TENSION FREE VAGINAL TAPE IN THE TREATMENT OF STRESS URINARY INCONTINENCE M. Meschia, U. Gattei, P. Pifarotti, L. Spreafico, F. Magatti, F. Bernasconi. Urogynecology Unit Dept. Obstetrics and Ginecology University of Milan Milan, Italy

Aims of the study: To evaluate the safety and efficacy of tension free vaginal tape (TVT) for the surgical correction of female stress urinary incontinence. Methods: The design of the study was an open multicenter study including six Italian hospitals. Between December 1997 and November 1999, 429 stress incontinent women were enrolled in the study, a minimum of 40 patients for each participating center was requested. The pre-and post-operative protocol included: 1) a thorough history of the duration and severity of stress incontinence, 2) a stress provocation test in the supine and standing positions with a comfortably filled bladder (300ml,) 3) a gynecologic examination to identify pelvic floor defects according to the method previously described by Baden et al.[1], 4) urodynamic evaluation including uroflowmetry, water-cystometry and urethral profilometry, 5)a 10 grade visual analogue symptoms scale (VAS)to quantify incontinence inconvenient. The post-operative evaluation also included the collection of data regarding operation time, additional surgical procedures performed, intra-and postoperative complications and length of hospital stay. Post-operatively patients were assessed after 6,12 and 24 months (urodynamic tests were performed after 12 months from surgery)

Results: the mean age of the patients considered was 57 years (31-83) and 78 of them had undergone to a previous operation for the treatment of stress urinary incontinence or genital prolapse. Out of the 429 women, 371 were followed for a minimum of 6 months, 11 were lost to follow-up, and 47, at the present time, have not been followed for at least 6 months. 190 patients were operated on under local anesthesia, 213 under epidural anesthesia and 26 using the general anesthesia. 88(20%)women required an additional surgical procedure to repair coexisting pelvic floor defects. The mean operation time was 41 minutes (range 15-165) and the mean blood loss was 31ml. There were few intra or post-operative complications: in 24 patients (6%) a vesical perforation occurred; a severe bleeding that required an open laparotomy was observed in two patients, whilst no rejection of the tape or defective healing occurred. After surgery 346 women (93%) were subjectively cured and 9 patients referred to be significantly improved. The cough provocation test showed no leakages of urine in 94 % (349)

195

of the patients. Finally the evaluation with the analogue symptoms scale showed a significant decrease of the discomfort referred by the patients.

<u>Conclusions:</u> From the present study it seems justified to conclude, according to other experiences [2] that tension free vaginal tape can be considered a safe and effective procedure for the surgical treatment of stress urinary incontinence; moreover it can be easily performed in addition to other surgical procedures in patients with associated pelvic floor defects. A longer follow-up is needed to verify the long-lasting effectiveness of this technique but data, recently published by Ulmsten and co-workers [3], encourage the use of this procedure as the first choice treatment for urinary stress incontinence. <u>References:</u>

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