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SINGLE INCISION TENSION-FREE VAGINAL TAPE (TVT-SECUR®) IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

TVT procedures (both retropubic and transobturator) have become the gold standard in the treatment of female stress urinary incontinence (SUI) (1,2). These procedure, even being mini-invasive, have intra-operative and post-operative complications that can be serious (1,2). In particular, retropubic TVT may cause vessel and organ injuries, while the most common complications following transobturator TVT are groin/thigh pain and urinary retention. To overcome these problems, a number of single incision devices that avoid retropubic or transobturator passages, have been marketed, TVT-Secur being the first (3). Aim of this study was to evaluate the efficacy and safety of this single incision device in the treatment of female SUI).

Study design, materials and methods

In this retrospective study, we analyzed the data of 68 patients treated with TVT-Secur for SUI and urethral hypermobility in the last two years. The approval of the Ethical Committe was not requested being a retrospective study. All patients signed the informed consent to the surgical procedure. All patients underwent a preoperative clinical examination with PoP-Q scoring, urodynamic tests and post-voidal residue (PVR) evaluation. Patients also completed the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF). TVT-Secur was performed under spinal anesthesia according the technique reported by Neuman (3). Duration of the procedure, a subjective estimate of blood loss performed by the surgeon, intraoperative and post-operative complications, post-operative (day one) PVR, time to first voiding and post-operative (day one) pain level on a VAS scale ranging from 0 (absence of pain) to 10 (worst of possible pain) were recorded. Patients were discharged from hospital the day after the procedure, if no complications arose. Subjects participating to the study were controlled six,12 and 24 months after the procedure. Six months after the procedure, women completed the ICIQ-SF and a urinary diary of two days during the month preceding the visit and the onset of any complication was recorded. During the follow-up controls 12 and 24 months after the procedure, women had to complete the ICIQ-SF questionnaire and the urinary diary. They also underwent urodynamic and PVR evaluation. Moreover, women had to score their satisfaction with the surgical procedure on a VAS scale from 0 (minimal satisfaction) to 10 (maximal satisfaction) and the onset of any complication was evaluted. Data distribution for continuous variables was assessed with the Shapiro-Wilk's test and all variables displayed a normal distribution. Differences in age, duration of SUI, duration of the procedures, time to first voiding, time to discharge and VAS scale scoring between groups was evaluated with the Student's t test for uncoupled samples. Difference for continuous, normally distributed variables within the same group (VAS scoring) were evaluated using the Student's t test for coupled samples. Differences in cure rates and complication rates between groups were assessed with the χ^2 test. Significance has been set for a value of $p < .05$.

Results

Mean age was 59.4 ± 7.3 years and mean BMI 28.2 ± 3.2 kg/m^2. Fifty-one patients were post-menopausal (75%) and 12 were on hormonal replacement treatment (HRT) (23.5%). Mean duration of SUI was 4.7 ± 2.1 years, urinary urgency was present in 35.1% of patients, while urge incontinence was observed in 14.3% of the cohort. 12 patients had previous hysterectomy (17.6%) and 15 (22.1%) underwent a concomitant procedure (2 operative hysteroscopy, 3 operative laparoscopy, 2 laparotomy for endometriosis and hysterectomy and 7 anterior vaginal wall prolapse repair). We observed only one intra-operative complication, represented by a vaginal tear. Intra-operative bleeding was mild in 83.8% of cases and moderate in 10 cases (14.7%). We observed only one case (1.5%) of severe vaginal bleeding (approximately 400 ml) that was treated by intra-operative compression and did not necessitate blood transfusion. Mean operative time was 7.3 ± 3.2 minutes, while mean time to first voiding was 68.3 ± 13.2 minutes. No pathologic PVR (> 100 ml) was observed. We had only one post-operative complication represented by urinary obstruction that appeared 36 hours after the procedure and needed the removal of the device. Postoperative mean pain score was 1.9 ± 1.0. Thirty patients (44%) completed the 2-year follow-up, while 28 (41.2%) attended the one-year follow-up visit 81 and 10 the 6 (14.7%) months follow-up visits. Overall objective cure rate was 83.8%, with 8 women (11.8%) reporting an improvement of their symptoms. We had three failure (4.4%), excluding the cases that needed tape removal for urinary obstruction. The was one case of tape exposure due to a prolapsed arm of the device in a patient that is now incontinent but does not wish to be re-operated. We also observed 5 cases of de novo urgency (7.3%). Mean ICIQ-SF score was significantly low since the first follow-up visit and remained low thereafter. Mean satisfaction VAS score at 12 and 24 months after the procedure was 8.9 ± 1.5 (cumulative data).

Interpretation of results

TVT-Secur yielded elevated cure rates even at long follow-up times and proved to be a safe method for treating female SUI, with low intra- and post-operative complications. Furthermore, operative times and hospital stay are limited. Low postoperative pain scores and high satisfaction rates indicate that this procedure is well tolerated by the patients. De novo urgency remains an issue that needs to be addressed since its rate should be lower.

Concluding message

TVT-Secur is an effective and safe method for the surgical treatment of female SUI with elevated satisfaction rates and cure rates, even after 24 months.

References

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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)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**It was a retrospective study on patients underwent surgical procedure with a clear indication for their pathology**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**