

MULTICENTER RANDOMIZED TRIAL OF TVT AND IVS FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

Aims of Study

To compare the efficacy and morbidity of two mini-invasive procedures, Tension-free Vaginal Tape and IntraVaginal Slingplasty for the treatment of stress urinary incontinence in women with urethral hypermobility.

Methods

The study design was a prospective randomized multicenter trial involving four Italian hospitals. Two-hundred patients with urodynamic proven stress urinary incontinence and urethral hypermobility were randomised to treatments according to a centralized computer-generated random list. Patients enrolment began in January 2002 and had to be completed at the end of December 2002. Follow-up visits were scheduled after 3, 6, 12, 24 months from surgery.

Exclusion criteria from the study were: age >75 years, previous anti-incontinence surgery, point Ba > -1, point C and Ap, Bp > than stage I, any coexistent pelvic pathology, urethral hypomobility (Δ Q-tip $\leq 20^\circ$) and obesity (BMI > 30). The pre- and postoperative protocol included the following: a detailed urogynecologic history, grading the severity of stress incontinence by means of the Ingelman-Sundberg symptoms score, a physical examination, with the patient recumbent and straining down, to identify the presence of pelvic floor defects according to the POP-Q system classification, a cotton swab test to assess the mobility of the urethra, a 1-hour pad test, a stress test in the supine and standing positions with a comfortably filled bladder (300 ml) and a multichannel urodynamic evaluation including uroflowmetry, provocative cystometry and urethral profilometry.

The post-operative evaluation also included the collection of data regarding time required for surgery, type of anesthesia, intra and postoperative complications, time to resumption of spontaneous voiding, length of hospital stay and analysis of outcomes. The outcome of surgical treatment was estimated both subjectively and objectively. All patients were informed about the study and procedure and gave their informed consent.

The Statistical Package for Social Sciences was used for data analysis. Continuous data were reported as means + standard deviation (SD) and analysed with Student's t test. Categorical relationships were analysed by the χ^2 test with Yates' correction or Fisher exact test, as appropriate.

Results

From January 2002 and December 2002, 164 patients with stress urinary incontinence and urethral hypermobility were enrolled in the study. After random assignment 92 patients underwent the TVT procedure and 72 the IVS procedure. Patients had mean age of 56 ± 9 years, BMI 25 ± 3 , and parity 1.08 ± 1 . All complained of stress urinary incontinence with 55 (34%) and 20 (12%) women also reporting symptoms of urgency and urge incontinence. The mean Q-tip value was $44^\circ \pm 15^\circ$ and the mean weight of pad test was 32 ± 16 g. Most of women (65%) were operated on under local anesthesia and the mean time required for surgery was 27 ± 6 min. There were no significant differences between the two groups with respect to any of these data and no differences were seen in urodynamic parameters.

Intraoperative complications included 6 bladder perforations (3.6%) and the development of 4 retroperitoneal hematomas (2.4%) that resolved spontaneously in 3 out of four patients. Postoperative data were analysed only for women with at least 6 months of follow up. Thus 141 patients were considered: 77 in the TVT group and 64 in the IVS group. Subjectively 69 (90%) of women in the TVT group were cured compared with 54 (84%) in the IVS group ($p = 0.91$). Objectively cure of stress incontinence was observed in 67 out of 77 (87%) and 50 out of 64 (78%) patients respectively ($p = 0.76$). The mean weight of pad-test in the TVT and IVS group was 0.9 ± 4.4 g. and 1.4 ± 4.4 g. respectively ($p = 0.53$). Symptoms of

urgency and urge incontinence were reported by 12% and 9% of the women in the TVT group and by 25% and 11% in the IVS group ($p = 0.13$). Resumption of spontaneous voiding was observed after a mean of 1.6 ± 1.7 days in the TVT group and 1.1 ± 0.4 days in the IVS group ($p = 0.02$) and 12% and 3% of the women respectively complained of voiding difficulties at follow-up visits. Finally in 4 patients (6%) who underwent the IVS procedure a defect healing of the vaginal wound occurred that had to be trimmed.

Conclusions

TVT and IVS are two different mini-invasive techniques sharing the objective to support the urethra in a tension-free manner. The main difference between them is the framework of the prolene tape (monofilament vs multifilament) that could be responsible of different effects on urinary tract function.

Our data show that both the procedures are effective for the treatment of stress incontinence in women with urethral hypermobility, even if, in the long run, the objective cure rate of TVT seems to be higher. Resumption of spontaneous voiding without significant residuals, on the contrary, seems to be delayed in women undergoing TVT when compared with IVS. Moreover we must take in account that 6% of women undergoing IVS showed a vaginal foreign body tissue reaction that needed to be trimmed.