Int Urogynecol J (2011) 22:145–156
DOI 10.1007/s00192-010-1264-4

ORIGINAL ARTICLE

The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial

Jean de Leval · Alexandre Thomas · David Waltregny

Received: 14 May 2010 / Accepted: 29 August 2010 / Published online: 21 September 2010

Abstract
Introduction and hypothesis The aim of this study is to compare a modified inside-out transobturator procedure with its original counterpart [inside-out transobturator (TVT-O)] for the treatment of female stress urinary incontinence (SUI).
Methods A prospective, randomized trial in women suffering from SUI was used. The modified procedure consisted of a shorter tape whilst the scissors or guide no longer perforated the obturator membrane. The primary outcome was the resolution of subjective and objective SUI at 1 year. Secondary outcome measures included adverse events, quality of life measures, and groin pain.
Results One hundred seventy-five patients were randomized. No intraoperative complications were recorded. The SUI cure rate was 91.7% versus 90.7% (original versus modified, respectively; $p=0.824$). Incidence and intensity of groin pain was higher in the original TVT-O group on day 0 and 1 ($p<0.05$), requiring more analgesics ($p=0.015$) but not thereafter.
Conclusions At 1 year follow-up, the modified inside-out transobturator tape procedure was as efficient and safe as the original technique but associated with less immediate postoperative groin pain.

Keywords Pain · Female stress urinary incontinence · Sub-urethral slings · Tension-free vaginal tape transobturator · TVT-O

Introduction

Transobturator tape procedures for treating female stress urinary incontinence (SUI) were pioneered in Europe a few years ago [1, 2]. As clinical evidence supporting their efficacy and safety at short/medium term has continued to grow [3–7], these procedures have become widely adopted by urogynecologists and urologists. Among various studies, one recent meta-analysis found similar cure rates for the three most commonly used surgical approaches for treating female SUI, namely the retropubic, the outside-in transobturator (TOT), and the inside-out transobturator (TVT-O) tape procedures [8]. In a recently published Cochrane review, the transobturator route, as compared with the retropubic route, generated slightly lower objective cure rates (84% versus 88%); yet, no difference in subjective cure rates was found between the two approaches [9]. The transobturator approach was associated with less voiding dysfunction, less blood loss, fewer bladder perforations, and with a shorter operating time [9].

Retropubic and transobturator tape procedures can cause postoperative pain symptoms [3, 10]. Following transobturator procedures, pain is typically experienced by women at the groin region and is temporary in the vast majority of cases [3]. In some cases, pain is described at the lumbar spine or hip regions, presumably as a result of the perioperative lithotomy position with the patient's hips in hyperflexion. Until now, it remains unknown whether there exist significant and/or clinically relevant differences in the incidence of postoperative pain and its severity between the

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retropubic, the TOT, and the TVT-O tape procedures [3, 6, 9, 11–20].

The source of groin pain after transobturator procedures may originate from trauma secondary to the penetration of the dissecting scissors, needles, and/or tape into muscular (i.e., obturator and adductor muscles) and/or aponeurotic (i.e., obturator membrane) structures. It could also be related, however, to the foreign body reaction to the tape, possibly in proximity to peripheral obturator nerve branches. In this context, newly developed mini slings, using one single vaginal incision and a shortened tape, may conceptually appear as an attractive alternative to the traditional transobturator tapes. Other potential advantages include reduced postoperative morbidity and surgery performed in a true outpatient setting (using only local anesthetics). Since the tape's length of mini slings generally does not exceed 8 cm, modifications to the tape's ends, such as changes in the tape's material or addition of anchors, were introduced to enhance fixation into the tissues. A variety of mini slings are currently marketed. To date, however, no firm clinical evidence has emerged to support the superiority—or equivalence—of mini slings over traditional sub-urethral tapes in terms of efficacy and safety. To our knowledge, only two randomized trials have compared the results of a mini sling versus a traditional tape. An interim analysis of a randomized trial comparing TVT-O versus a mini sling (TVT-Secur) has shown a significantly higher rate of persistent SUI symptoms at 6 weeks in the mini sling arm (8.5% and 21.5% in the TVT-O and mini sling groups, respectively) [21]. More recently, a retropubic tape (Advantage TVT) was compared with a mini sling (MiniArc) in a randomized trial comprising 71 patients. At 6 months, 3% and 35% of the women in the retropubic and mini sling groups, respectively, demonstrated persistent SUI [22].

