

SUI and TVT-Secur system: final results of a prospective, observational, multicentre study. V. Napolitano+, F. Bernasconi , , D. Lijoi *, E. Leone° , F. Armitano # , M. Luerti^, , G.C. Sugliano §, D. Vitobello ð, D. Rivaø D. Gregori ç, *M. Primicerio*+. Departments of Obstetrics and Gynaecology Hospitals: Tivoli+, Desio, Imperia *, M. Melloni (MI)°, Erba #, Lodi ^, Sanremo §, Abano Termeð, Cantùø Department of Environmental Medicine and Public Health , University of Padova ç

ABSTRACT

The aim of this study was to assess the long-term effectiveness and the perioperative morbidity, of TVT-Secur system (Ethicon, Sommerville, NJ, USA) used for the treatment of the Stress Urinary Incontinence (SUI). The final results of an observational, multicenter, prospective study regarding the use of the TVT-Secur for the treatment of SUI, (urodynamic and/or potential) associated with defects of the pelvic floor, over an average follow-up of 19 months, are shown. Initially, nine Italian Urogynecological centres participated in the study. The final results refer to cases treated in seven centres, as two interrupted the follow-up twelve months after the beginning of the study. Data were collected over the period from 1st March to 31st December 2007, from 147 female patients suffering from Urodynamic SUI and/or potential stress incontinence. In 64.6% (95/147) of the patients presenting Urodynamic SUI with urethral hyper mobility and cystocele of $\leq 2^\circ$ according to the POP-Q, TVT-S was used only (Group A); in 52 patients, the TVT-Secur procedure was used in a SUI associated with complex genital prolapse (Group B). The transobturator approach was chosen in the 74.8% of the cases (110/147), while in the 25.2% the retropubic approach was adopted. All centres used the same software for collecting data, as required for the recruitment of the patients and their admission to the trial protocol. Data were taken at 0, 6, 12 and >12 months after the operation. Statistical analysis was carried out on complete data collected from centres. Two criteria were used (one objective and one subjective) for the evaluation of the symptoms, in order to assess the success percentage of the treatment: the stress test sec Ferrari, and VAS with the Patient Global Impression of Improvement Questionnaire (PGI-I) respectively. In order to detect the symptoms related to overactive bladder, a micturition diary and the W-IPSS (Women Irritative Prostate Symptoms Score) questionnaire were used. In 64.6% (95/147) of the patients presenting urethral hyper mobility and cystocele of $\leq 2^\circ$ according to the POP-Q, only the Urodynamic SUI was treated (Group A); in 52 patients, the TVT-Secur procedure was used in a SUI associated with complex genital prolaxus (Group B). At the end of the study, data were collected from the 92.5% of the patients (136/147) after 6 months, from the 89.1% (131/147) after 12 months, and from the 83.6% (123/147) after a follow-up period longer than >12 months (average value of 19.3 +/- 6.4 months). In the short-term follow-up (12 months), the success percentage of this technique was 87.5% (119/136) in the total population, 85.3% in Group A (81/95) and 90.3% (37/41) in Group B respectively. In the long-term follow-up (longer than 19 months) the observed percentages were 89.4% (110/123), 88.5% (77/87) and 91.7% (33/36) respectively. The intraoperative complications were: two cases of accidental removal and replacement of the sling, one case of deep vaginal laceration, five patients with blood leakage greater than 200ml. Concerning postoperative morbidity, the following situations occurred: one case of hematoma, one case of pain at the implant site, eight patients (5 of Group B) reported voiding difficulties, with a post-void residual greater than 100ml. The following complications were observed in the long-term period: six reinterventions were necessary, due to recurrent SUI and two erosions of the sling. Clearly inferior appeared to be the probabilities to develop, *de novo* irritation symptoms, even in the long-term, and the presence of improvement percentages regarding cases of hyperactive bladder in the whole sample slightly lower than 50%. The results show the TVT-Secur efficacy, comparable to that of traditional mid-urethral transobturator / retropubic slings with the advantage of less traumatic and faster approach

Keywords: SUI, Tension free vaginal tape, Stress Test, polypropilene implant, mini-sling.