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RETROPUBIC TVT VS TRANSOBTURATOR OUTSIDE-IN TOT AND INSIDE-OUT TVT-O – ONE-YEAR RESULTS FROM OUR PROSPECTIVE RANDOMIZED STUDY

Hypothesis / aims of study

The transobturator (TO) technique has been developed to avoid complications caused by the passage of the tension-free vaginal tape (TVT) through the retropubic space, and to minimize voiding difficulties in the surgical treatment of female stress urinary incontinence. The aim of our study was to evaluate: (1) incidence of voiding problems, and (2) outcome, continence rates and complications.

Study design, materials and methods

Women undergoing sling surgery were randomized after informed consent in this ongoing prospective randomized two-center clinical trial for TVT, TOT (Monarc) 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 (OAB) or post-void residual urine volume (PVR) >100 ml. Preoperative urodynamic examination included assessment of quality of life (QoL) by means of King's Health Questionnaire (KHQ) and 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 [1-3]. 12 months postoperatively, medical history, KHQ, clinical and urodynamic data (PVR, perineal sonography, cough test in supine position, short pad test, and maximum urinary free flow rate 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 ANOVA, 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 1/2006 to 3/2009, 149 women were randomized. Preoperative characteristics are listed in table 1. 113 (75.8%) slings (53 TVT, 34 TOT, 26 TVT-O) were inserted under local anaesthesia, which was well tolerated (VAS for pain: 2.9, n.s.). Mean operation time was 26.8±10.8 min, blood loss 38.0±54.1 ml (n.s.). Additional urogynaecological procedures were hysterectomy, colporrhaphia anterior or posterior and vaginal sacrospinous ligament fixation (3/1/2, 3/0/3, 5/0/2, 2/0/0, resp.; n.s.). Of the 113 slings inserted under local anaesthesia, 21/53 TVT, 19/34 TOT, and 13/26 TVT-O could void without elevated PVR (<100 ml) on the same day of operation, 28/53 TVT, 10/34 TOT, and 11/26 TVT-O at day 1, and 4 TVT, 5 TOT and 2 TVT-O at day 2 or later (p=0.1). Postoperative findings are summarized in table 2. Overall Qmax decreased by 28.1% to 21.0ml/s (TVT 33.4%, p<0.001; TOT 32.2%, p=0.021; TVT-O 24.5%, p=0.1). Whereas 84.4% reported normal voiding, 15.6% complained about obstructive symptoms like straining or slow stream, which correlated with a lower Qmax and higher PVR (p<0.05). No correlation was found between Qmax and continence, irrespective of sling type (p>0.05). QoL improved significantly with no difference between tapes. Intraoperatively, all 3 bladder perforations occured in the TVT group, from which 1 was converted to TOT, while the 11 vaginal perforations happened mostly in TOs (6 TOT, 4 TVT-O, 1 TVT; p=0.005). 1 TVT led to haemorrhage in the retropubic space, requiring laparotomy. This patient remained incontinent and needed subsequently a TOT. Another patient remained incontinent after TOT, therefore a TVT was inserted later on. Tape release by complete midline incision was necessary for reason of bladder outlet obstruction with urinary retention in 1 TVT as well as 1 TVT-O, for de-novo urge in 1 TVT, and for tape protrusion in another TVT. 5 tape erosions occurred: 1 TVT with the above mentioned protrusion, and 4 TOT (p=0.03), of which 2 TOT required tape incision. 1 patient after TVT, 3 after TOT and 2 after TVT-O complained about thigh pain (p =0.155). Only 1 out of 52 sexually active women with TVT (1.9%) reported de-novo pain related sexual dyscomfort, but 5 out of 32 TOT (15.6%) and 3 out of 22 TVT-O (13.6%) (p=0.024). 1 patient after TVT-O became pregnant and remained continent after spontanous vaginal delivery.

