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ORIGINAL ARTICLE

Twelve months effect on voiding function of retropubic compared with outside-in and inside-out transobturator midurethral slings

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Abstract
Introduction and hypothesis The purpose of this study is to compare retropubic tension-free vaginal tape (TVT) with transobturator out-in TOT and in-out TVT-O for female stress urinary incontinence. Uroflow rate was primary; continence rates, quality of life (QoL) and complication pattern were secondary endpoints.
Methods A prospective randomised trial with 2:1:1 randomisation at two Swiss teaching hospitals. Patients were followed up at 12 months.
Results Eighty TVT, 40 transobturator tape (TOT) and 40 TVT-O were randomised. At 12 months, there was no difference in Qmax among the groups. Continence was comparable (≥89%). QoL was improved significantly in all groups ($P<0.05$). Five vaginal tape exposures occurred (one TVT, four TOT, zero TVT-O; $P=0.028$). Two percent (1/52) of sexually active patients after TVT, 17% (5/29) after TOT, but 0% (0/25) after TVT-O reported de novo female sexual dysfunction ($P=0.011$). We considered this clinically important enough to stop enrolment.
Conclusions There was no difference for Qmax at 12 months between TVT, TOT and TVT-O. Female sexual dysfunction and tape exposure may be higher with a transobturator tape.

Keywords Tension-free vaginal tape · Transobturator tape · TVT · TOT · TVT-O · Stress urinary incontinence (SUI)

Introduction

The concept of the retropubic tension-free vaginal tape (TVT) facilitated surgery for female stress urinary incontinence (SUI) [1]. An 11-year follow-up showed the effectiveness of the TVT operation with a long-term objective cure rate of 90% [2]. However, the retropubic trocar passage is associated with intraoperative complications, including bladder perforation, major blood vessel injuries and postoperative voiding difficulties [3–6]. These concerns resulted in the introduction of the transobturator (TO) technique in 2001. The TO tape is inserted tension-free from the thigh folds (outside-in) in a horizontal plane underneath the midurethra between the two obturator foramina [7]. It was hypothesised that the horizontal course would cause less obstruction. To minimise bladder and urethra perforation, an inside-out modification was developed by passing the tape from underneath the urethra (inside) through the obturator foramina towards the thigh folds (outside) under guidance of a protecting introducer [8].

We introduced the TVT operation in 1999 and the TO technique in 2003. Until 2005, no randomised trial compared these three procedures while few trials showed comparable postoperative continence rates for TVT and TO

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tapes. Only recently, an equivalence trial has been designed to determine if efficacy rates were the same [9]. So far, there is no longer-term comparative data of efficacy between retropubic and transobturator tapes. The importance of looking at any issue with any midurethral sling is for patient safety and efficacy. We started the present study to address this. We opted for uroflow rates as primary outcome as reduction in urinary flow rate was shown after midurethral sling insertion [10, 11]. Primary endpoint was micturition (urinary flow); secondary endpoints were continence, quality of life (QoL) and complications at 12 months.

Materials and methods

Two public teaching hospitals in Switzerland, the University Hospital Zurich and the Cantonal Hospital Uri, participated in this study. Women with urodynamically confirmed SUI or mixed urinary incontinence with predominant component of SUI who were referred for incontinence surgery between January 2006 and October 2009 were invited to participate. After written informed consent, they were randomised for one of the following three tapes: the TVT (Gynecare, Johnson & Johnson, NJ, USA), the outside-in transobturator sling Monarc (American Medical Systems, Minnetonka, USA) and the inside-out TVT-O (Gynecare, Johnson & Johnson, NJ, USA), in a relation of 2:1:1, using predetermined computer-generated block randomisation in blocks of eight to promote group balance. Exclusion criteria were missing urodynamic assessment, previous sling procedure, predominant overactive bladder syndrome (OAB), a post-void residual urine volume (PVR) above 100 ml, pregnancy or considering further pregnancy, known or suspected coagulopathy and known allergy to local anaesthetics. Patients unable to understand German, or unavailable or unwilling for follow-up were excluded as well. Preoperatively, conservative measures for SUI were recommended, such as use of local estrogens, pelvic floor reeducation, or incontinence pessaries. A symptomatic cystocele stage 2 or higher according to the POP-Q system was corrected first. Patients with concomitant sling insertion to prolapse repair were eligible as well.

Experienced gynaecologists performed the procedures according to the original methods, preferably under analgesia and sedation. In addition, the first ten procedures were supervised by a urogynaecologist. There was no randomisation between operators and additional procedures. Cefazolin or—in case of penicillin allergy—clindamycin was given as prophylactic single-shot antibiotic. Cystoscopy was mandatory for every procedure. To determine appropriate tape tension, a cough test was performed, and Metzenbaum scissors were placed as spacer between tape and urethra to ascertain a tension-free position. An indwelling catheter was placed in case of concomitant prolapse surgery, intraoperative bladder injury or increased intraoperative bleeding with need of intravaginal packing.

