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A PROSPECTIVE RANDOMISED CONTROLLED TRIAL COMPARING VAGINAL PROLAPSE REPAIR WITH AND WITHOUT TENSIONFREE VAGINAL TAPE (TVT) IN WOMEN WITH SEVERE GENITAL PROLAPSE AND OCCULT STRESS INCONTINENCE: LONG TERM FOLLOW UP

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 vaginal prolapse repair.

Study design, materials and methods
A prospective, multicentre randomized controlled trial was conducted of women with OSI defined as symptomatically continent women with urodynamic stress incontinence (USI) with (or without) reduction of prolapse (> Stage 2 on POPQ examination). Ethics committee approval 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. Women were randomized to either prolapse surgery and TVT or prolapse surgery alone. Prolapse repair was performed according to surgeon preference. The primary endpoint assessment was the need for subsequent anti incontinence surgery. Follow up at six month has been previously reported (1) and has been continued annually thereafter. Further women were recruited to the study to allow for the participants that were deceased, lost to follow up and withdrawn.

Results
From Feb 2004 to Feb 2009 eighty (80) women were enrolled with randomization of 43 to no sling (i.e. prolapse surgery alone) and 37 to TVT and concurrent prolapse repair. No significant differences in demographic or clinical characteristics of either group were detected. The types of prolapse surgery was similar in the no TVT and TVT groups.(Table1) The median follow up [25th – 75th percentile] was 31 months [12 – 58]**.** The primary endpoint was the clinical need for stress incontinence surgery postoperatively. Four (9.3%) TVT slings were inserted in the group of women with prolapse surgery and no sling procedure; and none in the prolapse and TVT group. The time from prolapse repair to sling insertion in the group of women with prolapse surgery alone was 1.8, 7.5, 9.3 and 27 months. The difference in times of sling insertion was tested using the log-rank test for equality of survivor function, p = 0.07. Post operative complications such as haemorrhage, bladder perforation, and voiding difficulty specific to insertion of TVT at the time of prolapse repair were already presented.(1) The six month postoperative urodynamic assessment demonstrated USI in twenty one (48%) of the non TVT and three (8.1%) of the TVT group (p = 0.0001). In the non TVT group 4/ 43 women (9.3%) had bothersome objective USI requesting a TVT insertion. Seventeen of 43 women (39.5%) with USI remained asymptomatic and 12/43 (27.9%) women with occult USI in the no TVT group had no USI on repeat urodynamic testing following vaginal repair of the prolapse. The remaining 10/43 declined repeat urodynamic assessment at 6 month. The QOL questionnaires and VAS showed no significant difference between the groups at follow-up.

Interpretation of results
These results indicate that in women with occult SI and prolapse a clinician would have to insert 12 TVT slings to prevent one woman needing a sling postoperatively. A lack of correlation is noted between USI and subjective SUI as demonstrated by the 39.5% of women who remained asymptomatic postoperatively. This may be due to the high sensitivity of the urodynamic testing demonstrating leakage at capacity of 400 - 500 ml. There is no difference in QOL between the two groups demonstrated, as the number of symptomatic women requiring further surgery was small. The long term results (median follow up of 31 months) confirm the trend reported on previously at six months (1). Prolapse surgery without TVT cured occult USI at 6 month repeat testing in at least 12/43 patients**.** Furthermore 39/43 women in the non TVT group, who were asymptomatic, did not require any further surgical intervention in the long term.

Concluding message
At greater than 2 years following pelvic organ prolapse surgery, these results indicate that the routine insertion of a mid-urethral sling, TVT, in women with occult stress urinary incontinence and prolapse cannot be recommended. Women should be counselled regarding the possibility of stress urinary incontinence postoperatively. Longer term follow up will be continued.

Table 1: Type of prolapse surgery performed in each group

	No TVT (n= 43)	TVT (n= 37)
Vaginal Hysterectomy	22 (51.2 %)	11 (29.7%)
Anterior colporrhaphy	16 (37.2 %)	8 (21 %)
Posterior colporrhaphy	16 (37.2%)	10 (27 %)
Ant and post repair	15 (34.8. %)	21 (59 %)
Vaginal vault suspension	16 (37.2%)	19 (51.3 %)
Post IVS	1 (2.3%)	0 (0%)
Apogee	0 (0%)	1 (2.7%)
Abd sacrocolpopexy	1 (2.3%)	1 (2.7%)

References
1. 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 Schierlitz L, Dwyer P, Rosamilia A, Murray C, Thomas E, Taylor N, Hiscock R, Lim Y, Achtari C, De Souza A Abstract 114 ICS 2007 Rotterdam

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**This study was approved by** **Institutional Research Ethics Committee, Mercy Hopsital for Women, Heidelberg** **Institutional Research Ethics Committee, Southern Health, Monash Medical Centre,Clayton**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**