

## OPERATIVE PERFORMANCES, SAFETY AND SHORT TERM FOLLOW-UP OF A MODIFIED RETROPUBIC TENSION-FREE VAGINAL TAPE (TVT-EXACT®)

### Hypothesis / aims of study

The introduction of tension-free vaginal tape (TVT) revolutionized surgical treatment of female stress urinary incontinence. Indeed, retropubic TVT drastically reduced operative times, return to daily activities, and costs, with higher efficacy in comparison with Burch's colposuspension (1). The major drawback of this technique are lesions to organs (mainly bladder and bowel) and large vessels. To reduce these complications, alternative routes for the passage of polypropylene sling were sought, with the introduction of the trans-obturator technique and, lately, of single-incision slings. Even though these new techniques seem to be safer, retropubic TVT appeared to be followed by significantly higher objective continence rates. Aim of this preliminary study was to evaluate intraoperative performances and safety of a modified retropubic vaginal tape (TVT-Exact™) and to report on short term follow-up.

### Study design, materials and methods

TVT-Exact™ is composed by a stainless steel 3.0 mm trocar shaft and a plastic trocar handle. The trocar shaft is designed to fit inside the white Trocar Sheaths on the polypropylene, laser-cut mesh. Differences with the original retropubic TVT are the diameters of the trocar, that are thinner, and the single use trocar handle that is more ergonomic. Thirteen patients were included in this preliminary study. Inclusion criteria were: diagnosis of stress incontinence and no contraindication to surgical procedure. Exclusion criteria were: urge incontinence, pelvic organ prolapse ≥ 2 stage, contraindication to surgical procedure. 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). Procedure was performed under spinal anesthesia as here reported: with the patient in dorsal lithotomy with hips flexed at 90°, a 18 F Foley catheter was inserted. Reference exit points (2 cm on each side of the midline, immediately above the pubic symphysis) were marked and ischemic and anesthetic solution injected at the level of the middle urethra. A full thickness vaginal sagittal incision for 1.5 cm was performed starting 1.0 cm cephalad from the urethral meatus and two 0.5-1 cm paraurethral dissection carried out. The trocar is passed through the paraurethral dissection up to the uro-genital diaphragm and then through the retropubic space up to the marked skin, keeping the bladder to the contralateral side with a intravesical trocar passed through the catheter. After having repeated the same procedure on the other side, a cystoscopy and a stress test was performed. A colpography ended the procedure. 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 three months after the procedure.

### Results

Mean age was 63.2 ± 8.5 years and mean BMI 29.5 ± 4.5 kg/m<sup>2</sup>. All patients were post-menopausal. Mean duration of SUI was 3.6 ± 2.2 years. Five patients had previous hysterectomy (38.5%). No intra-operative complication was observed. Intra-operative bleeding was mild in 10 cases (76.9%) and moderate in 3 cases (23.1%). Mean operative time was 28.3 ± 4.9 minutes, while mean time to first voiding was 98.3 ± 21.2 minutes from catheter withdrawal. We observed only one PVR > 100 ml, that resolved spontaneously without the need for further catheterization. Postoperative mean pain score was 5.7 ± 1.9. All patients were continent at the stress test three months after the procedure. No short term post-operative complication was observed three months after the procedure.

### Interpretation of results

The modified retropubic TVT-Exact was easily performed in all cases. In comparison with traditional retropubic TVT, the effort in the introduction of the trocar seemed reduced, even though the feeling transmitted by the new handle is different and a period of adaptation should be allowed to surgeons accustomed to the traditional retropubic TVT. Even though the number of patients is very limited, TVT-Exact seems to be a safe procedure.

### Concluding message

Modification to retropubic TVT aiming at a reduction in the complication rate seems promising. More patients and longer follow-up are needed.

### References

1. Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V, Hilton P, Nilsson CG, Waltregny D. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. *Eur Urol.* 2010; 58: 218-38.

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<b>Is this a clinical trial?</b>	<b>Yes</b>
<b>Is this study registered in a public clinical trials registry?</b>	<b>No</b>
<b>Is this a Randomised Controlled Trial (RCT)?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>

<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	Patients underwent diagnostic and surgical procedures indicated for their pathologies.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes