

MULTICENTER RANDOMIZED TRIAL OF TENSION-FREE VAGINAL TAPE (TVT) AND INTRAVAGINAL SLINGPLASTY (IVS) FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

Hypothesis / aims of study

To compare the efficacy and morbidity of two mini-invasive procedure, TVT and IVS for the treatment of stress urinary incontinence in women with urethral hypermobility.

Study design, materials and methods

The study design was a prospective randomized multicenter trial involving four Italian hospitals. Patients with urodynamic proven stress urinary incontinence and urethral hypermobility were randomised to treatments according to a centralized computer-generated random list. On the assumption of 90% cure rate after TVT [1] it was calculated that 190 patients would be required (95 in each arm) to detect a clinically significant difference of 15% in cure rate between procedures with 80% power and an α level of 0,05. 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 primary outcome measure was rate of success for both the procedures. The secondary outcome measure was rate of complications observed. The postoperative evaluation 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 \pm 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. Probability values of < 0.05 were considered statistically significant.

Results

From January 2002 and December 2002, 179 patients with stress urinary incontinence and urethral hypermobility were enrolled in the study. After random assignment 92 patients underwent the TVT procedure and 87 the IVS procedure. Patients had mean age of 56 ± 10 years, BMI 26 ± 3 , and parity 1.7 ± 1 . All complained of stress urinary incontinence with 62 (35%) and 24 (13%) women also reporting symptoms of urgency and urge incontinence. The mean Q-tip value was $43^\circ \pm 14^\circ$ and the mean weight of pad test was 33 ± 23 g. Most of women (64%) were operated on under local anesthesia and the mean time required for surgery was 27 ± 7 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 (3.3%) and the development of 4 retropubic hematomas (2.2%) that resolved spontaneously in 3 out of four patients. Resumption of spontaneous voiding was delayed in patients undergoing TVT when compared with those who received IVS (1.6 ± 1.7 days vs 0.9 ± 0.4 , $p = 0.02$)

The median follow-up time for each group was 22 and 23 months respectively. Subjectively 80 (87%) of women in the TVT group were cured compared with 68 (78%) in the IVS group ($p = 0.71$). Objectively cure of stress incontinence was observed in 79 (86%) and 65 (75%) patients respectively ($p = 0.62$). Postoperative complications included: voiding difficulties in 12 and 9 women respectively, recurrent UTI in 11 and 14 subjects and vaginal erosions in 8 (9%) of the patients who underwent IVS procedure ($p = 0.013$), of whom 6 required surgical removal of the tape.

Interpretation of results

TVT and IVS are two different mini-invasive techniques sharing the objective to support the mid-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 urinary incontinence. Resumption of spontaneous voiding without significant residuals was delayed in women undergoing TVT when compared with IVS, however we must take in account that 9% of women undergoing IVS showed vaginal erosions that required in most of them the surgical removal of the tape.

Concluding message

TVT and IVS are equally effective in the treatment of stress urinary incontinence

References:

1.Meschia et al. Tension-free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. Int Urogynecol J 2001(Suppl.2):S24-S27