

## ULTRASONOGRAPHIC EVALUATION OF THE POSITIONING OF TVT-O VS. TVT-SECUR AND THEIR EFFECT ON THE URETHRA: AN ANCILLARY ANALYSIS OF A 36-MONTHS FOLLOW-UP RANDOMIZED STUDY

### Hypothesis / aims of study

Ultrasonography proved to be an useful tool for post-operative evaluation of TVT positioning and function (1,2). Different devices could have different appearance at ultrasound evaluation, and this kind of evaluation could show differences in their action on the urethra and may shed some light on failures. This study used ancillary data from an effectiveness randomized study with a 36 months follow-up (3) to compare the appearance of TVT-O vs. TVT-Secur and the modification of urethral morphology following their positioning using ultrasonography.

### Study design, materials and methods

This ancillary analysis uses data from a single-blind, randomized study performed in 2 Urogynecological Units enrolling patients affected by IUS from April 2008 to April 2009 to be randomized either to the TVT-O or the TVT-Secur hammock procedure (3). Inclusion criteria were: SUI as diagnosed by clinical evaluation and urodynamics, age >30 years, and previously failed pelvic floor muscle training. Exclusion criteria were as follow: previous surgery for SUI, isolated overactive bladder symptoms, pelvic organ prolapse POP-Q stage II, neurologic disease, and serious contraindications to surgical procedures. All patients underwent preoperative clinical evaluation, Q-tip testing, challenge stress testing (CST) with 250-mL bladder filling, post-void residual urine (PVR) evaluation, QoL questionnaire and urodynamic testing. All procedures were performed by 1 investigator per site who had already performed more than 50 TVT-O and 40 TVT-Secur procedures. TVT-O was performed according to the original technique. TVT-Secur was performed using an hammock approach. During the last follow-up visit scheduled 36 months after the procedure to evaluate the primary end-point of the study (effectiveness), patients also underwent introital ultrasonography (Esaote Twice System) with a 3.5 MHz transvaginal probe. A maximum of 36 months follow-up data were available. The following parameters were recorded, both at rest and under Valsalva: in the axial view (Fig. 1A), the angle  $\theta$  between the arms of the sling and the hypoechoic cross-sectional area of each part of the urethra (proximal, middle, and distal), calculated multiplying  $\pi$  by the longest and shortest diameters of the urethral core; in the sagittal view (Fig.1B-C), the distances between bladder neck and proximal tip of the tape and between tape and the urethral lumen, and the tape length. Student's t tests for paired and unpaired data for continuous variables and  $\chi^2$  test for categorical data were used.

### Results

Data from 66 patients in the TVT-O group and from 64 patients in the TVT-Secur group who completed the 36 months follow-up were available for the analysis. Objective cure rates were not different between the two groups: 57/66 (86.4%) in the TVT-O group and 50/64 (78.1%) in the TVT-Secur group. Both at rest and during Valsalva, no differences were observed among the two groups in the distance between the tape and the urethral lumen, as well as in the angle  $\theta$ . Hypoechoic area in the three urethral segments was similar in the two groups, both at rest and under strain. In the two groups, area, long and short urethral axis during Valsalva at mid-urethral level were significantly reduced in comparison with values at rest, even though at a less extent for patients treated with TVT-Secur (Table 1). The distance between the tape and the urethral lumen was also reduced during Valsalva for the two groups ( $p < .05$ ). The tape length was not different among the three groups. Cured, but not failed, patients showed a significant reduction of the short urethral axis during Valsalva in comparison with values at rest in all urethral sections. There was also a significantly higher distance between the tape and the urethral lumen in the failed in comparison with the cured patients.

### Interpretation of results

Ultrasonographic parameters were not significantly different, even though TVT-Secur showed a more limited reduction of mid-urethral area, long and short urethral axis during Valsalva. Failed patients did not show a significant reduction of the urethral short axis in all urethral sections, indicating that the sling did not produce a significant tension-free support. This is also reflected by a significant higher distance between the tape and the urethral lumen in comparison with cured patients.

### Concluding message

TVT-Secur seems to exert a non significantly lower urethral compression. Failures seem to be due to a lack of tension-free support, irrespective of the type of sling used.

Table 1. Ultrasound parameters in the two group studied.

	TVT-O (n = 66)		TVT-Secur (n = 64)	
	Rest	Valsalva	Rest	Valsalva
Sling-urethral lumen distance (mm)	3.5±1.6	2.8±0.9*	3.9±1.9	3.1±1.0*
Sling-bladder neck distance (mm)	15.1±2.5	11.9±4.9	15.2±4	12.1±5.3
Angle between arms (°)	119.9±11.5	99.5±15.3*	111.6±13.5	92.4±15.1*
$\Delta$ hypoechoic area Valsalva/rest (mm <sup>2</sup> ) at mid-urethra	-18.6±5.1		-12.7±7.0	
Sling length (mm)	8.4±1.1	-	7.9±0.9	-

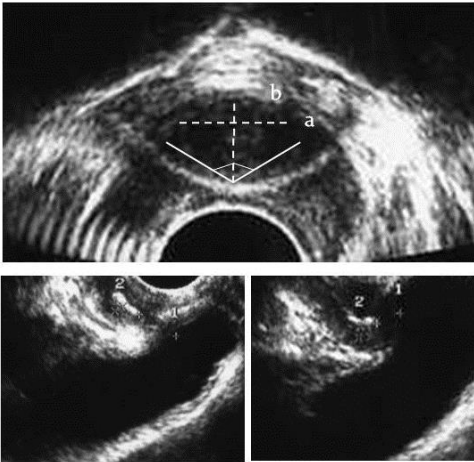


Figure 1. Ultrasound parameters evaluated. A. Axial view. B. Sagittal view.

#### References

1. Ultrasound Obstet Gynecol. 2012; 39: 452-7.
2. Int Urogynecol J Pelvic Floor Dysfunct 2011; 22: 493-498.
3. J Minim Invasive Gynecol 2013; 20: 198-204.

#### Disclosures

**Funding:** None **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics not Req'd:** Ancillary analysis of a randomized trial performed for another end-point using data from a routine post-operative diagnostic evaluation using ultrasonography **Helsinki:** Yes **Informed Consent:** Yes