347

Waltregny D[1], Reul O[1], Mathantu B[1], Gaspar Y[1], Bonnet P[1], de Leval J[1]
1. University of Liege

INSIDE-OUT TRANSOBTURATOR VAGINAL TAPE (TVT-O): RESULTS OF A PROSPECTIVE STUDY AFTER A MINIMUM FOLLOW-UP TIME OF 1 YEAR

Hypothesis / aims of study

The aim of this study was to prospectively evaluate the efficacy of the TVT-O inside-out transobturator procedure for the treatment of female stress urinary incontinence (SUI) after at least 1 year follow-up.

Study design, materials and methods

Between 03/2003 and 12/2003, a sub-urethral tape (Gynecare™) was inserted *via* an inside-out transobturator approach (TVT-O) as previously described (1) in 118 consecutive patients with clinical evidence of SUI. Preoperative evaluation included complete history, physical examination, multichannel urodynamics, urine analysis, and cystoscopy. In this prospective trial, the following inclusion criteria were required: age > 25 and < 85 years, clinically demonstrated SUI, positive Ulmsten test, and maximum cystometric capacity ≥ 300mL. Patients were excluded from the trial when 1 of the following exclusion criteria was found: post-void residual (PVR) ≥ 100mL, detrusor overactivity or acontractility, contraindication to anesthesia, pregnancy, neurological pathology, or active urinary or vaginal infection. Among the 118 patients, 102 fulfilled the inclusion and exclusion criteria and were enrolled in the trial. Evaluation of SUI, urgency/urge urinary incontinence, daytime 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 and quality of life (QoL) were assessed with a visual analog scale graded from 0 to 10 and the validated Ditrovie self-administered questionnaire (3), respectively. Outpatient follow-up was perfomed at 1, 6 and 12 months, and every year 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 a ≥ 50% decrease in symptoms' severity using the questionnaire's results. Chart review was conducted by a physician not associated with the original procedure. Methods, defintions, and units conform to the standards recommended by the ICS.

Results

Mean age of the patients was 60.4 years (range: 34-83). Of the 102 patients, 52 had undergone previous pelvic and/or incontinence surgery. Ninety-seven 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 16 patients. Maximal urethral closure pressure was ≤ 30cm H_20 in 20 patients. A total of 73, 29, and 1 women received spinal, general, and local + sedation anesthesia, respectively.

Intraoperative blood loss was ≤ 200cc in all cases. No urethral or bladder perforation was encountered. No hematoma, neurological complication, fistula, or urethral erosion was observed. In 1 patient, a perforation of the vaginal sulcus was noted intra-operitavely and immediately sutured; after reorientation of the dissection, the tape was inserted without any further problem. None of the patients presented vaginal erosion. Some patients reported pain symptoms, directly after the procedure, mainly located in the thigh regions (either uni- or bilaterally). Pain was always mild and did not require opioid antalgics. No patient complained of persistent pain.

Follow-up time was ≥ 12 months in all women (max = 24.2; mean = 14.3). Three patients were completely lost to follow-up. At last visit, PVR was < 100mL in 96 (97.0%) patients. Two patients who had an associated POP cure (laparoscopic sacral colpopexy) underwent an immediate tape release procedure for complete retention 2 and 7 days after TVT-O. Thereafter, the patients had no PVR and were completely dry. The tape was sectioned in 2 patients who developed chronic retention (with recurrent cystitis) and/or urgency associated

with bladder outlet obstruction, 4 and 7 months after the operation. Both patients remained improved in terms of SUI with a PVR < 100cc and reported no urgency at the last visit.
Based on the SUI questionnaire results and physical examination, 90 (90.9%) patients were cured. SUI symptoms had improved in 5 (5.0%) patients. Failure was observed in 4 (4.1%) patients, including one with POP (not complaining of SUI preoperatively) who developed SUI after the combined procedure.
Analysis of the urgency questionnaire's results revealed that among the 99 patients, 59 did not complain of urgency before the operation. Of these 59 patients, 6 patients developed *de novo* urgency (10.2%), with one of them requiring tape sectioning because of obstruction-associated urge incontinence. Among the 40 patients with preoperative urge symptoms, 31 of them (87.5%) reported a reduction or disappearance of urgency after the procedure. Urge symptoms were unchanged in the remaining 9 patients (22.5%).
Daytime frequency/nocturia symptoms scale scoring showed that 2 (2.0%) 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 analog scale scores

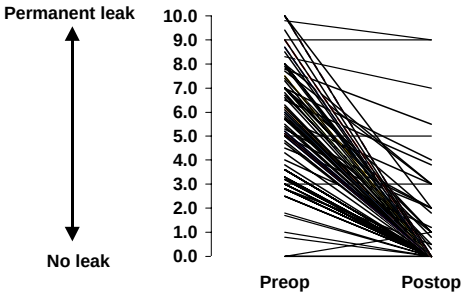
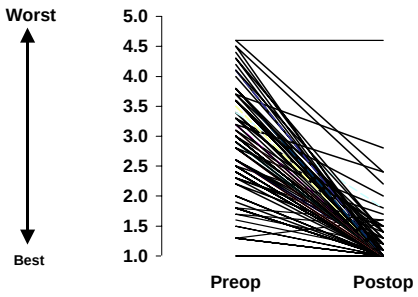


Figure 2. QoL scores



Interpretation of results

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 or urethra was encountered and we have not observed any vascular, digestive or neurological complication. Our data also indicate 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 one-year 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
3. Scores de symptômes et de qualité de vie dans l'insuffisance sphinctérienne de la femme. *In* : Insuffisance sphinctérienne de la femme. Paris, Elsevier, pp 67-86, 2000