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PATIENT-REPORTED MID- AND LONG-TERM OUTCOME AFTER INSERTION OF RETROPUBIC AND TRANSOBTURATOR TAPES

Hypothesis / aims of study

Midurethral tapes are by now standard procedure in the surgical treatment of women with stress urinary incontinence. While the retropubic TVT – introduced by Ulmsten and Petros in 1995 – is well documented with long-term results up to 11 years and continence rates of 90 % [1], the published data for the transoburator tapes (TO) – introduced by Delorme in 2001 (outside-in TOT) and by de Leval in 2003 (inside-out TVT-O) – cover yet only short- or mid-term follow-up of 3 years. So far, all tapes establish continence effectively [2]. Recently, the detailed 27-item Incontinence Outcome Questionnaire (IOQ) was constructed to assess patient-reported outcome and quality of life (QoL) after insertion of a midurethral tape and validated for the German language [3]. The aim of this study was to evaluate patient-reported mid- and long-term outcome after insertion of TVT, TOT and TVT-O.

Study design, materials and methods

In this retrospective study, 626 women who underwent midurethral sling procedure between January 1999 and December 2007 at two medical centers (one university hospital, and one district hospital) were identified by using a computerized medical record system: 452 (72.2 %) TVT, 119 (19.0 %) TOT (Monarc), 36 (5.8 %) TVT-O, 9 (1.4 %) IVS, and 10 (1.6 %) Remeex, a readjustable sling system. Patients after IVS and Remeex procedure were excluded, leaving a total of 363 (58.0%) IOQs eligible for the following analysis. The remaining were sent the IOQ, which consists of 27 questions: four related to symptoms (pain, postoperative symptoms, preoperative OAB, change in OAB symptoms pre- or postoperatively), four to complications (urinary or other infection, hospital readmission, residual urine), seven to QoL (felt tired/drained/lacking, felt irritable/snappy, felt depressed/tearful, global evaluation of health, limitations in daily activities, change in sexual life, change of body self-perception), five to satisfaction (symptoms changes pre- and postoperatively, time of recovery, satisfaction with information, improvement in well being, recommending the operation), one to problems with urinary incontinence before surgery, and six address demographic and treatment-related information (age, occupation, living arrangements, reason for operation, hormone replacement therapy, and time interval to operation). Each item is transformed into a 0-100 scale (0 = minimum, 100 = maximum complaints), from which two scores are calculated: one consisting of the 7 items for QoL and the 5 for satisfaction, and an extended one which additionally includes items for postoperative symptoms, post-void residual urine volume and change in OAB symptoms as well. We added a visual analogue scale (VAS, scoring from 0 “no” to 10 “maximum impairment”) to assess the subjective grade of discomfort for urine loss. We included all patients after TVT, TOT Monarc or TVT-O procedure, who completed the questionnaire. Statistic evaluation was undertaken by means of Kruskal-Wallis, ANOVA, chi-square, Fisher’s exact test or regression analysis, as appropriate, using Intercooled Stata 8.2. P values <0.05 were considered to indicate statistical significance (two-sided). Because of the retrospective character of this study, no sample size analysis was performed.

Results

After our first mailing, 372 (59.4%) of the 626 patients completed the IOQ, 187 (29.9%) didn’t answer yet, 47 (7.5%) had moved away, 14 (2.2%) died, and 6 (1%) returned an empty IOQ. Patient compliance was good with a maximum of 3.9% of missing data per item. Table 1 shows the basic characteristics. Except for the younger age for TVT, no statistically significant differences were found between the three sling types.