Urogynaecologic assessment included preoperative collection of medical history, PVR by catheterisation, clinical examination and urodynamic study with cystometry and urethral pressure profilometry, perineal sonography, cough and short-pad test and free-flow uroflowmetry to assess maximum urinary free-flow rate (Qmax). Quality of life (QoL) was assessed by means of the validated German version of the King's Health Questionnaire (KHQ) [12]. The KHQ consists of 32 items that address ten domains of QoL. Each domain is scored using a range between 0 and 100, while higher scores indicate greater impairment of QoL. In addition, a visual analog scale (VAS), where 0 represents no urinary complaints and 10 unbearable urinary complaints, was used to assess symptom bother at baseline and at follow-up [13].

Data collection included perioperative characteristics and complications. A first postoperative follow-up was performed at 2 weeks for clinical examination and assessment of PVR. Follow-up at 6 weeks, 6 and 12 months included medical history, re-assessment of QoL, clinical examination, PVR by catheterisation, perineal sonography, cough and short-pad test and free-flow uroflowmetry. Urodynamic studies were performed in supine position, using "Andromeda Ellipse" with three-lumen water-filled 9-French catheters, as well as perineal sonography (Kretz Voluson 530 D and Voluson 730 Pro with 3D abdominal probe) at a bladder filling of about 300 ml of physiological saline solution, using a midsagittal view [14]. We assessed tape position as the mid-point of the sling in relation to the urethral length, where 0% represents the internal and 100% the external meatus urethrae [15]. The physicians carrying out the follow-up were not blinded.

Objective continence was defined as both a negative cough and a negative short-pad test, performed with a bladder filling of 300 ml. The cough test is performed in supine position and defined negative as no involuntary leakage occurs synchronously with coughing. Our short-pad test is suitable for lesser agile patients and consists of ten times coughing, ten times climbing up and down a small base and ten times coughing while squatting. A pad weight gain less than 3 g is defined as negative. Subjective continence was assessed by means of patient's global impression (cured, improved, failed). Normal postoperative voiding was achieved as soon as PVR was below 100 ml within the first week. Tape loosening or division by complete incision was discussed in case of persisting symptomatic PVR with voiding difficulties (e.g. straining), requiring intermittent clean self-catheterisation, de novo urge or recurrent urinary tract infection. After having

noticed the occurrence of postoperative sexual dysfunction, we subsumed disorders associated with sexual intercourse under the term "female sexual dysfunction" (FSD) while excluding partner dyspareunia, (hispareunia) caused by vaginal tape exposure, as a separate entity [16, 17].

Based on published data at study initiation, we assumed equivalence for all techniques in regard to efficacy and continence but fewer obstruction in the TO group. Therefore, we used Qmax at 12 months as primary endpoint. We hypothesised a postoperative Qmax of 26 and 30 ml/s (SD±10) in the TVT and TO group, respectively. Based on 0.8 power to detect this difference, a total of 200 patients was estimated (P=0.05, two-sided). Secondary outcome measures included objective and subjective continence, QoL, PVR, tape position, urinary retention, tape loosening or division and tape exposure.

Data entry and management were carried out using FileMaker Pro 9.0 (FileMaker, Inc., CA) and the clinical information system KISIM (Cistec AG, Zurich, Switzerland). The data were treated anonymously. Statistic evaluation was undertaken using Intercooled Stata 8.2 (StataCorp LP, College Station, TX) by means of the non-parametric Kruskal–Wallis test for continuous and count data and Fisher's exact test for categorical data, as appropriate. Patients with and without obstructive symptoms within treatment groups were compared using the Mann–Whitney U test. Changes within treatment groups were analysed using Wilcoxon signed rank test. P values below 0.05 indicate statistical significance (two-sided). Analysis is undertaken following the intention-to-treat principle by analysing the groups according to their randomisation. Our study followed the guidelines for good urodynamic practice for the measurement and, where possible, the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomised clinical trials. Ethical approval was obtained from the local Cantonal ethics committees of Zürich (ref StV 20/2005, December 2005) and Altdorf (Amt für Gesundheit, 24.2.2006), with obligation of yearly interim reports. After the mandatory interim analysis revealed an unanticipated high rate of FSD for transobturator tape (TOT), we stopped further enrolment. This study is registered with ClinicalTrials.gov, number NCT00642109.

Results

Between January 2006 and October 2009, 243 women met the study inclusion criteria (Fig. 1). Eighty-three patients were excluded from enrolment—44 preferred the TVT as established method; three lived too far away for follow-up, and, in 36 cases, we followed the preference of the referring gynaecologist. Therefore, 160 were included—150 at the University Hospital Zurich and ten between February 2006 and December 2007 at the Cantonal Hospital Uri. Twelve-month follow-up data was not available in 24 patients due to patient withdrawal, tape release, second tape insertion at 6 months or intravesical Botox injection for persistent refractory OAB at 10 months (P=0.72). The last 12-month follow-up was in October, 2010.

Preoperative baseline data are listed in Table 1. The three groups showed comparable baseline characteristics. The trial was stopped early due to an unexpected occurrence of de novo FSD in TOT.

Perioperative characteristics including operative details and hospitalisation time are presented in Table 2. No statistically significant differences were found between the three groups. Nine surgeons performed the sling procedures with similar distribution of the performed procedures. One TVT did not receive allocated surgery because of intraoperative conversion to TOT after futile attempts to place the trocar correctly, repeatedly ending in bladder perforation.

Outcome and findings of the 136 eligible patients at the 12-month follow-up are summarised in Table 3. Qmax was decreased significantly by TVT, TOT and TVT-O (P<.001, P=.050, P=.010, respectively; Tables 1 and 3). The mean difference of Qmax at 12 months between the retropubic TVT and the transobturator slings (TOT and TVT-O together) was 1.6 ml/s with a 95% confidence interval from −1.5 to 4.6 ml/s. So we cannot exclude a moderate difference of 4.6 ml/s between retropubic and transobturator slings. No statistically significant difference was found postoperatively between the groups for Qmax (P=0.26), PVR (P=0.66), or obstructive voiding symptoms like straining or slow stream (P=0.71). Compared with patients reporting normal voiding, obstructive symptoms were associated with lower Qmax (TVT 21.5±7.6 vs. 12.6±8.0 ml/s, P=0.007; TOT 24.4±8.6 vs. 11.0±3.5 ml/s, P=0.050; TVT-O 21.6±6.3 vs. 14.1±7.3 ml/s, P=0.07) but not with elevated PVR.

Objective continence was comparable for all three groups (TVT 94%, TOT 91% and TVT-O 89%; P=0.72). Assuming incontinence for all excluded patients, continence would have been achieved in 73%, 78% and 83%, respectively (P=0.48). Assuming continence, a comparable rate for the three groups would be found as well (95%, 93%, 90%, respectively; P=0.60). All sling types improved quality of life (P<0.05), assessed by KHQ and VAS (Table 4).

After excluding nine women with concomitant prolapse surgery, no statistically significant differences were found either for objective continence (P=0.79) or subjective success by means of patients global impression (P=0.79); also, Qmax, PVR or midtape position at 12 months were comparable (P=0.34, P=0.90, P=52, respectively).

