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A TWO YEAR STUDY ON THE OUTCOME OF THE TENSION-FREE VAGINAL TAPE PROCEDURE : CLINICAL AND FUNCTIONAL EVALUATION

Hypothesis / aims of study

The aim of our work was to evaluate the impact of correction of stress urinary incontinence (SUI) and mixed urinary incontinence using the Tension-free Vaginal Tape (TVT) procedure on both clinical and functional parameters (pelvic floor anatomy, urinary symptoms, constipation, dyspareunia and urodynamic parameters).

Study design, materials and methods

Between June 1994 and November 2003, 164 female patient with stress and mixed urinary incontinence were enrolled in this study. The pre- and post-operative work up included: history (age, parity, menopausal status, previous continence or prolapse surgery), clinical examination with vaginal profile evaluation using the Baden Walker Half Way System, Q-tip test for urethral hypermobility, conventional urodynamic studies and administration of questionnaires (Wexner Score and sexuality). All the patients underwent the TVT procedure.

The results were analyzed using two statistical tests : the T-Test for paired data and the McNemar Chi Square test. We considered p values <0.05 as statistically significant.

Results

Mean age of the sample was 55.8 years (range 36-72); 118 were post-menopausal (71.9%); median parity was 2 (range 0-4). During the surgery there were no major complications; the only minor complication was bladder perforation which occurred in 22 patients (13.4%). The patients were evaluated for a period ranging from 6 to 73 months (mean 21 months). 142 patients (87%) were objectively cured after the procedure. There was a statistically significant reduction of storage symptoms - daytime frequency, nocturia, urgency (67% vs 34% ; $p<0.005$). There was no significant increase in voiding or post micturition symptoms. De novo frequency was reported by 7.3%, de novo urgency 12.3%, and de novo urge incontinence by 3.7% of the sample. There was no impact on constipation (20% vs 13% ; $p=0.33$) and no significant effects on dyspareunia (22% vs 12%; $p=0.13$) were observed. Anatomically, we noted a statistically significant reduction of urethrocele ($p<0.005$) while other aspects of pelvic floor anatomy were not altered ($p=0.68$). We also observed a reduction of urethral mobility measured using the Q-Tip test ($p<0.005$). No vaginal erosions appeared. Functional results showed no significant variations in urodynamic parameters. (Table 1). In particular the analysis of pressure/flow study values based on the Blaivas and Groutz nomogram for urinary obstruction did not demonstrate a statistically significant difference between pre-and post operative values (T-Test; $p= 0.18$). 2 patients underwent incision or partial removal of the tape for persistent urinary retention.

Interpretation of results

This study demonstrates the following characteristics of the TVT procedure: it is an effective treatment for stress urinary incontinence; there is statistically significant postoperative reduction of storage symptoms; there is no increase in constipation or dyspareunia; other than correction of urethrocele, pelvic floor anatomy remains unchanged. The most important information that we obtained is

that the TVT procedure achieves continence without any negative effect on voiding dynamics parameters.

Concluding message

As well as confirming the excellent cure rate for incontinence, this study demonstrates that a significant proportion of women undergoing the TVT procedure can expect an improvement in storage symptoms without an increase in voiding symptoms. This clinical finding is confirmed by the postoperative urodynamic data.

References

1. Bladder outlet obstruction nomogram for women with lower urinary tract symptomatology. Neurourol Urodyn 2000; 19: 553.

Table1- **Pre and post-op. urodymanic findings**

	Pre-op	**Post-op**	**P**
Mean maximun cystometric capacity (ml)	415.90	412.05	0.72
Mean first sensation of bladder filling (ml)	147.42	162.28	0.29
Mean pressure at maximum flow (cmH2O)	22.43	24.40	0.29
Mean maximum flow rate (ml/sec)	21.43	18.91	0.19
Detrusor overactivity	24%	27%	0.02
"de novo" detrusor overactivity		8.6%	
Reduced Compliance	2.4%	3.7%	0.12