	TVT	*TOT Monarc*	*TVT-O*	*p-value*
N	268 (73.8%)	71 (19.6%)	24 (6.6%)	-
Age at operation (years)	60.1±12.3	64.1±12.9	64.3±13.5	0.047*
Body mass index (kg/m^2)	26.8±4.9	26.0±4.3	27.8±4.8	0.226*
Max. urethral closure pressure (cmH2O)	43.2±22.6	36.8±18.1	49.0±24.6	0.151*
Volume at first desire to void (ml)	247.5±107.7	241.3±125.8	283.0±103.0	0.228*
Max. bladder capacity (ml)	456.4±103.8	438.8±129.4	479.6±115.4	0.621*
Preoperative post-void residual urine volume (ml)	20±42.8	29.2±68.3	30.8±31.8	0.130*
Short-pad-test (g)	66.9±67.7	58.6±68.9	108.5±145.7	0.281*
Parity	2.5±1.1	2.7±1.4	2.6±1.1	0.700*
History of smoking	90 (34.1%)	24 (34.3%)	5 (21.7%)	0.475**
Hormone replacement therapy	60 (22.8%)	15 (21.4%)	7 (29.2%)	0.734**

Table 1. Basic characteristics including preoperative urodynamic data of the 363 eligible patients. Data are expressed as mean±standard deviation, or number of patients (percentage).
*Kruskal-Wallis test. **chi-square test.

The impact of postoperative incontinence situation and QoL, measured by VAS and IOQ, didn’t differ for the sling types, as shown in table 2. No statistically significant difference was found between the groups. With increasing age, the score for QoL decreased (QoL = 14 + 0.3 x age; p<0.001). 29 patients needed reoperation for sling related complications (18 TVT, 9 TOT, 2 TVT-O; p=0.367): for tape erosion in 9 cases (6 TVT, 3 TO; p=0.702), for bladder outlet obstruction, recurrent urinary tract infections or de-novo urge in 9 cases (7 TVT, 2 TO; p=1.0), for pain in 1 TVT, for abscess in 1 TVT, and for relapse of stress urinary incontinence in 9 cases (3 TVT, 6 TO; p=0.012). The 6 patients with relapse after TO slings got a retropubic sling (TVT/Reemex) 3 to 61months after first operation. Subjective continence didn’t alter in the course of time (p>0.05).

	TVT	*TOT Monarc*	*TVT-O*	*P value*
Follow-up (time interval between operation and IOQ, in years)	5.4±2.4 (1.2 – 10.0)	3.5±1.1 (1.7 – 5.5)	2.9±1.0 (1.7 – 4.9)	<0.001
VAS (0-10)	2.4±2.6	2.1±2.9	2.5±3.0	0.400*
IOQ QoL Score (0-100)	33.4±17.2	36.0±19.2	32.9±18.8	0.714*

IOQ QoL extended Score (0-100)	31.7±17.0	34.0±19.3	30.0±18.7	0.639*

Table 2. Postoperative subjective long-term results. Data are expressed as mean±standard deviation (range).
*Kruskal-Wallis test.

Interpretation of results

The slightly younger mean age at operation in the TVT group could be explained by a possible selection bias: in younger, sexual active patients, we prefer the retropubic route to avoid pain related sexual dysfunction caused by the TO passage. Mean follow-up for retropubic TVT (5.4 years) was obviously longer than for transobturator TOT (3.5 years) and TVT-O (2.9 years), as these were subsequently developed. Outcome parameters for QoL and subjective continence are similar for all three sling types, showing no time related decrease. Despite comparable reoperation rate in all groups, we found a statistical significant difference in reoperation for recurrent incontinence, in favour of TVT: more TOs than TVT needed a second sling procedure for recurrent incontinence. And this after a shorter follow-up time for TO.

Concluding message

Both TVT and TO sling procedures restore continence effectively with comparable mid-term outcome regarding quality of life in women with stress urinary incontinence. In our study, TOs show a higher postoperative incontinence rate than TVT, and thus in a shorter observational interval. This raises the question, whether TO tapes will reach comparable long-term efficacy as TVT.

References

1. Int Urogynecol J (2008) 19(8):1043-7
2. BJOG (2007) 114(5):522-31
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What were the subjects in the study?	**HUMAN**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**