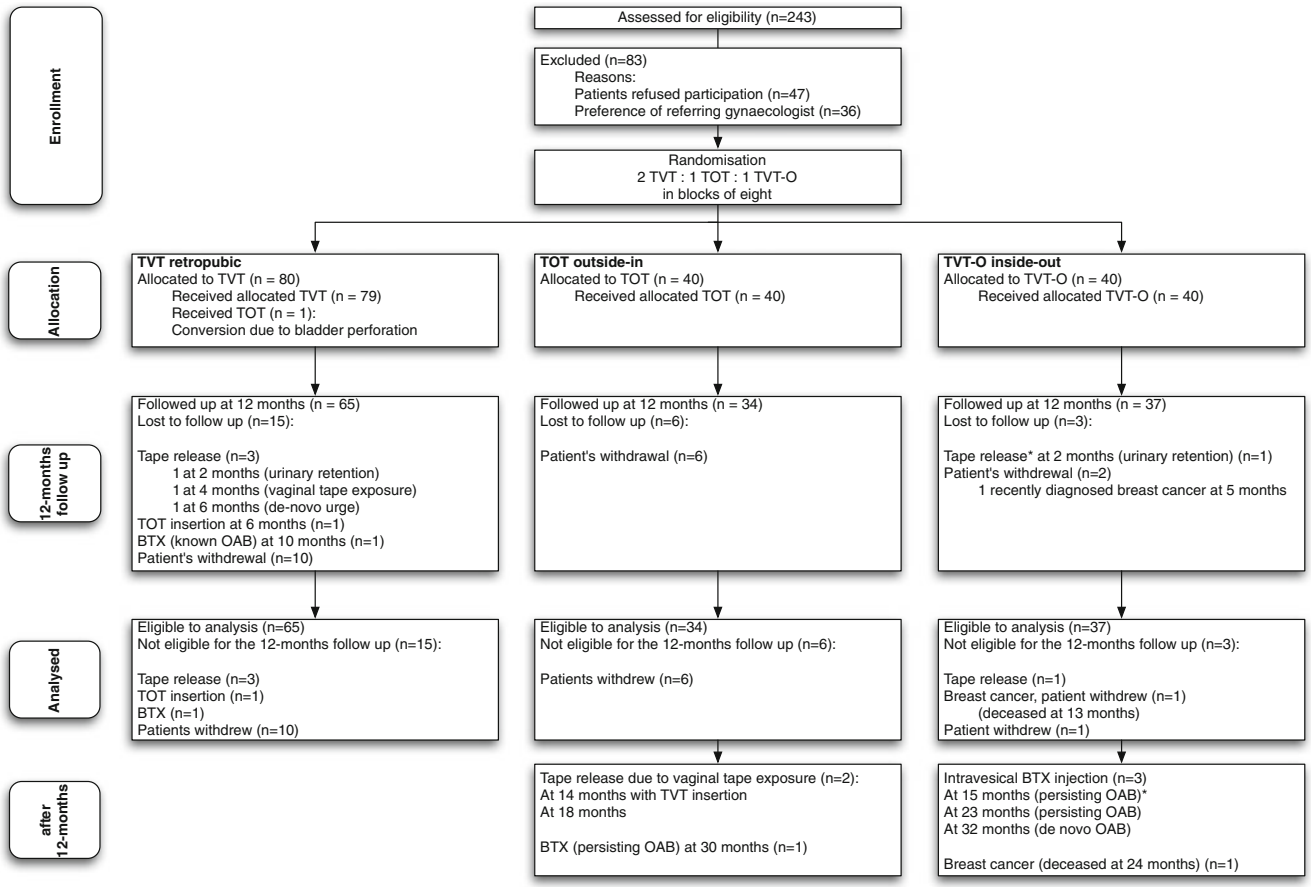

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) flow chart of enrolment and follow-up showing progress of patients through trial. *TVT* tension-free vaginal tape, *TOT* outside-in transobturator tape Monarc, *TVT-O* inside-out transobturator tape, *OAB* overactive bladder syndrome, *BTX* intravesical injection of Botox

Table 1 Patient characteristics (N=160)

	N	TVT	TOT	TVT-O
N randomised	160	80	40	40
Age, years	160	57.8±13.0 (33.9–85.4)	56.6±10.3 (40.5–84.8)	59.3±12.1 (33.9–81.8)
BMI, kg/m^2	160	26.4±3.7 (18.9–35.9)	27.8±4.6 (18.7–41.5)	27.6±4.8 (19.2–39.2)
Parity	160	2.0±1.0 (0–4)	2.6±1.5 (0–8)	2.3±1.1 (0–5)
MUCP, cmH_2O	160	49.9±26.4 (2–121.8)	48.4±25.0 (14–114.2)	51.4±25.0 (13.7–104.8)
Qmax, ml/s	146	28.9±12.1 (9.6–64.6)	29.9±11.7 (13.1–58.5)	27.0±13.7 (8–69.8)
PVR (ml)	156	18.9±19.6 (0–95)	15.0±18.4 (0–60)	13.2±14.9 (0–50)
OAB dry	160	25 (31.3%)	9 (22.5%)	13 (32.5%)
OAB wet		8 (10.0%)	2 (5.0%)	3 (7.5%)
S/p hysterectomy	160	24 (30.0%)	14 (35.0%)	10 (25.0%)
S/p colporrhaphia anterior	160	5 (6.3%)	4 (10.0%)	7 (17.5%)
S/p colporrhaphia posterior	160	5 (6.3%)	3 (7.5%)	4 (10.0%)

Data are expressed as mean±standard deviation and range (minimum—maximum), or number of patients (percent)

TVT tension-free vaginal tape, *TOT* outside-in transobturator tape Monarc, *TVT-O* inside-out transobturator tape TVT-O, *BMI* body mass index, *MUCP* maximum urethral closure pressure, *Qmax* maximum urinary free flow (Uroflow), *PVR* post-void residual urine volume, *OAB* overactive bladder syndrome

MUCP: excludes missing values (n=1 in the TVT group)

PVR: excludes missing values (n=2 in the TVT group, n=1 in the TOT group, n=1 in the TVT-O group)

Table 2 Perioperative details (n=160)

