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THREE YEAR RESULTS OF A PROSPECTIVE RANDOMIZED TRIAL COMPARING THE ORIGINAL INSIDE-OUT TRANSOBTURATOR (TVT-O™) PROCEDURE WITH A MODIFIED VERSION USING A SHORTENED TAPE AND REDUCED DISSECTION FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

In 2007, a randomized clinical trial (RCT) was initiated to compare a modified inside-out transobturator procedure, using a shortened sling (12cm long) and reduced lateral dissection, with its original counterpart (TVT-O™) for the treatment of female stress urinary incontinence (SUI). At 1-year followup, the modified TVT-O procedure was found to be as safe and efficient as the original procedure for treating female SUI, with less severe and frequent groin pain in the immediate postoperative period (1). An anatomical study had shown that the shorter, inside-out transobturator tape traversed less muscular structures than its original counterpart, while still consistently anchoring in the obturator membrane at a similarly safe distance from the obturator canal (2). The aim of the current study was to evaluate the results of the RCT after a longer followup, at 3 years postoperatively.

Study design, materials and methods

Randomized, single-blinded, prospective trial in which women suffering from SUI were randomized to the original or modified procedure as sole surgery. The following inclusion criteria were required: age > 25 and < 85 years, clinically and urodynamically demonstrated SUI, positive stress 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, neurogenic bladder, active urinary or vaginal infection or associated pelvic organ prolapse (POP) requiring surgical correction (symptomatic or grade ≥ 3).

Evaluation of SUI, urgency/urge urinary incontinence (UUI), daytime frequency/nocturia and LUTS suggestive of bladder outlet obstruction was carried out by using the Measurement of Urinary Handicap (MUH) symptom scoring questionnaire. QoL was assessed using the validated Ditrovie self-administered questionnaire. Modifications to the original procedure were twofold: 1. the tape was shortened to 12 cm without any changes to the characteristics of the mesh and 2. during lateral dissection, perforation of the obturator membrane by the scissors and guide was avoided. A standardized postoperative analgesia protocol was followed. The primary outcome measures were the objective (negative cough test) and subjective (as assessed by a SUI symptom scale score equal to 0) cure of SUI. Symptom severity was arbitrarily considered as improved or worsened when symptom scale score had decreased or increased by at least 50%, respectively (1). Secondary outcomes included complication rates, QoL measures, and severity of postoperative groin pain, as assessed by a visual analogue scale. Follow-up evaluations included physical examination with a cough test, uroflowmetry with maximum flow rate (Qmax) and postvoid residual (PVR) measurement, and scoring of urinary symptom, QoL, and groin pain scales.

The sample size calculation was performed assuming that the original TVT-O™ procedure would be associated with a 90% success rate at 1-year follow-up and that a 14% decrease in success rates would be clinically important. With a 70% statistical power (1-β) to show this 14% difference at α=0.05, it was determined that the sample size should be 160 patients, 80 patients in each group. To compensate for patients lost to follow-up post-operatively (estimated rate of 5%), 84 patients per group needed to be enrolled.

Results

Between 01/2007 and 12/2008, 87 and 88 were recruited in the original and modified TVT-O™ procedure groups, respectively. Baseline patients characteristics (age, BMI, parity, previous surgery, irradiation, or physiotherapy, symptom scale scores, urodynamic data, QoL scale scores, and type of anesthesia) were similar in the 2 groups (p>0.05). No intraoperative complication was recorded. After catheter removal, 2 patients presented with a clinically significant PVR and underwent either suprapubic catheter placement (original procedure group) or an immediate tape release procedure (modified procedure group). One patient who had undergone the original procedure developed a sub-urethral vaginal exposure of the mesh, requiring partial tape excision.

Among the 170 (97%) patients who completed the 1 year followup, the SUI cure rate was 91.2% and no difference was noted between the original and modified treatment groups (91.7% versus 90.7%, respectively, p>0.5).

