

TENSION FREE VAGINAL TAPE VS TRANS OBTURATOR TAPE AS SURGERY FOR STRESS URINARY INCONTINENCE: RESULTS OF A MULTICENTRE RANDOMISED TRIAL.

Hypothesis / aims of study

This prospective, multicentre, randomised study compared outcomes after two mini-invasive techniques: the Tension Free Vaginal Tape (TVT) and the Trans Obturator Tape (TOT) in patients with stress urinary incontinence (SUI). Intra-operative, early and late post-operative complications, effects on urinary incontinence and onset of ex novo micturitional disturbances were analysed.

Study design, materials and methods

Between April 2002 and January 2005, 116 consecutive women with SUI were randomised to TVT (55) or to TOT (61). Inclusion criteria: stress or mixed urinary incontinence, urethral hypermobility, positive Bonney test. Exclusion criteria: > grade II prolapse in any vaginal compartment. Standard operative techniques were respectively, the Ulmsten and Delorme techniques (1,2). The pre-operative work-up included a detailed case history, the urogenital distress inventory (UDI-6) and the impact incontinence quality of life (IIQ-7) questionnaires, a clinical, neurological and urogynaecological examination (prolapse classification according to the Half-Way system), 1-hour pad test, pelvic statics ultrasound, conventional urodynamic study. Parameters for data analysis included: type of anaesthesia, operating time, intra-operative complications, hospital stay, time to recovery of spontaneous micturition, subjective and objective changes in urinary incontinence, ex novo lower urinary tract dysfunctions, early and late post-operative complications. Subjective assessment, based on case history and questionnaire scores, classified results as dry, improved, failed. Patients were asked to measure satisfaction with surgery on a scale of 1-10. Objective assessment, based on clinical examination and stress test, classified patients as dry or not. Follow-up included clinical check-ups every 3 months, symptoms questionnaires and free flowmetry, with post micturitional residue evaluation. The Mann-Whitney, Wilcoxon, Chi square and McNemar tests were used for the statistical analysis.

Results

Table I shows clinical and demographic details of patients grouped according to surgical technique. No intergroup differences emerged pre-operatively.

Table I	TOT (61)	TVT (55)	p value
Age (yr) (mean \pm SD)	61.6 \pm 10	61.1 \pm 11.1	N.S.
Parity (median, range)	2 (0-6)	2 (0-5)	N.S.
Body Mass Index (Kg/m ²) (median, range)	25.3 (19.5-34.3)	27.9(21.4-34.5)	N.S.
Menopause (n)	54	49	N.S.
Previous Hysterectomy (n)	29	22	N.S.
Previous continence surgery (n) (ACT, MMK, Burch, Four corner)	8	2	N.S.
Mean duration of incontinence (months) (mean \pm SD)	34.9 \pm 38.2	30.1 \pm 19.4	N.S.
Stress incontinence (n)	36	36	N.S.
Mixed incontinence	25	19	
Incontinence grade sec. Ingelman Sundenberg (n):			N.S.
G1	7	3	
G2	47	42	
G3	7	10	
Pad test	60 \pm 87	47 \pm 46	N.S.
Sexual intercourse dyspareunia	22 14	27 5	N.S.

Table II shows intra- and post-operative data.

Table II	TOT (61)	TVT (55)	P value
Follow-up (months)*	24.3 (12-44)	24.2 (12-46)	N.S.
Operating time (minutes)*	23.1(15-60)	31.2(20-60)	< 0.001
Recovery to normal micturition (days)*	1.3 (1-4)	1.5 (1-7)	N.S.
Hospital stay (days)*	1.5 (1-6)	1.9 (1-8)	N.S.
Intra-operative complications (n):			N.S.
• Bladder injury	1	2	
Early complications (n):			
• Fever	3	0	
• Retropubic hematoma	0	1	
• Transient voiding dysfunction	2	2	
• Transient urinary retention	1	0	

Late complications (n):			
• Vaginal erosion	2	0	
• Voiding dysfunction	3	3	
• Wound discomfort	1	2	
• Foreign body granuloma	0	1**	
• Paraincisional hernia	0	1	

* (mean and range) ** removal of sovrapubic mesh edges

In the TOT group, 2 needed self-catheterism for 7 and 10 days respectively. Vaginal erosion occurred in 2 patients, mesh had to be removed in both cases after conservative treatment failed. Subjectively, 47/61 (77%) patients were dry and 11/61 (18%) improved and 3/61(4.9%) dissatisfied. Objectively TOT was successful in 59/61 (97.%). Urgency improved in 5/29 (17%), disappeared in 16/29 (55%), persisted in 8/29 (27.5%) .Ex novo urgency and voiding symptoms developed in 2 (6%) and 4 (7.8%) patients respectively. Mean satisfaction rate was 8.03 (range: 1-10), 54/61 (88.5%) pts are satisfied .

In the TVT group two required self-catheterism for significant post-void residue; suprapubic catheter was inserted in 1 for 20 days because of inability to perform self-catheterism. Subjectively, 38/55 (69%) were dry, 11/55 (20%) improved and 6/55 (11%) dissatisfied. Objectively, 52/55 (94.5%) were dry. Urgency improved in 12/27 (44.4%), worsened in 2/27 (7%) and remained unchanged in 13/27 (48%). Ex novo urgency and voiding symptoms developed respectively in 3 (10,7%) and 4 (8.5%) patients. Mean satisfaction rate was 7.91 (range:1-10), 47/54 (87%) pts are satisfied.

Interpretation of results

TOT appear as efficient as TVT in surgery for female SUI, with minimal complications at mean follow-up of 24 months. Post operative voiding symptoms are not different in the two groups. Outcome after TVT seems slightly worse in patients with mixed incontinence. Urgency remains a post-operative problem especially in the TVT group.

Concluding message

TVT and TOT were effective in the treatment of female SUI but further studies are needed to establish long-term efficacy and safety of both procedures.

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HUMAN SUBJECTS: This study was approved by the Regional Ethic Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.