	TVT	TOT	TVT-O	P value
N randomised	80[a]	40 [a]	40	–
Local anesthesia (time for application) (min)[d]	6.4±1.8 (3–10)	5.7±1.6 (3–10)	6.0±1.8 (5–12)	0.19[b]
Operation time (from incision to closure) (min)[d]	26.7±11.5 (15–100 [a])	25.8±9.7 (15–50)	27.4±10.0 (15–54)	0.68[b]
Blood loss (ml)[d]	34.4±36.5 (5–250)	31.5±22.2 (10–100)	49.4±89.6 (10–500)	0.96[b]
Type of anesthesia				0.088[c]
Local	60 (75.0%)	36 (90.0%)	28 (70.0%)	
Regional	8 (10.0%)	1 (2.5%)	8 (20.0%)	
General	12 (15.0%)	3 (7.5%)	4 (10.0%)	
Concomitant surgery	7 (8.8%)	2 (5.0%)	4 (10.0%)	0.81[c]
Concomitant POP surgery	6 (7.5%)	0 (0%)	3 (7.5%)	0.25[c]
Hysterectomy	3 (3.8%)	2 (5.0%)	4 (10.0%)	0.44[c]
Colporrhaphia anterior	3 (3.8%)	0 (0%)	3 (7.5%)	0.22[c]
Colporrhaphia posterior	6 (7.5%)	0 (0%)	2 (5.0%)	0.23[c]
Sacrospinal ligament fixation	2 (2.5%)	0 (0%)	0 (0%)	0.50[c]
Other procedure(s)	11 (13.8%)	3 (7.5%)	4 (10.0%)	0.65[c]
Hospitalisation (days)[d]	3.5±1.1 (3–10[e])	3.2±0.5 (3–5)	3.3±0.8 (3–6)	0.14[b]

Data are expressed as mean±standard deviation and range (minimum–maximum), or number of patients (percent)

TVT tension-free vaginal tape, *TOT* outside-in transobturator tape Monarc, *TVT-O* inside-out transobturator tape TVT-O, *POP* pelvic organ prolapse

[a] One conversion from TVT to TOT due to bladder perforation, resulting in 79 inserted TVT, 41 TOT and 40 TVT-O

[b] Kruskal–Wallis test

[c] Fisher's exact test

[d] Sling insertion without concomitant procedure (n=131)

[e] One TVT required laparotomy for haemorrhage into the retropubic space, resulting in a hospitalisation duration of 10 days

Of the 124 slings inserted under local anaesthesia, a postoperative PVR below 100 ml was achieved on day of operation in 23 TVT (40%), 21 TOT (37%) and 13 TVT-O (23%), the next day in 31 TVT (58%), 11 TOT (20%) and 12 TVT-O (22%), and on day 2 or later, in six TVT (50%), four TOT (33%) and two TVT-O (17%) (P=0.34).

Table 5 shows the tape-related complication pattern including all events up to 12 months postoperatively. Work-up of one patient in the TVT-O group with intraoperative blood loss of 500 ml revealed von Willebrand disease. In one TVT, haemorrhage in the retropubic space required laparotomy the next day. Because this patient remained incontinent, she received a TOT at 6 months and was cured then. Urinary retention necessitated tape release by complete midline incision in one TVT after 2 months as well as in one TVT-O after 2 months. One TVT was released after 6 months due to persisting de novo urge. Vaginal tape exposure within 12 months occurred more often in the TOT group (one TVT, four TOT, zero TVT-O) (P=.028) and required after 4 months partial excision of the TVT, after 14 months of one TOT and after 18 months in another TOT causing hispareunia. Twelve patients (7%) reported sexual dysfunction—two TVT, six TOT and four TVT-O. None of these 12 patients had concomitant prolapse surgery, but two patients with TOT and two with TVT-O had combined colporrhaphia anterior and posterior at a separate event prior to sling insertion. After excluding one TVT and one TOT with vaginal tape exposure as cause for hispareunia, and four patients with TVT-O reporting persisting preoperative FSD, de novo FSD occurred in one out of 52 sexually active patients with TVT and in five out of 29 with TOT, but in 0 out of 25 TVT-O (P=0.011; Table 5). Complaints included de novo dyspareunia in one TVT and two TOT, a feeling of vaginal narrowing in two TOT, and neuralgiform pain at the ischiocrural tape exit point in one TOT. In two patients with TOT, de novo FSD subsided after 12 months. The other four patients preferred an expectant procedure. No association between tape exposure or FSD and surgeon was found.

We considered the unexpected occurrence of de novo FSD in TOT in our trial clinically important enough to stop enrolment. Generating one million datasets with two cumulative interim analysis in order to correct the P value for "picking extreme values" revealed a corrected P value of P=0.016. Further enroling without informing about the possible occurrence of FSD was not regarded as ethical.

