

A PROSPECTIVE RANDOMISED CONTROLLED STUDY COMPARING VAGINAL PROLAPSE REPAIR WITH AND WITHOUT TENSIONFREE VAGINAL TAPE (TVT) IN WOMEN WITH SEVERE PELVIC ORGAN PROLAPSE AND OCCULT STRESS INCONTINENCE.

Hypothesis / aims of study

To compare the use of TVT™ retropubic sling or not in the treatment of occult urinary stress incontinence (OSI) at the time of prolapse repair.

Study design, materials and methods

A prospective, randomized controlled trial was conducted of women with OSI defined as symptomatically continent women with urodynamically demonstrable stress incontinence with (or without) reduction of prolapse (> Stage 2 on POPQ examination). Ethics committee approval at the Mercy Hospital for Women and Monash Medical Centre was obtained, the rules in the declaration of Helsinki were followed and informed consent was obtained prior to entry in the study. The pre- and 6 month post-operative protocol included: complete urogynaecological history, physical examination, multi channel urodynamics testing, 1-hour pad test and a three day bladder diary. The UDI 6 SF, IIQ7 SF, PISQ and visual analogue score (VAS) were used for subjective assessment of quality of life (QOL) and treatment success. The type of surgery performed was determined by the site of the prolapse and its most appropriate route of correction. The primary endpoint assessment was the need for subsequent anti incontinence surgery. Follow-up was at 6 weeks and 6 months.

Results

From Feb 2004 to Feb 2007 sixty nine women were eligible to participate and 52 were enrolled with randomization of 27 to no sling and 25 to TVT sling procedure which was performed concurrently with the prolapse repair. No differences in demographic or clinical characteristics of either group were detected. Type of surgery was similar in no TVT and TVT group. Especially anterior vaginal colporrhaphy (standard midline fascial repair without bladder neck placation) (5 vs 3) and anterior and posterior repair (12 vs 14) were the same in both groups. Primary endpoint assessment was the clinical need for stress incontinence surgery postoperatively. There was one (1) TVT sling inserted after 6 months following prolapse surgery in the group of women with prolapse surgery and no sling procedure and none in the prolapse and TVT group. Postoperative urodynamic study demonstrated urodynamic stress incontinence (USI) at 6 months in nine (9) of the non TVT and one (1) in the TVT group ($p = 0.002$) and only one of these women had clinically significant stress incontinence requiring further surgery. The 1 hour pad weigh data showed no difference in the median score between the two groups at 6 months. Subjective assessment with VAS at 6 months follow-up (cure = VAS > 80) showed median of 90 in TVT vs 95 in the non TVT group ($p=0.81$). The QOL questionnaires showed no difference between the groups at follow-up. Within both groups there was no difference in IIQ 7 SF with difference score mean of 1 [range; 0-6] and in the UDI 6 SF with a difference score mean of 0 [range; (-1) - 3]. Sexual function was assessed by PISQ and more than half of this patient group either declined to answer the PISQ or were not sexually active. In the patients with available data, the PISQ scores were not significantly different between the 2 groups.

Complications reported in the TVT / non TVT groups were: haemorrhage (defined as blood loss > 500ml) with 1 (4%) vs 2 (7.%) (however no blood transfusion was required in any patient), voiding difficulty postoperatively with urethral catheterisation in 1 (4%) vs 1 (3.7%) or intermittent clean self catheterisation in 2 (8%) vs 0 (0%) for 6 - 10 days post surgery.

Interpretation of results

In this study only one woman of 27 had clinically significant SI requiring a TVT insertion after six months in the non TVT group, despite the diagnosis of USI in eight other women in that group. 18 of the 27 women with occult USI in the no TVT group had no USI on repeat urodynamic testing following vaginal repair of the prolapse. These short-term results indicate that a clinician would have to insert 26 TVT slings unnecessarily to prevent 1 woman needing a sling postoperatively. Longterm follow up will be needed to confirm whether this trend continues. A potentially confounding factor (anterior vaginal repair) has been eliminated as the same number of anterior repairs were performed in both groups. There is a lack of correlation post operatively between the UD result and subjective results such as the symptom of stress incontinence and VAS. This might be due to the high sensitivity of the urodynamic testing demonstrating leakage at capacity of 500 ml. There is no difference in QOL and sexual satisfaction scores between the two groups. There was no significant haemorrhage attributable to the tape procedure. There was a significantly higher rate of temporary voiding difficulty in the TVT group requiring either indwelling or intermittent self catheterisation for less than 10 days. None required further surgery.

Concluding message

Our study demonstrates that based on follow up at 6 months the routine insertion of a suburethral sling where occult stress urinary incontinence has been demonstrated prior to prolapse repair can not be recommended. Longer term follow up will be performed.

FUNDING: No Funding was received

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Research Ethics Committee, Mercy Hospital for Women, Heidelberg Research Ethics Committee, Southern Health, Monash Medical Centre, Clayton and followed the Declaration of Helsinki Informed consent was obtained from the patients.