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RETROPUBIC OR TRANSOBTURATOR OUT-IN OR IN-OUT SLING? A PROSPECTIVE RANDOMIZED STUDY!

Hypothesis / aims of study

Since Ulmsten introduced the retropubic tension-free vaginal tape (TVT), the transobturator technique (TO) first described by Delorme in 2001 (TOT out-in) and De Leval in 2003 (TVT-O in-out) has been developed to avoid complications caused by the passage through the retropubic space or to minimize voiding difficulties. Recent reviews note a higher rate for bladder injuries and voiding difficulties for TVT and more thigh pain for TO. Nevertheless, TVTs and TOs seem to have equivalent short- or middle-term success rates. The aim of our study was to evaluate voiding difficulties after insertion of TVT, TOT (Monarc) or TVT-O in the treatment of female stress urinary incontinence. Primary endpoints were post void residual urine volume (PRV), maximum urinary flow rate (Qmax), tape position, tape release and quality of life (QoL), secondary endpoints were continence and complications.

Study design, materials and methods

Women undergoing sling surgery were randomized after informed consent in this ongoing prospective randomized multicenter clinical trial for TVT, TOT or TVT-O in a relation of 4:2:2, using predetermined computer-generated block randomization. Exclusion criteria were relapse incontinence after previous sling procedure, predominant overactive bladder syndrome or PVR >100 ml. Preoperative urodynamic examination included assessment of QoL (King's Health Questionnaire, KHQ), visual analogue scale (VAS, scoring from 0 "no" to 10 "maximum impairment"), perineal sonography and free flow uroflowmetry. Experienced surgeons performed the procedure, preferably under local anaesthesia and analgosedation, according to the original methods after having been supervised for the first 10 insertions per technique. 6 weeks, 6 and 12 months postoperatively medical history, KHQ, clinical and urodynamic data consisting of measuring PVR, perineal sonography at 300 ml bladder volume in a sagittal view to determine the midtape position in relation to the urethra (0% = meatus internus, 100% = meatus externus), cough test in supine position, short pad test, and Qmax were collected by an unprejudiced investigator. We defined objective continence as both a negative cough and a short pad test <4g. In this noninferiority study design we assumed a reduction of Qmax by TVT to 26ml/s and by TO to 30ml/s (SD±10). Based on 0.8 power to detect a significant difference of 15% for Qmax (P=0.05, two-sided), a total of 200 patients is needed. Statistic evaluation on Intercooled Stata 8.2 was undertaken by means of Student t, Wilcoxon rank-sum, Kruskal-Wallis or Fisher's exact test, as appropriate. P values <0.05 were considered to indicate statistical significance (two-sided). The study complies with the recommendations of the CONSORT group.

Results

From January 2006 to January 2008, the first 100 women were randomized. Preoperative characteristics are listed in Table 1. Mean operation time was 29.6 min, blood loss 39.5 ml (n.s.). Additional urogynaecological procedures were hysterectomy, colporrhaphia anterior or posterior and vaginal sacrospinous ligament fixation (3/1/2, 3/0/2, 4/0/2, 1/0/0, resp.; n.s.). Postoperative findings are summarized in Table 2. Objective continence was achieved in ≥88% without elevated PVR. 6 months postoperatively, overall Qmax decreased by 29.8% to 21.9ml/s (TVT 39.4%, P<0.001; TOT 23.2%, P=0.098; TVT-O 14.6%, P=0.4), whereas 84.5% of the women reported normal voiding, irrespective of sling type or Qmax. The tapes remained in midurethral position (51%; 6 months) – TVT distally at 54%, TVT-O proximally at 48%, and TOT intermediate at 52% (P=0.04) – and at constant distance to the urethra (2.9mm at 6 weeks, 2.7mm at 6 months). 73 slings (35 TVT, 22 TOT, 16 TVT-O) were inserted under local anaesthesia, which was well tolerated (VAS for pain: 3.1, n.s.). Of these 73, 32 had PVR <100 ml on the day of operation, 34 at the first postoperative day, and 7 after >1 day (no difference between tapes, P=0.07). Intraoperatively 3 perforations of the bladder (3 TVT, whereof 1 switch-over to TOT) and 7 of the vagina (4 TOT, 2 TVT-O, 1 TVT; P=0.06) occurred. 1 haemorrhage in the retropubic space after TVT required laparotomy, and this patient remained incontinent. 3 TVT were released by complete midline incision (1 urinary retention, 1 de-novo urge, 1 tape protrusion), concerning the first 12 cases of each surgeon. At 12 months, 4 (17.4%) of 23 sexually active women with TO (3 TOT, 1 TVT-O) complained about de-novo dyspareunia, but none of the 19 with TVT (P=0.016). 3 tape erosions occurred (1 TVT at 6 weeks, 1 TOT at 6 and 1 TOT at 12 months). QoL improved after 6 weeks (P<0.05) with further improvement after 6 and 12 months (difference between tapes n.s.).