Table 3 Twelve-month assessment (n=136)

	N	TVT	TOT	TVT-O	*P* value
	136	65	34	37	–
12-month follow-up, months		12.4±0.8 (11.7–16.0)	12.8±1.6 (10.8–18.3)	12.5±1.3 (9.9–18.2)	0.75[a]
Objective continence	133				0.72[b]
Yes (both negative cough and negative short-pad test)		58 (93.6%)	31 (91.2%)	33 (89.2%)	
No (positive cough or positive short-pad test)		4 (6.4%)	3 (8.8%)	4 (10.8%)	
Subjective success (patient's global impression)	136				0.77[b]
Continent		57 (87.7%)	28 (82.4%)	29 (78.4%)	
Improved		6 (9.2%)	3 (8.8%)	5 (13.5%)	
Incontinent (failure)		2 (3.1%)	3 (8.8%)	3 (8.1%)	
Micturition					
Voiding pattern	136				0.71[b]
Normal		53 (81.5%)	30 (88.2%)	32 (86.5%)	
Changed[c]		12 (18.5%)	4 (11.8%)	5 (13.5%)	
PVR, ml	135	14.2±22.4 (0–100)	14.2±25.6 (0–120)	18.1±25.2 (0–120)	0.66[a]
Qmax, ml/s	111	20.4±8.1 (6.5–40.1)	23.5±9.0 (5.1–44.9)	20.6±6.9 (7.4–33.7)	0.26[a]
Midtape position, %[d]	135	53.8±6.7 (31.5–65.7)	52.5±8.1 (23.6–66.9)	50.6±10.8 (15.4–67.5)	0.55[a]

Data are expressed as mean±standard deviation and range (minimum–maximum), or number of patients (percent)

TVT tension-free vaginal tape, *TOT* outside-in transobturator tape Monarc, *TVT-O* inside-out transobturator tape TVT-O, *PVR* post-void residual urine volume, *Qmax* maximum free-flow rate

[a] Kruskal–Wallis test

[b] Fisher's exact test

[c] Any obstructive symptom like straining, requirement of postural changes in order to void, slow stream or hesitancy

[d] 0%=at meatus internus, 100%=at meatus externus

Discussion

Based on anatomical and theoretical considerations, the rational for the TO techniques was to reduce bladder, bowel and major blood vessel injuries as caused by the retropubic route, but not superiority over TVT [18]. When TO slings started to spread increasingly, few randomised trials compared the techniques at that time. The importance of looking at any issue with any midurethral sling is for patient safety and efficacy. Thus, we initiated this trial to compare the three commonly used midurethral slings in Switzerland.

Authors increasingly discuss complication issues in recent literature [3, 9, 19]. But, to compare complications meaningfully, meta-analysis, multi-centre or national registries are preferable [20]. In contrast, voiding dysfunction after incontinence procedures are common [21]. We calculated the sample size based on Qmax. In our trial, voiding dysfunction occurred comparably in the three groups. In this respect, no group was advantageous. Obstruction was easily resolved within the first postoperative days by tape loosening [22]. However, because the trial was stopped sooner, it is under-powered to detect a difference in Qmax as primary outcome.

Our trial showed comparably good continence as well as improved QoL after 12 months for the three groups. We were aware that a higher number of subjects would be needed in order to detect statistically significant differences in continence. Several meta-analysis, systematic reviews and recent large multicentre comparative-effectiveness trial could not reveal clear superiority of one technique [3–6, 9]. A recent meta-analysis showed evidence for equivalent effectiveness of TOT and TVT-O [23]. In the long-term, recurrent incontinence could be higher after TOT [24].

An unexpected complication pattern led us to stop enrolment prematurely: de novo female sexual dysfunction. We noted a higher perioperative complication rate in the TVT group, such as bladder perforation, quickly solved by replacing the trocar. In contrast, we found more mid-term complications in the TOT group, such as vaginal tape exposure, FSD or hispareunia. For future reporting of these complications, the recently published consensus-based terminology and classification report for prostheses and grafts complications in female pelvic floor surgery will be helpful in clinical practice and research [25]. One possible explanation for the higher incidence of tape exposure in TO tapes is their close passage next to the vaginal sulci. In women with high lateral sulci, vaginal tape exposure could occur more frequently. Here, a procedure under protected guidance of an introducer could be favourable by avoiding a too-close passage to the vaginal wall. Then again,

Table 4 Quality of life at baseline and at 12 months follow-up

	Baseline					12 months follow-up				
		TVT	TOT	TVT-O			TVT	TOT	TVT-O	
	N	Mean±SD (range)			*P* value preop[a]	*N*				*P* value postop[a]
		74	38	37			47	28	28	
Visual analogue scale on incontinence impact	144	7.5±2.1 (0–10)	7.7±1.9 (3–10)	7.1±2.6 (0–10)	0.84	100	0.7±1.3* (0–6)	1.2±1.7* (0–5)	1.3±1.8* (0–7)	0.21
King's Health Questionnaire										
General health perception	142	36.1±21.8 (0–100)	42.9±24.7 (0–100)	33.6±26.4 (0–100)	0.23	101	22.3±18.4*** (0–75)	22.3±19.6** (0–75)	25.0±20.8*** (0–75)	0.85
Incontinence impact	142	75.9±24.5 (0–100)	82.9±26.0 (0–100)	68.6±31.3 (0–100)	0.08	100	8.5±14.7* (0–33.3)	11.9±22.6* (0–66.7)	10.7±18.6* (0–66.7)	0.95
Role limitations	139	63.2±28.0 (0–100)	73.0±26.9 (0–100)	64.6±32.5 (0–100)	0.21	99	4.6±11.4* (0–33.3)	6.8±17.5* (0–66.7)	6.0±12.6* (0–50)	0.70
Personal limitations	140	68.5±28.2 (0–100)	68.1±26.6 (0–100)	63.7±30.8 (0–100)	0.78	99	5.3±12.1* (0–50)	6.0±20.9* (0–100)	4.9±7.7* (0–16.7)	0.38
Social limitations	140	35.1±31.3 (0–100)	40.3±32.1 (0–100)	29.7±27.2 (0–100)	0.42	98	1.7±6.6* (0–33.3)	6.0±20.4* (0–100)	1.4±5.0* (0–22.2)	0.77
Personal relations	104	39.7±36.6 (0–100)	46.4±32.7 (0–100)	46.2±36.0 (0–100)	0.57	68	3.2±8.0* (0–33.3)	7.1±18.7** (0–83.3)	3.1±9.1** (0–33.3)	0.66
Emotional problems	137	38.3±32.2 (0–100)	39.9±31.0 (0–100)	36.4±32.7 (0–100)	0.83	100	2.4±7.3* (0–33.3)	2.8±7.8* (0–33.3)	5.8±15.4* (0–66.7)	0.75
Sleep and energy	135	31.8±27.2 (0–100)	26.5±29.0 (0–100)	29.9±26.2 (0–100)	0.47	100	4.3±8.1* (0–33.3)	6.5±13.1* (0–50.0)	6.7±12.7** (0–33.3)	0.91
Severity measures	134	61.3±21.6 (6.7–100)	63.1±16.2 (20–86.7)	60.0±22.9 (0–100)	0.86	98	16.4±20.3* (0–86.7)	17.5±22.1* (0–100)	17.3±17.8* (0–53.3)	0.86
Overactive bladder	142	46.9±31.7 (0–100)	44.6±33.3 (0–100)	48.7±39.6 (0–100)	0.84	102	3.9±13.0* (0–66.7)	5.2±19.3* (0–83.3)	4.9±14.5* (0–50.0)	0.90

Data are expressed as mean±standard deviation and range (minimum–maximum)

[a] Comparison between groups (Kruskal–Wallis test)

Comparison between pre- and postoperative scores for each group (Wilcoxon signed rank test): *$P \leq 0.001$ post- vs. preoperative QoL; **$P \leq 0.01$ post- vs. preoperative QoL; ***$P < 0.05$ post- vs. preoperative QoL

Table 5 Tape-related complication pattern (n=160)

	TVT	TOT	TVT-O	P^a value
N randomised	80, *n* (%)	40, *n* (%)	40, *n* (%)	
Intraoperative complications				
Bladder perforation	3[b] (3.75)	0 (0)	0 (0)	0.43
Vaginal perforation	1 (1.25)	6 (15.0)	4 (10.0)	0.006
Postoperative complications				
Haemorrhage	1[c] (1.25)	0 (0)	0 (0)	1.0
Postoperative interventions due to voiding obstructions				
Early (tape loosening within the first week)	1 (1.25)	1 (2.5)	0 (0)	1.0
Late (tape release procedure within 12 months by complete incision, including partial excision)	2[d] (2.5)	0 (0)	1[e] (2.5)	0.81
Second sling insertion	1[c] (1.25)	1 (2.5)	0 (0)	1.0
Short- and mid-term complications				
Vaginal tape exposure[f]	1 (1.5)	4 (10)	0 (0)	0.028
Thigh or groin pain (not associated with sexual activity)	1 (1.5)	3 (8.3)	1 (2.7)	0.23
FSD (in sexually active patients; not associated with tape exposure)	1/52 (1.9)	5/29 (17.2)	0/25[g] (0)	0.011

Data are expressed as number of patients (percent)

