyspareunia, physical investigation including vaginal inspection, urodynamics with cough stress test, cystoscopy as indicated, PGI-I [23] and evaluation of patient's overall satisfaction. Descriptive statistical analysis was performed using Microsoft Excel® software. The study protocol was approved by the local Ethics Committee.

Results

Between November 2006 and June 2010 a total of 158 patients underwent the TVT-Secur procedure. The mean age of the patients was 60.4 years (range 35–91, median 60). Mean parity was 2.2 (range 0–8, median 2) and mean BMI was 27.5 (range 19.3–40.7; median 27.1).

Two patients died in the interim of causes unrelated to the incontinence procedure, two patients declined follow-up because of frailty. 28 patients refused a follow-up visit, 30 patients could not be reached due to changed address informations. 96 patients (61%) attended follow-up investigations after a mean of 29.8 months (range 5–50, median 30) (Table 1). The mean age of these patients at the time of surgery was 60.5 years. 51 patients (53%) had undergone previous gynecologic surgery (mostly hysterectomy (29/96), colporrhaphy (19/96), two previous incontinence procedures). 37 patients (39%) had additional urgency complaints before surgery (mixed urinary incontinence). Concomitant procedures were performed in nine patients (eight hysterectomies, one vaginal mesh placement) (Table 1).

At follow-up 8/96 (8%) patients had been reoperated for recurrent stress urinary incontinence (these patients underwent retropubic or transobturator tapes). In one of these patients the TVT-S was removed 4 weeks after insertion due to a bladder lesion and a TVT-O placed another 7 weeks later. There were no reoperations reported for bleeding or hematoma, tape erosions or obstructed micturition. At the time of follow-up no tape erosions were detected.

At follow-up 29 of 96 (30%) patients had a negative cough stress test, 62 (65%) had a positive cough stress test or TVT procedure in the interim, and five (5%) did not have a cough stress test (Table 2). Subjectively 44 of 96 (46%) patients considered themselves "cured", 30 (31%) "improved", 11 (12%) "unchanged", and three (3%) "worse". The eight patients (8%) with repeat incontinence procedures in the interim are outlined separately in this analysis (Table 2).

Regarding overall satisfaction with the procedure, 68 of 96 patients (71%) indicated themselves "satisfied", 13 (14%) "dissatisfied", and 7 (7%) did not respond. Again, the eight patients with reoperations in the interim were outlined separately in this calculation (Table 2).

25 of 96 patients (26%) reported urgency symptoms at the time of follow-up and 63 (66%) did not (excluding the 8 patients with repeat stress incontinence procedures). Additionally we investigated the change in urgency complaints in patients without repeat surgery in the interim: of the 35 patients with preoperative urgency complaints, 24 (69%) were free of urgency symptoms whilst 11 continued to have urgency symptoms. Of 43 patients without urgency symptoms preoperatively nine (21%) developed de novo urgency symptoms. Of 10 patients with unknown urgency status preoperatively, five had urgency complaints and additional five patients were free of urgency symptoms (Table 3).

Preoperative the data regarding sexual activity and dyspareunia were incomplete. At follow-up 54 patients without repeat incontinence surgery were sexually active. Four of these patients (7.5%) indicated dyspareunia. (Table 4).

Table 1
Perioperative data of patients with complete follow-up at the time of surgery ($n = 96$).

	Mean	Range	Median
Age (years)	60.5	38–86	60
Parity	2.16	0–6	2
BMI	27.8	19.3–40.7	27.1
		n	%
Surgeries in patient's history			
Hysterectomy		29	30.2
Hysterectomy + colporrhaphies		19	19.8
Colposuspension		1	1.0
Posterior IVS		1	1.0
Undefined incontinence procedure		1	1.0
Total		51	53.1
Concomitant surgeries			
Abdominal hysterectomy		2	2.1
Vaginal hysterectomy		6	6.3
Vaginal mesh		1	1.0
Total		9	9.4

Table 2
Objective and subjective outcome, overall satisfaction ($n = 96$).

	n	%
Cough stress test		
Negative	29	30.2
Positive	54	56.3
Unknown	5	5.2
Repeat anti-incontinence surgery	8	8.3
Subjective result		
Cured	44	45.8
Improved	30	31.3
Unchanged	11	11.5
Worse	3	3.1
Repeat anti-incontinence surgery	8	8.3
Satisfaction		
Satisfied	68	70.8
Undetermined	7	7.3
Dissatisfied	13	13.5
Repeat anti-incontinence surgery	8	8.3