Table 1: Preoperative characteristics according to the inserted tape

	TVT	***TOT***	***TVT-O***	***Total***	***P***
N	49‡ (rand. 50)	26‡ (rand. 25)	25 (rand. 25)	100	-
Age (years)	57.2±13.5	54.7±10.4	58.9±12.0	56.9±12.4	0.4*
BMI (kg/m^2)	26.6±4.2	28.6±4.8	27.6±5.2	27.4±4.6	0.2*
Parity	2.1±1.0	2.7±1.6	2.4±1.2	2.34±1.2	0.3*
MUCP (cmH_2O)	54.5±28.8	52.0±27.4	52.8±23.9	53.4±27	0.9*
Qmax (ml/s)	30.9±13.8	31.4±13.2	26.9±15.9	30.1±14.1	0.3*
PVR (ml)	22.5±22.6	17.1±21.6	19.9±26.1	20.5±23.2	0.2*
S/p hysterectomy	15	10	5	30	0.4**
S/p colporrhaphia ant.	5	3	3	11	1.0**
S/p colporrhaphia post.	3	3	1	7	0.6**
QoL (KHQ; VAS)	10 domains; 7.4	10 domains; 7.9	10 domains; 7.0	10 domains; 7.4	n.s.*

Rand., randomized; BMI, body mass index; n.s., non significant.
Data are expressed as mean±standard deviation or number of patients.
‡1 switch-over to TOT after futile attempt to insert a TVT (bladder perforation).
*Kruskall-Wallis test. **Fisher's exact test.

Table 2: Postoperative clinical and urodynamic findings at follow-up

	Sling	*6 weeks*	*P*	*6 months*	*P*	*12 months*	*P*	*P*
No of patients		97		71		48		
Obj. continence	TVT	40/2 (95.2%)		31/2 (93.9%)		22/1 (95.7%)		1.0**
yes/no	TOT	22/1 (95.7%)		17/0 (100%)		11/0 (100%)		1.0**
(% continent)	TVT-O	22/3 (88%)	0.5**	17/2 (89.5%)	0.5**	12/1 (92.3%)	1.0**	1.0**
Changed voiding	TVT	36/8 (81.8%)		30/4 (90.5%)		20/4 (83.3%)		0.8**
pattern[#] no/yes	TOT	23/2 (92%)		16/2 (88.9%)		10/1 (90.9%)		1.0**
(% normal)	TVT-O	19/6 (76%)	0.3**	14/5 (73.7%)	0.4**	12/1 (92.3%)	0.9**	0.5**
PVR (ml)	TVT	21±33.3		21±27.4		22±38.1		0.9*
	TOT	9±8.2		11±14.6		10±9.7		0.9*
	TVT-O	11±17.9	0.7*	15±20.9	0.5*	23±27.1	0.9*	0.4*
Qmax (ml/s)	TVT	22±9.5		19±8.5		19±6.7		0.7*
	TOT	23±6.4		24±12.9		24±9.6		0.8*
	TVT-O	20±8.5	0.3*	23±9.7	0.2*	20±4.7	0.3*	0.7*
Tape position	TVT	52±6.7		54±7.0		53±5.1		0.2*
0 = at meatus	TOT	50±7.7		52±8.7		48±8.9		0.4*
int.								
100=at meatus ext.	TVT-O	48±8.8	0.2*	48±9.0	0.044*	47±11.0	0.1*	0.9*

Data are expressed as number of patients, %, or mean±standard deviation.
*Kruskall-Wallis test. **Fisher's exact test.
[#]Any obstructive symptoms like straining, postural changes, slow stream, or hesitancy.

Interpretation of results

Our interim analysis shows that TVT, TOT and TVT-O achieve similar short-term continence of at least 88% and re-establish QoL. TOs reduce Qmax less than TVTs and seem therefore to be less obstructive. Over time, there is no relevant tape dislocation, while TVTs seem to be positioned more distally and TVT-Os more proximally. Anyway, these findings have apparently no effect on patient perception or PVR. TVT can cause perioperative complications like haemorrhage, bladder injuries or urinary retention, requiring manageable (immediate) correction, while TO, in particular TOT, leads rather to mid- or long-term complications like tape erosion or dyspareunia. The latter may significantly impair QoL. Due to the small sample, the differences between out-in and in-out TOs are not conclusive.

Concluding message

As all techniques restore continence effectively, the issue of side-effects, like tape erosions or dyspareunia, and long-term results must be emphasized. We inform our patients particularly about the risk of de-novo dyspareunia after TO.

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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 (NCT00642109)**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Spezialisierte Unterkommission Gynäkologie/Geburtshilfe/Urologie der Kantonalen Ethik-Kommission (SPUK/KEK)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**