TVT tension-free vaginal tape, *TOT* outside-in transobturator tape Monarc, *TVT-O* inside-out transobturator tape TVT-O, *FSD* female sexual dysfunction

[a] Fisher's exact test

[b] Whereof one conversion to TOT

[c] This patient needed a subsequent laparotomy. A second sling (TOT) was inserted at 6 months

[d] Due to one urinary retention and one de novo urge

[e] Due to urinary retention

[f] Erosion detected in one TVT at 4 weeks, in two TOT at 6 months, and in two TOT at 12 months

[g] Four TVT-O with preexisting FSD (and sexually active) are not included

different mesh properties may play a role. Indeed, the three tapes consist of knitted polypropylene, and TOT has the most similar mechanical behaviour to TVT or TVT-O [26].

There is a concern about presence of palpable tape, particularly among the TO group, needing a longer-term follow-up to determine whether this leads to extrusion [27]. Furthermore, TOT seems to give rise to more FSD than TVT-O or TVT, probably as a result of vaginal narrowing [28]. Incontinence surgery can affect sexual function. This issue needs to be discussed in the informed consent.

Our study revealed a higher frequency of de novo FSD in the TOT group. This is in contrast to anatomical studies that compared TOT with TVT-O and presumed a lower complication rate for outside-in TOT [29]. At initiation of our study, we have not anticipated this issue, and only recently, the importance of these complications is independently and increasingly mentioned in the literature [19, 28]. In a 27-month follow-up of 233 women after TO tape procedure, a de novo rate for dyspareunia of 9% was found [19]. In our study, we found an FSD rate of 17% in the TOT group. We decided to stop recruitment after having observed this complication pattern about patients have to be informed [9, 19].

Our study was undertaken in a teaching hospital setting, involving several surgeons. Indeed, it is difficult to obtain objective and clinical evidence in the daily clinical setup. The strength of our study is its prospective randomised design, comparing not only TVT with one TO technique, but with the two TO techniques outside-in TOT and inside-out TVT-O. The reason for the 2:1:1 relation was to achieve an equal 1:1 distribution for TVT and TO techniques and not to favour the TO techniques with a 1:1:1 distribution.

The weakness of our study was its design to detect a difference in the voiding pattern by means of Qmax, whereas for complication pattern a much higher number of patients would be needed. In our study, we chose free-flow rate to assess voiding function instead of a pressure-flow study. This could be a limitation, although the literature is quite controversial about this subject. In fact, it was reported that free Qmax was significantly higher in free uroflow studies than in pressure-flow studies, in both obstructed and unobstructed patients [30]. Moreover, comparison of detrusor pressure at maximum flow and maximum detrusor pressure during voiding values did not reveal significant differences, in both obstructed and unobstructed patients. Due to the preterm stop of enrol-

ment, our study is underpowered with 160 subjects, reducing confidence in the primary endpoint outcomes.

A further weakness of the study was that we were only partially able to follow the CONSORT guidelines. The ethic committees requested a mandatory annual interim analysis, and this may have led to an important information bias. Nevertheless, we believe that our study adds to the current knowledge about sling operations and that this prospective randomised controlled trial is useful in representing the daily clinical life.

Another weakness is the amount of missing data regarding Qmax and QoL at 12 months. Eighteen percent of patients could not void for the uroflow exam. In regard to QoL, up to 26% of the patients did not fill in the questionnaires. For the domain “personal limitations”, missing data are even more common due to missing partner or family.

Our study shows that it is important to follow-up patients carefully, not only concerning defined endpoints, but also concerning "new" side effects and symptoms that can decrease QoL.

The patient complaint about FSD was very clear and therefore clinically important. When we discussed the yearly interim analysis, we realised the weakness of our trial in this regard, namely that it was not designed for detecting differences of this particular issue and that FSD was no determined endpoint. We considered the higher occurrence of FSD particularly in the TOT group clinically important enough to stop our trial. This decision is supported by the analysis of the corrected *P* value for FSD. But due to the likelihood of bias caused by repeated analyses and subgroup analyses, the results for FSD cannot be generalised. Further prospective studies are needed using a validated measure to evaluate FSD.

Our study adds to the growing evidence that TO tapes—though equally effective in restoring continence—can, in the mid- and long-term, impair patient’s satisfaction due to complications like vaginal exposure or FSD [19, 28]. FSD is a very important issue for any operation restoring quality of life. Our data do not allow for generalisation. Therefore, well-powered randomised controlled trials are needed to answer this issue.

Women should be informed of these potential complications preoperatively and require careful follow-up after the procedure. Further studies should focus on long-term follow-up and the complication pattern particularly for the current slings, as well as on a possible differential indication, such as TVT for younger patients or for patients with low-pressure urethra.

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