6

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IS THE FIXATION OF SINGLE INCISION TAPE (TVT-S) AS GOOD AS A TRANSOBTURATOR TAPE (TVT-O)? AN ULTRASOUND STUDY, RESULTS FROM RANDOMIZED TRIAL.

Hypothesis / aims of study

Synthetic midurethral slings are at present considered the gold standard for surgical treatment of stress urinary incontinence, but they are also associated with some complications. To reduce the occurrence of such complications, transobturator tapes were introduced, followed by single incision tapes. In our randomize trial we proved the lower efficacy of TVT-S procedure, H a U approach, as compared to the TVT-O procedure (results of primary outcomes were published previously). However, as part of the patient monitoring procedure ultrasound examinations were performed, especially post-operative monitoring of the tape position and descent.

The aim of this study was to assess possible reasons for the lower efficacy of the TVT-S procedure in comparison to TVT-O, based on the postoperative monitoring of the position of the tape and its descent. The hypothesis was that the reason for the lower efficacy of TVT-S procedure may be primary malposition of the tape, or poor fixation, leading in time to an increase in tape mobility after procedure.

Study design, materials and methods

Between January 2007 and November 2009, 197 women with proven urodynamic stress urinary incontinence (USI) were included in the randomized trial. The study was approved by the local ethics committee. The recruitment period for the study started in November 2006 and ended in October 2009. During the study period 711 patients were indicated for surgical treatment for SUI: 408 of them were suitable for the study, and 205 patients agreed with randomization and signed informed consent prior to treatment. 197 of these underwent randomization, 67 allocated to TVT-O, 64 to TVT-S H and 65 to TVT-S U (all those patient received planned surgery). Based on pre-study statistical calculations it was indicated that the required sample size for final statistical analysis in each group was 65 patients (allocation ratio 1:1:1). The study was only intended to establish differences in efficacy between TVT-O and TVT S groups. Pre-operatively the patients underwent a complete urogynaecological examination, including ultrasound examination. Before the ultrasound examination the urinary bladder was filled to 300 ml with sterile saline. The measurements were taken in a supine position at rest and during maximal Valsalva. Position of the bladder neck was assessed, as was the position of the tape after surgery: the upper and lower tape margins. Checks were planned 3 months, one year, two years and three years after surgery. For a subgroup of patients we added ultrasound examination on the first day after surgery and two weeks after surgery (this examination was not mandatory, because we were unable to provide it during the weekends).

Results

There were no significant differences in patient characteristics before surgery (Tab. 1) as regards, for example, age, body mass index (BMI), parity, gynaecological disorders and urethral mobility. Median follow-up after surgery was 2 (SD 0.8) years.

Using LOCF analysis three months after surgery, the stress test was positive in 18% of patients in the TVT-S H group, 23.3% of patients in the TVT-S U group and 4.6% of patients of the TVT-O group (186 patients analysed, $p=0.005$). One year after surgery the stress test was positive in 22.6% of the TVT-S H group, 31.2% of the TVT-S U group and 6.1% of the TVT-O group (192 patients analysed, $p<0.001$), two years after surgery was positive in 28.1% of the TVT-S H group,30.8% of the TVT-S U group and 7.4% of the TVT-O group (197 patients analysed, $p<0.001$). 3 years after surgery a positive stress test was observed in 31.2% of women after TVTS-H, 30.8% after TVT-S U and 7.4% after TVT-O procedures (197 patients analysed, $p<0.001$).

In post-operative follow up we obtained ultrasound data on the first day after surgery in 44 patients in the TVT–O group, 46 in the TVT-S H group and 44 in the TVT-S U group. Two weeks after surgery the figures were 40, 39 and 42; three months after surgery the results were 63, 59 and 56; one year after surgery the figures were 50, 44 and 54, two years after surgery they were 52, 40 and 35; and three years after surgery 14, 14 and 12. After surgery there was no difference between the position of the tape at rest and at maximal Valsalva between the TVT-S and TVT-O groups. The length of the upper and lower tape descent was similar (Tab 2). In TVT-O patients the mean length of upper tape margin descent increased from 6 mm on the first day after surgery to 9mm three months after surgery; afterwards it remained stable. In contrast, for TVT–S patients there was further increase in the tape descent after three months, the increase being up to 15 mm.

Interpretation of results

Increased tape descent in the TVT-S groups corresponds with the increased number of patients with positive stress test and failure rate. In contrast, in the TVT-o group the results were stable, and no increase in tape descend was observed. Immediately after surgery there was no difference in the resting position and tape descent between TVT-S and TVT-O patients, and the recurrence of SUI was observed to a minimal extent six weeks after surgery. The urethral and tape mobility shortly after surgery may well be partially influence by post-operative oedema and the presence of suture of the vaginal incision.

Concluding message

Fixation of the single incision tape – TVT-S in both positions U and H is inadequate, and there is an increase in tape descent over the time after surgery; this corresponds with a higher rate of recurrence of stress urinary incontinence.

Tab. 1 Preoperative patient characteristics

	TVT-o	TVT-S H	TVT-S U
N	68	64	65
Age, years	56.6±9.7	55.2±10.2	57.7±10.1
BMI , kg/m2	27.0±4.5	26.2±4.2	27.6±4.8
Parity	1.8±0.9	2.1±0.9	2.0±0.7
Prior Hysterectomy n/%	19 (27.9%)	18 (28.1%)	16 (24.6%)
Mixed UI n/%	29 (42.6%)	25 (39.1%)	27 (41.5%)
ICIQ	15.1±2.7	15.0±2.2	14.7±2.9
iQoL	53.5±9.6	52.9±8.4	55.1±14.0

Values are given as mean ±SD or number of patients /%

Tab. 2a Upper tape margin descent

	mean	mean	mean	sd	sd	sd	Ftest
Control	TVT-O	TVTS-H	TVTS-U	TVT-O	TVTS-H	TVTS-U	p
	(mm)	(mm)	(mm)	(mm)	(mm)	(mm)	
1	6.2	8.2	7.4	4.3	5.2	4.0	0.1
2	6.3	8.3	8.7	3.4	4.6	5.0	0.05
3	9.4	12.1	13.5	4.9	5.9	5.1	<0.0001
4	10.5	14.5	15.2	5.6	6.9	6.1	0.0001
5	9.8	14.9	14.9	4.5	7.0	5.7	<0.0001
6	8.5	14.8	14.3	5.3	6.5	4.4	0.01

Tab. 2b Lower tape margin descent

	mean	mean	mean	sd	sd	sd	Ftest
Control	TVT-O	TVT-H	TVTS-U	TVT-O	TVTS-H	TVTS-U	p
	(mm)	(mm)	(mm)	(mm)	(mm)	(mm)	
1	5.6	7.4	6.2	3.5	5.4	3.8	0.4
2	5.7	6.8	7.7	2.9	3.9	4.1	0.1
3	8.5	9.2	11.3	4.8	5.3	4.3	0.0009
4	9.1	12.4	12.5	4.6	5.7	4.8	0.001
5	8.5	12.5	12.7	3.8	5.9	4.9	<0.0001
6	6.9	11.1	12.6	4.2	4.7	4.2	0.01

1. Fist day after surgery, 2. Two weeks after surgery, 3. 3 months after surgery, 4. One year after surgery, 5. Two years after surgery 6. 3 years after surgery

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