487

Meschia M[1], Barbacini P[2], Pifarotti P[3], Ambrogi V[4], Ricci L[5], Spreafico L[6]
1. *Dept. Obstetrics and Gynecology, Magenta. Italy,* ***2.*** *Dept. Obstetrics and Gynecology, Magenta. Italy,* ***3.*** *Dept. Obstetrics and Gynecology, IRRCS Fondazione Policlinico Mangiagalli e Regina Elena, Milano. Italy,* ***4.*** *Dept. Obstetrics and Gynecology, Anzio. Italy,* ***5.*** *Dept. Obstetrics and Gynecology, Montecchio Emilia. Italy,* ***6.*** *Dept. Obstetrics and Gynecology, Montecchio Emilia. Italy*

TVT SECUR: A MINIMALLY INVASIVE PROCEDURE FOR THE TREATMENT OF PRIMARY STRESS URINARY INCONTINENCE. ONE YEAR DATA FROM A MULTICENTER PROSPECTIVE TRIAL.

Hypothesis / aims of study
To evaluate the efficacy and morbidity of the new minimally invasive TVT-secur procedure in the treatment of primary stress urinary incontinence**.**

Study design, materials and methods
The study design was a prospective multicenter trial involving four different hospitals. All patients with primary urodynamic stress urinary incontinence (SUI) and urethral hypermobility were prospectively selected to receive the TVT-s procedure. Each center was allowed to perform the procedure either in the "hammock" or "U" shape approach. Exclusion criteria from the study were: previous anti-incontinence surgery, pelvic organ prolapse requiring treatment, any coexistent pelvic pathology, urethral hypomobility (Δ Q-tip $\leq$ 20°) and detrusor overactivity. The pre- and postoperative protocol included the following: a detailed urogynecologic history, a physical examination, a cotton swab test, a stress test in the supine and standing positions with a comfortably filled bladder (300 ml) and a multichannel urodynamic evaluation. The ICI-SF, W-IPSS, PGI-S questionnaires were used to evaluate the impact of incontinence and voiding dysfunction on QoL and to measure patient's perception of incontinence severity.
The post-operative evaluation included collection of data regarding intra- and postoperative complications and analysis of outcomes. The outcome of surgical treatment was estimated both subjectively and objectively using the same tools as before surgery and the PGI-I questionnaire was added to assess the subjective perception of improvement . Objective cure was defined as no leakage of urine while coughing during the post-operative stress test. Subjective cure was defined as no urine loss during exertion and failure as any reported leakage of urine during 'stress'. All patients were informed about the study and procedure and gave their informed consent. Follow-up visits were scheduled after 3, 6, and 12, months from surgery.
The Statistical Package fo Social Sciences was used for data analysis. Continuos data were reported as means $\pm$ standard deviation (SD)and analysed with Student's t test. Categoric relationship were analysed by the χ^2 test with Yates' correction or Fisher exact test, as appropriate. Probability values of < 0.05 were considered statiscally significant.

Results
From November 2006 and September 2007, 95 consecutive patients with primary stress urinary incontinence and urethral hypermobility were enrolled in the study. After enrolment 55 patients received the procedure with insertion of the tape in the "hammock" shape and 40 subjects in the "U" shape". There were no differences between these two groups with respect to pre-operative demographic and clinical characteristics, total score in the different questionnaires used, and urodynamic parameters.
Most (68%) of the procedures were performed under general anaesthesia and cystoscopy was performed in all the patients who underwent the procedure in the "U" shape approach while only 14 out of 55 patiens (25%) in the "hammock" shape group underwent cystoscopy. The intra-operative cough stress test was performed in only 6 patients. No bladder perforation occurred. There was an excessive bleeding, greater than 500 ml. in 2 patients both receiving the "hammock" shape approach and some difficulties with the detachment of the device were reported in two subjects. Four women (4.2%) had voiding difficulty that resolved spontaneously within the first five days from surgery and no one had urinary retention. The average hospital stay was 1.4 $\pm$ 0.9 days and post-operative pain was reported by only one women.
The mean follow-up time was 9 $\pm$ 3.1months (median 12). Ninety one patients were available for the analysis. Subjectively 71 (78%) women were cured by the procedure and objectively the cough stress test was negative in 74 (81%) patients.
The ICI-SF questionnare symptoms score showed an higly statistical decrease from a mean of 15 $\pm$ 3.8 before surgery to a mean of 4,4 $\pm$ 5.7 at the last follow-up visit forwarded (p=0.000), the W-IPSS decreased from 7.7 $\pm$ 6.6 to 5.1 $\pm$ 4.6 (p=0.002). Most of the women were satisfied of their post-operative condition with a mean score of 0.8 $\pm$ 1.1at the PGI-I questionnaire (scale 0-5). Postoperative complications included: voiding difficulty in 7 women (8%), recurrent UTI in 9 (10%) and dyspareunia for a defect healing, with vaginal protrusion of the mesh, in two patients. Eight out of 20 failures received a new surgery for stress incontinence within the first year of follow-up, four women were treated with duloxetin and two patients underwent pelvic floor muscle training. Seven women with distressing OAB symptoms were given a trial with antimuscarinic drugs.

Interpretation of results
Our data show that the TVT-s procedure is effective for the treatment of primary stress urinary incontinence with 78% and 81% subjective and objective cure rates associated with an highly significant improvement in incontinence related QoL. Nevertheless a comparison with our own previously published data on TVT and TVT-O, shows that TVT secur is associated, at the same follow-up time, with a 10% less success rate.

Concluding message
TVT-secur can be considered as primary treatment for women with stress urinary incontinence

References
Int Urogyn J 2007; 18:1257-61

Specify source of funding or grant	**No grant or funding**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**

Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Azienda Ospedaliera Ospedale Civile di Legnano. Italy**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**