

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

Hypothesis / aims of study

To compare a modified inside-out transobturator procedure, using a shortened sling and reduced dissection, with its original counterpart (TVT-O™) for the treatment of female stress urinary incontinence (SUI).

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 \geq 300mL. Patients were excluded from the trial when 1 of the following exclusion criteria was found: post-void residual (PVR) \geq 100mL, detrusor overactivity or acontractility, contraindication to anesthesia, pregnancy, neurogenic bladder, active urinary or vaginal infection or associated pelvic organ prolapse requiring surgical correction (symptomatic or grade \geq 3). Evaluation of SUI, urgency/urge urinary incontinence (UUI), daytime frequency/nocturia and LUTS suggestive of bladder outlet obstruction was done using the 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 mesh's characteristics and 2. during lateral dissection, perforation of the obturator membrane by the scissors and guide was avoided. A standardized postoperative analgesia protocol was followed, including on-demand administration of analgesics. The primary outcome measure was defined as the resolution of both subjective (no SUI reported by the patient) and objective (negative cough test) SUI at 1 year. Secondary outcomes included complication rates, QoL measures, and severity of postoperative groin pain, as assessed by a visual analogue scale. 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 $\alpha=0.05$, 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 modified and original 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) or an immediate tape release procedure (modified procedure). Among the 170 (97%) patients who completed the 1 year follow-up, 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, $p = 0.824$). Postoperatively, evolution of other urinary symptoms, maximum flow rate, postvoid residual, complication rates, and QoL scores 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 day 1 ($p = 0.003$ and $p = 0.011$, respectively), but not thereafter (Figure 1), and patients in this group required more analgesics ($p = 0.015$).

Interpretation of results

The results of this RCT provide a proof-of-principle for the use of a transobturator 12 cm long tape that 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. Our data originating from a single-center, single-surgeon, randomized study should be repeated in a multi-center multi-surgeon context for external validation.

Concluding message

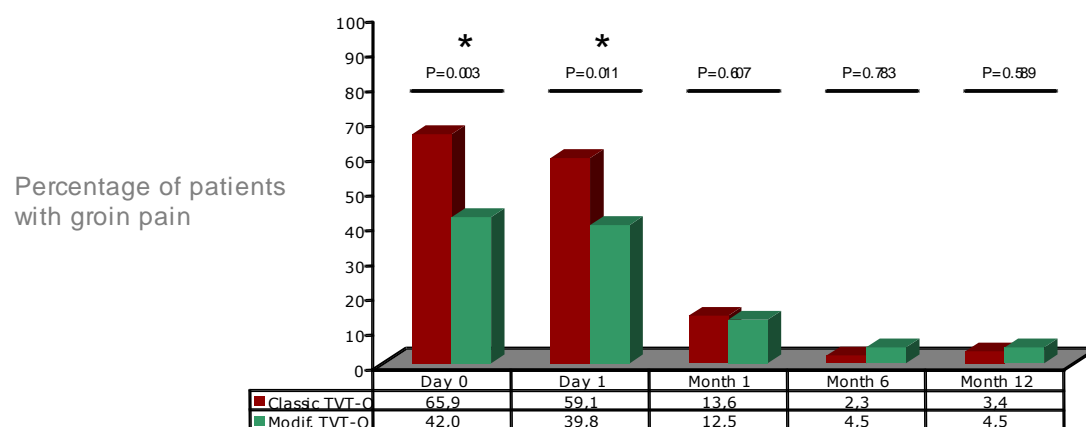
At 1-year follow-up, a modified version of the TVT-O™ procedure, with a shorter tape and reduced lateral dissection, was as safe and efficient as the original procedure for treating female SUI, and was associated with less postoperative groin pain.

Table 1. Comparison of 1-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)	0.3 ± 1.2 (0-6)	0.3 ± 1.2 (0-8)	0.939
Urgency / UUI (/8)	1.1 ± 2.0 (0-7)	1.2 ± 2.1 (0-7)	0.869
Daytimefrequency /nocturia(/8)	0.4 ± 1.0 (0-5)	0.4 ± 0.9 (0-4)	0.400
LUTS suggestive of bladder outletobstruction (/4)	0.1 ± 0.4 (0-2)	0.1 ± 0.5 (0-3)	0.889
Voiding parameters			
PVR (mL)	3.7 ± 10.6 (0-60)	4.1 ± 12.7 (0-78)	0.790
Qmax(mL/sec)#	24.5 ± 11.4 (6.6-60.0)	23.2 ± 11.0 (6.0-79.2)	0.567
Quality of Life scale scoring			
Impact of urinary symptoms on QoL (from 10 to 50)	11.9 ± 4.3 (10-30)	12.5 ± 5.8 (10-38)	0.830

Qmax data not available or not interpretable in 22 and 18 patients from the original and modified TVT-O groups, respectively

Figure 1. Evolution of postoperative groin pain



Specify source of funding or grant	None
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
Specify Name of Public Registry, Registration Number	ISRCTN65635093 http://www.controlledtrials.com/ISRCTN65635093
Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes