

## INSIDE-OUT TRANSOBTURATOR VAGINAL TAPE (TVT-O): SHORT-TERM RESULTS OF A PROSPECTIVE STUDY

### Hypothesis / aims of study

The aim of this study was to prospectively evaluate the efficacy of the TVT-O inside-out procedure for the treatment of female stress urinary incontinence (SUI).

### Study design, materials and methods

From March 2003 through September 2003, 53 patients with clinical evidence of SUI participated in this prospective clinical trial. Preoperative evaluation included complete history, physical examination, multichannel urodynamics, urine analysis, and cystoscopy. None of the patients presented the following exclusion criteria: post-void residual volume (PVR)  $\geq 100$  cc, detrusor overactivity or acontractility, contraindication to anesthesia, pregnancy, neurological pathology, or active urinary or vaginal infection. All patients met the following inclusion criteria: age  $> 25$  and  $< 85$  years, clinically demonstrated SUI, positive Ulmsten test, and maximum cystometric capacity  $\geq 300$  mL. In all patients, a sub-urethral tape (Gynecare®) was inserted by one single surgeon *via* an inside-out transobturator approach (TVT-O), as previously described (1). Evaluation of SUI, urgency/urge incontinence, daytime urinary frequency/nocturia, and lower urinary tract symptoms (LUTS) suggestive of bladder outlet obstruction/retention was carried out using the Measurement of Urinary Handicap scale questionnaire (2). The importance of urinary incontinence was assessed with a visual analog scale graded from 0 to 10. Quality of life (QoL) assessment was performed using the validated Ditrovie self-administered questionnaire. Outpatient follow-up was performed at 1 and 6 months, and every 6 months thereafter. Follow-up evaluation included physical examination with a stress test, uroflowmetry, PVR, and symptom, visual analog, and QoL scales scoring. Cure was defined as no leakage based on both symptom scale scoring and physical examination. Improvement was defined as at least a 50% decrease in symptoms based on the questionnaire's evaluation. Chart review was conducted by a physician not associated with the original procedure. The specific protocol used in this study was approved by the Medical Ethics committee of our Institution. All patients had given their written informed consent. Methods, definitions, and units conform to the standards recommended by the ICS.

### Results

Mean age of the patients was 61.2 years (36 to 80). Of the 53 patients, 20 had undergone previous pelvic surgery. Forty-eight patients suffered from SUI. Five patients did not complain of SUI but had clinical evidence of SUI after reduction of pelvic organ prolapse (POP) during vaginal examination. The TVT-O procedure was associated with POP cure (performed before TVT-O) in 12 patients. Maximal urethral closure pressure was  $< 30$  cm H<sub>2</sub>O in 6 patients. Follow-up time was  $\geq 6$  months in all women (max = 12.5; mean = 8).

A total of 33 and 20 women received spinal and general anesthesia, respectively. Intraoperative blood loss was  $< 100$  cc in all cases. No vaginal wall, urethral, or bladder perforation was encountered. No hematoma, neurological complication, fistula, vaginal or urethral erosion, or tape rejection was observed. Some patients reported pain symptoms, directly after the procedure, mainly located in the thigh regions (either uni- or bilaterally). Pain was always mild, never requiring opioid analgics. No patient complained of persistent pain; indeed, pain had completely vanished within the first post-operative month in all cases.

At the latest follow-up visit, PVR was  $< 100$  cc and max flow rate was  $\geq 10$  mL/sec in 49 (92.4%) and 39 (73.6%) patients, respectively. One patient underwent an immediate tape release procedure for complete retention 2 days after TVT-O. Thereafter, the patient had no PVR and was completely dry. The tape was sectioned in 2 patients for chronic retention and/or urgency associated with bladder outlet obstruction, 4 and 7 months after the operation. Based on the SUI questionnaire evaluation and physical examination, 50 (94.3%) patients were cured. SUI symptoms had improved in 1 patient and had not changed in another. One patient with POP not complaining of SUI preoperatively (but with clinically demonstrated SUI following POP reduction) developed SUI after POP cure associated with TVT-O.

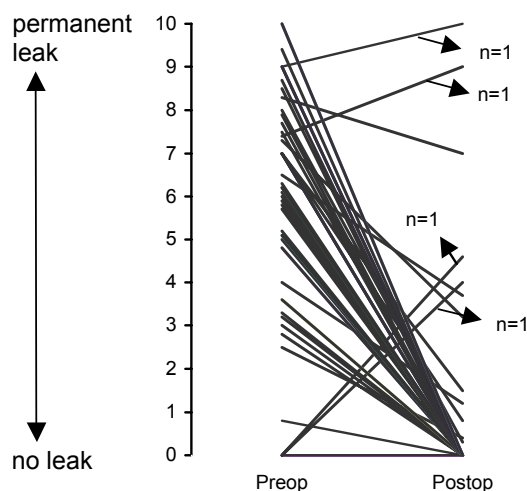
Analysis of the urgency questionnaire's results revealed that among the 53 patients, 32 did not complain of any urgency before the operation. Of these 32 patients, 3 patients developed *de novo* urgency, with one of them requiring tape sectioning because of obstruction-associated urge incontinence. Among the 21 patients with preoperative urge symptoms, 15 of them reported disappearance of urgency after the procedure. Urge symptoms were unchanged in the remaining 6 patients.

Daytime frequency/nocturia symptoms scale scoring showed that 4 patients had a worsening of these symptoms while all other patients were either improved or unchanged.

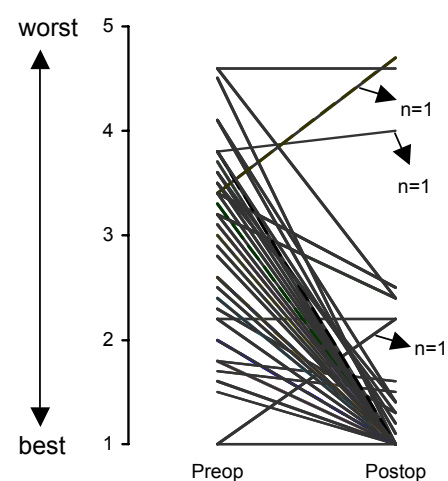
LUTS suggestive of bladder outlet obstruction/retention appeared or worsened in 3 patients, amongst which the 2 patients who required tape sectioning. These symptoms were unchanged or decreased (mainly in patients with associated POP cure) in all other patients.

Analysis of the urinary incontinence visual analog and QoL scale scores demonstrated that the majority of patients reported disappearance of urinary leakage together with significant improvement of their QoL (Figures 1 and 2).

**Figure 1: Urinary incontinence visual analog scale scores**



**Figure 2: QoL scale scores**



#### Interpretation of results

As already suggested by the results of a recent feasibility study (1), TVT-O appears to be associated with a minimal risk of peri-operative complications. Indeed, in our present prospective study, no injury to the bladder, vagina, or urethra was encountered and we have not observed any vascular, digestive or neurological complication. Our data suggest that TVT-O is associated with high objective and subjective SUI cure rates and a low incidence of post-operative complications. Longer follow-up times are required to determine the long-term efficacy of TVT-O.

#### Concluding message

The short term results of this prospective study suggest that TVT-O is a safe and efficient surgical procedure for the treatment of female SUI.

#### References

1. Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator vaginal tape inside-out. Eur Urol 44:724-730, 2003
2. Elaboration and validation of a specific quality of life questionnaire for urination urgency in women. Prog Urol 7:56-63, 1997