Between the 1-year and 3-year visits, 10 and 7 patients were lost to followup or had died from an unrelated cause in the original and modified groups, respectively. At 3 year, 74 (85%) patients in the original TVT-O group and 79 (90%) patients in the modified group were assessed. In each treatment group, about one third of the patients (31% (n=23) in the original group and 28% (n=22) in the modified group) denied the invitation to present to the followup visit but agreed to be interviewed by telephone and to answer the questionnaires.

Among the 153 (87%) patients who completed the 3 year followup, the subjective SUI cure rate was 84.3% with no difference between the original and modified treatment groups (85.1% (63/74) versus 83.5% (66/79), respectively (p>0.05). At 3 year, 88.9% (48/56) and 87.7% (50/57) of the patients in the original and modified groups, respectively, had a negative cough test (p>0.05). The cough test was negative in all patients who reported disappearance of SUI. Urinary symptom and QoL scale scores as well as voiding data (Qmax and PVR) were similar in both groups (Table 1).

The incidence and intensity of groin pain was higher in the original TVT-O group on day 0 and postoperative day 1 (p<0.05), but not therafter. At 3 year, 3 (4.1%) and 1 (1.3%) patients reported, but did not complain of thigh pain in the original and modified groups, respectively; all 4 patients had a pain score ≤3. Between the 1-year and 3-year visits, 1 tape needed to be cut in the modified group because of LUT obstruction; in each group, 1 patient required a hysterectomy because of uterine disorder and another had surgery for symptomatic POP.

Table 1. Comparison of 3-year postoperative urinary symptom and QoL scores, and voiding parameters between the original and modified TVT-O procedure groups

	Original TVT-O	Modified TVT-O	P value
Symptom scale scoring			
SUI (/8)	0.6 ± 1.7 (0-6)	0.7 ± 1.7 (0-8)	0.919
Urgency / UUI (/8)	1.7 ± 2.5 (0-8)	2.1 ± 2.6 (0-8)	0.238
Daytime frequency / nocturia (/8)	0.4 ± 0.8 (0-3)	0.6 ± 0.9 (0-3)	0.156
LUTS suggestive of bladder outlet obstruction (/4)	0.2 ± 0.5 (0-2)	0.1 ± 0.4 (0-2)	0.896
Voiding parameters			
PVR (mL)	5.2 ± 16.0 (0-80)	4.2 ± 18.9 (0-119)	0.720
Qmax (mL/sec)	27.8 ± 13.4 (4-67)	26.2 ± 14.8 (8-71)	0.311
Quality of Life scale scoring			
Impact of urinary symptoms on QoL (from 10 to 50)	13.1 ± 5.7 (10-34)	14.0 ± 6.8 (10-42)	0.165

Values are given as mean ± SD (range). *SUI*, stress urinary incontinence; *UUI*, urge urinary incontinence; *LUTS*, lower urinary tract symptoms; *QoL*, quality of life; *PVR*, postvoid residual; *Qmax*, maximal flow rate

Qmax data not available or not interpretable in 37 and 36 patients from the original and modified TVT-O groups, respectively

Interpretation of results

The results of this RCT, after a 3-year followup, suggest that the use of a 12 cm long transobturator sling, which relies on a velcro-effect (i.e. without further modification to the tape) for creating the initial holding forces and subsequent tissue ingrowth of the tape to provide fixation, is as efficient to cure SUI as its longer counterpart, which traverses the adductor muscles. These data originating from a single-center, single-surgeon, randomized study should be repeated in a multi-center multi-surgeon context for external validation. A shortcoming of this study was that about one third of the patients did not undergo physical examination at last followup.

Concluding message

At medium term followup, a modified version of the TVT-O™ procedure, with a shorther tape and reduced lateral dissection, was as safe and efficient as the original procedure for treating female SUI; the modified procedure was associated with less immediate postoperative groin pain.

References

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Disclosures

Funding: None **Clinical Trial:** Yes **Public Registry:** Yes **Registration Number:** This clinical trial has been registered at http://www.controlled-trials.com; its identification number was ISRCTN65635093. **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of the University Hospital of Liège **Helsinki:** Yes **Informed Consent:** Yes