

ARE THERE PREDICTING FACTORS FOR EFFICACY AND SAFETY WITH COMBINED PELVIC ORGAN PROLAPSE REPAIR AND TENSION FREE VAGINAL TAPE?

Hypothesis / aims of study

Tension Free Vaginal Tape (TVT) has been proven to be effective in the treatment of urodynamic stress incontinence (USI) with a reported TVT continence rates at two years that vary between 66% (1) and 86% (2) but the predictors of failure are unclear.

In addition majority of women with urinary incontinence present with variable degree and type of pelvic organ prolapse. With this study we aimed to analyse the existence of possible predicting factors for safety and efficacy of TVT placement in conjunction with vaginal prolapse surgery for restoration of normal pelvic anatomy in women with urodynamic stress incontinence and concomitant pelvic organ prolapse.

Study design, materials and methods

This study was designed as a prospective, open, nonrandomized study. A standardized protocol was applied for pre- and postoperative evaluation. The protocol included medical history, physical examination, urodynamic evaluation (including filling cystometry, uroflowmetry and urethral pressure profilometry), ICS grading for prolapse and quality of life assessment. Follow-ups were performed after 2, 6, 12 and 24 months.

From November 1999 until December 2001 102 women with urodynamic stress incontinence underwent TVT procedure. Complete data are available for 68 women. Of these 44 (64.6%) presented with combined pelvic organ prolapse of various degree and type. Twenty four (24) women had uterine prolapse, 32 cystocele and 20 rectocele. Twenty four (n=24, 35.2%) women underwent vaginal hysterectomy with high uterosacral ligaments suspension and anterior / posterior repair. Twenty (n=20, 29.4%) women had anterior and / or posterior repair. In all women TVT tape was placed. All procedures started with the introduction of the TVT device without removing the plastic sheath. Tape adjustment was performed at the end of the procedure after all pelvic organ support defects were reconstructed.

Results

Mean follow- up period was 15.8 months (range 6-30 months). Mean age was 63±11 (range 38-86) and parity 3.5±2 (range 1-10). Seven (n=7, 10.3%) women had prior continence surgery and 18 (26.5%) had past history of a major gynaecologic surgery (Total Abdominal Hysterectomy, Vaginal Hysterectomy). Indications for performing the TVT procedure were USI in 61 (89.6%) women, mixed incontinence in 7 (10.4%). Sixty three (n=63, 92.6%) fulfilled the criteria of complete cure, four (n=4, 5.9%) women were considered to have improvement and one (n=1, 1.5%) experienced failure. Mean hospitalization time was 2.5days (SD 2.3) for TVT only and 3.4 days (SD 2.6) for those who underwent a concomitant prolapse surgery (Student t-test: p<.001). Only minor complications were observed [bladder penetration – 7.4% (n=5), transient incomplete emptying – 4.4 % (n=3), De novo overactive bladder – 1.5% (n=1) and need for catheterization for more than 24 hours in 17.6% (n=12)]. These complications did not adversely affect our cure rates. The incidence of postoperative complications among women aged >70 years was found to be significantly higher than among women aged <70 years. (Chi-square test: $\chi^2=4.7$, p=.03). Fewer complications were observed among those women who underwent TVT only in comparison to those with a combined prolapse surgery (Chi-square test: $\chi^2=5.2$, p=.028). Need for catheterization for more than 24 hours occurred mainly in those who had a combined prolapse surgery and TVT.

Interpretation of results

In view of the high success rates for USI (92.6%) we could not disclose any statistically significant predicting factors for efficacy. Age above 70 years and a combined prolapse surgery with TVT procedure increase the minor complication rate but do not adversely affect the medium term results.

Concluding message

The TVT procedure is also effective and safe when combined with other surgical reconstructive procedures for the correction of pelvic organ prolapse and urodynamic stress incontinence.

References

1. BMJ 2002.325(2355): 67
2. BJOG 1999. 106(4): 345-350