	TVT	***TOT***	***TVT-O***	***Total***	***P***
N	74‡ (ins. 73)	37‡ (ins. 38)	38 (ins. 38)	149	-
Age (years)	57.6±13.3	56.0±10.4	59.2±12.3	57.6±12.3	0.5*
BMI (kg/m^2)	26.4±3.8	27.9±4.7	27.7±4.9	27.1±4.4	0.2*
Parity	2.1±1.0	2.6±1.5	2.4±1.1	2.3±1.2	0.2*
MUCP (cmH_2O)	51.8±26.4	49.6±25.6	52.4±25.9	51.4±25.9	0.7*
Qmax (ml/s)	29.6±12.0	30.0±12.0	27.4±14.1	29.2±12.5	0.5*
PVR (ml)	19.1±20.0	16.3±19.7	16.2±23.0	17.6±20.7	0.4*
OAB dry/wet	22/6	8/2	11/3	41/11	0.8**
Sexually active#	52	32	22	106	0.04**
S/p hysterectomy	22	14	10	46	0.6**
S/p colporrh. ant.	6	5	6	17	0.5**
S/p colporrh. post.	4	4	4	12	0.5**
QoL (KHQ)	10 domains	10 domains	10 domains	10 domains;	n.s.*
VAS	7.5	7.8	7.0	7.5	0.3*

Table 1: Preoperative characteristics according to randomization. Data are expressed as mean±standard deviation, or number of patients.
Ins., inserted tape; BMI, body mass index; n.s., non significant.
‡1 switch-over to TOT after futile attempt to insert a TVT (bladder perforation).
#None of the sexually active patients reported preoperative pain related sexual dysfunction (PrSD). The TVT-O group in this sample is sexually less active.

*Kruskal-Wallis test. **Fisher's exact test.

	N	*TVT*	*TOT*	*TVT-O*	*Total*	*P*
Obj. continence (yes/no) (% continent)	87	37/3 (92.5%)	21/0 (100%)	23/3 (88.5%)	81/6 (93.1%)	0.4**
Voiding pattern[#] (normal/changed) (% normal)	90	36/7 (83.7%)	19/2 (90.5%)	21/5 (80.8%)	76/14 (84.4%)	0.6**
PVR (ml)	90	17.6±30.2	11.5±18.7	14.1±21.0	15.2±25.3	0.6*
Qmax (ml/s)	75	19.7±8.1	22.7±8.8	22.0±6.8	21.0±7.9	0.4*
Midtape position (%)[¶]	88	52.2±7.1	52.0±9.2	49.4±11.9	51.4±9.2	0.4*
Tape distance to urethra (mm)	87	3.0±1.4	2.8±1.1	2.8±1.4	2.9±1.3	0.8*

Table 2: Postoperative clinical and urodynamic findings at follow-up (12 months). N = 90. Data are expressed as mean±standard deviation, or number of patients (%).
*Kruskal-Wallis test. **Fisher's exact test.
[#]Any obstructive symptoms like straining, postural changes, slow stream, or hesitancy.
[¶]0% = at meatus internus, 100% = at meatus externus

Interpretation of results

Except for TVT-O, all tapes reduce Qmax significantly. In our sample TOs are not significantly less obstructive than TVT. TVT, TOT and TVT-O achieve equivalent short-term continence of at least 88% and re-establish QoL. TVTs cause more perioperative complications like haemorrhage or bladder injuries, requiring manageable (immediate) correction, while TOs, in particular TOT, lead rather to mid-term complications like tape erosion, thigh pain or pain related sexual dysfunction, which may impair QoL.

Concluding message

As all slings restore continence effectively and improve QoL, the issue of complication pattern must be emphasised. We inform our patients particularly about the risk of de-novo pain or pain related sexual dysfunction as well as tape erosion after TOs.

References

1. Scand J Urol Nephrol (1995) vol. 29 (1) pp. 75-82
2. Prog Urol (2001) vol. 11 (6) pp. 1306-13
3. Eur Urol (2003) vol. 44 (6) pp. 724-30

Specify source of funding or grant	**none**
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, no. NCT00642109**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Spez. Unterkommission Gynäkologie, Geburtshilfe & Urologie USZ (SPUK)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**