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RETROPUBIC TVT COMPARED WITH TRANSOBTURATOR TVT (TVT-O) IN TREATMENT OF STRESS URINARY INCONTINENCE: FIVE-YEAR RESULTS OF A RANDOMIZED TRIAL

Hypothesis / aims of study

To compare the long-term outcomes of the tension-free vaginal tape (TVT) with those of the tension-free vaginal tape obturator (TVT-O) midurethral sling procedures in the treatment of female stress urinary incontinence (SUI) within a multicenter randomized trial

Study design, materials and methods

Power calculation required 130 patients in both groups to detect a 10% difference in either success rate or rates of complications, which was thought to be clinically important. Of the 273 randomized patients 136 were treated with TVT and 131 with TVT-O under local anesthesia (1). A cough test was used as an objective outcome measure. The following validated questionnaires were used for condition specific assessment: UISS (Urinary Incontinence Severity Score), DIS (Detrusor Instability Score), Visual Analog Scale (VAS 0-100), IIQ-7 (Incontinence Impact Questionnaire-short form) and UDI-6 (Urogenital Distress Inventory-short form). Quality-of-life (QoL) assessment was carried out with use of the EQ-5D VAS (EuroQoL-5D Visual Analog Scale). A 24-hour pad test was included to be performed pre-operatively and at the two months, one, three and five years follow-up visits.

Results

At five years 95 % of the patients were evaluated according to the protocol; 131 in the TVT and 122 in the TVT-O group. The objective cure rate defined as a negative stress test was 91.6 % in the TVT and 91.8 % in the TVT-O group, p=0.954. The corresponding percentages were 94.6% and 89.5% at the three years follow-up respectively, p=0.131 (2). There was a significant decrease in leakage measured by a 24 h pad test from 44+/-39g to 3+/-10g at three years follow-up to 4+/-12g 5 years postoperatively in the TVT group and from 44+/-48g to 3+/-10g at three years follow-up to 2+/-5g 5 years postoperatively in the TVT-O group with no difference between the groups, p=0.558 (3 years) and p=0.202 (5 years) respectively (2). The pad test was negative (<8g) in 89.2% in the TVT and 93.4% in the TVT-O group, p=0.237. Significant improvement from preoperative scores for both groups was seen in the condition specific parameters with no difference between the groups (Table). The EQ-5DVAS score increased from mean 80 preoperatively to mean 84 5 years postoperatively (p<0.0001) in the TVT group and from mean 81 preoperatively to mean 83 5 years postoperatively (p=0.079) in the TVT-O group with no difference between the groups, p=0.335. Twenty seven patients (20 %) in the TVT and 27 (21 %) in the TVT-O group experienced at least one episode of urinary infection between three and five years follow-up visits, p=0.848. Antibiotic treatment for 5 or more urinary tract infections during the two years was needed in 0.8% of the patients in the TVT and 4.0% of the patients in the TVT-O group, p=0.113. The median post-void residual urine volumes were 6 (0-180) ml in the TVT and 10 (0-360) ml in the TVT-O group, p=0.167. A DIS score 7 or less was one of the exclusion criteria. Five patients (3.9%) in the TVT group and 7 patients (5.6%) in the TVT-O group had urgency symptoms, which was defined as having urgency or frequency of moderate or severe degree in the UDI-6 or a score >7 in the DIS, p=0.518. De novo urgency, defined as new symptoms of frequency or urgency of moderate or severe degree in the UDI-6 or a score >7 in the DIS, was found in 1 (3.6 %) in the TVT and in 1 (4.6%) in the TVT-O group, p=>0.999. Nine (7%) patients in the TVT and 3 (2%) in the TVT-O group used anticholinergic treatment, p=0.088. The number of patients complaining of lower abdomen or external genital pain of moderate or severe degree in the UDI-6 was 3 (2.3%) in the TVT and 6 (4.8%) in the TVT-O group, p=0.325. Two patients in the TVT and three in the TVT-O group were re-operated with a TVT procedure. One of these TVT-O patients had tape erosion tape resection was performed, which resulted in recurrence of incontinence. Eighty eight % of the TVT and 93 % of the TVT-O patients were completely satisfied with the operation, p=0371. In both groups 96% would definitely recommend the operation to a friend.

Interpretation of results

A majority of new surgical methods, mostly modifications of the TVT procedure, have been offered for routine clinical use without proper evaluation and with the clinical experience of only a small number of patients with inadequate follow-up. The present trial is one of the largest, in which the number of patients required by the power calculation could be operated on. We managed to bring back 95% of the women in our trial for the 5-year follow-up visit. We had seen a trend of lower cure rates by time for the TVT-O group during 3 years of follow-up (2). The 5 years results of this randomized trial, however, shows no significant differences in cure rates or complications rates between the ``gold standard´´ TVT procedure and the TVT-O procedure.

Concluding message

The TVT and the TVT-O procedures result in high long-term cure rates and low rates of complication despite the fact that the mid-urethra support is different between the two studied procedures.

Table. Condition specific and General Health Quality-of-Life Parameters, Preoperatively and at 5-Year Follow-up

	TVT (n=131)		TVT-O (n=122)	
	Preoperative	At 5-year follow-up	Preoperative	At 5-year follow-up
UISS	11+/-3	1+/-3*	11+/3	1+/-2*
DIS	4+/-2	3+/-3*	4+/-2	3+/-3*
VAS	65+/-20	11+/-21*	67+/-21	9+/-17*
IIQ-7	16+/-4	8+/-2 *	16+/-4	8+/-2*
UDI-6	14+/-3	8+/-2*	13+/-3	8+/-2*
EQ-5DVAS	80+/-14	84+/-10*	81+/-12	83+/-14**

Data are expressed as mean+/- standard deviation.
*p<0.0003, significant difference compared with preoperative figures.
**p=0.079

References
1. Obstet Gynecol (2007) 109:4-11
2. Int Urogynecol J (2010) 21:1049-1055

Specify source of funding or grant	**This study was instigated by the responsible researchers and funded by University-Administered funds.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov.www.clinicaltrials.gov,NCT00379314**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Helsinki University Central Hospital Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**