In this study, we report on the results of a single-center, single-blinded, randomized prospective trial comparing the 1-year outcome of patients suffering from female SUI who underwent either the TVT-O procedure or a standardized modified version of it. Modifications to the original procedure were twofold: (1) the tape was shortened to 12 cm without any changes to the mesh's characteristics and (2) during lateral dissection, perforation of the obturator membrane by the scissors and/or guide was avoided.

Material and methods

Patients

One hundred and seventy-five women were randomized into this single-center trial between January 2007 and December 2008. The ethics committee of the University Hospital of Liège gave approval to the study and written informed consent was obtained from each patient. This clinical trial has been registered at http://www.controlled-trials.com; its identification number was ISRCTN65635093.

Preoperative evaluation included history, physical examination with a stress test, urine analysis, urethrocystoscopy, and multichannel urodynamics. Preoperative evaluation of SUI, urgency/urge urinary incontinence (UUI), daytime frequency/nocturia, and lower urinary tract symptoms (LUTS) suggestive of bladder outlet obstruction was done using the Measurement of Urinary Handicap symptom scoring questionnaire, as previously described [5, 23, 24]. Quality of life (QoL) was assessed using the validated Ditrovie self-administered questionnaire [5, 23, 24].

Inclusion and exclusion criteria (Table 1) were similar to those used in a previously published prospective observational study assessing the outcome of the TVT-O procedure [5, 24]. The sole exclusion criterion that differed was that, in the current trial, patients with associated pelvic organ prolapse requiring surgical treatment (either symptomatic and/or grade 3 or higher [25]) were excluded to avoid any confounding postoperative pain resulting from the prolapse surgery.

Randomization

Randomization was performed at the time of preoperative assessment after written informed consent had been obtained. Those patients who appropriately fulfilled the inclusion criteria were randomly assigned to undergo either the original or the modified TVT-O procedure. The randomization process was performed with five sequential patients undergoing one approach before alternating surgical modality.

Surgical procedures

The TVT-O (Ethicon Women's Health and Urology, Sommerville, NJ, USA) procedure was performed as originally described [2]. The modified procedure differed from its original counterpart by two aspects. The first modification related to the shortening of the total tape length to 12 cm. Tape shortening was carried out directly in the operating theater. A non-absorbable suture loop was placed at either end of the shortened tape, allowing tension adjustment, as required, after plastic sheaths removal, similarly to the original procedure (Fig. 1). The other variation involved a reduction in the depth of lateral dissection, the obturator membrane being no longer perforated with the scissors nor the guide (Fig. 2). Following its insertion into the dissected tract, the winged guide was only allowed to reach and be in contact with the inferior pubic ramus. All other surgical steps were identical between the two procedures.

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Age between 25 and 85 years
Clinical and urodynamically demonstrated stress urinary incontinence
Positive stress test
Maximum cystometric capacity 300 mL or greater
Exclusion criteria
Urodynamically proven detrusor overactivity/acontractility
Post void residual 100 mL or greater
Pregnancy
Neurogenic bladder
Active urinary or vaginal infection
Contraindication to anesthesia
Associated pelvic organ prolapse requiring surgical correction (symptomatic or grade 3 and higher)

Patients were blinded to the type of surgery they underwent. All procedures were performed by one surgeon (JdL), without intraoperative cystoscopy, under spinal or general anesthesia. All patients received prophylactic antibiotic therapy (cefazolin 2 g i.v.) at the start of the operation. Intraoperative complications were recorded. A 16-French urinary catheter was left in situ overnight in all patients. After catheter removal, when complete urinary retention or a significant postvoid residual (PVR) was observed, patients were offered several treatment options: reinsertion of a catheter for 24 to 48 h followed by a new voiding trial with PVR measurements, intermittent catheterization together with completion of voiding diaries, suprapubic catheter insertion, or a tape release procedure for persistent complete retention [24]. All other immediate postoperative complications, e.g., hematoma or sepsis, were also recorded during the patient's hospital stay.

Assessment and management of postoperative pain

All patients received 1 g of paracetamol intravenously perioperatively. Four hours following surgery, 1 g of paracetamol was administered orally. All patients were informed upon their return in the urology ward that they could request additional analgesia if needed. The on-demand analgesia regimen was standardized. If pain control was insufficient, the patient received an additional 1 g of paracetamol (class I analgesics); this could be repeated every 6 h if required. If paracetamol proved to be insufficient, the patient was administered 100 mg of tramadol intravenously (class II analgesics), to be repeated every 8 h if necessary. In those patients in whom tramadol administration also proved to be insufficient to alleviate their pain, a single dose of 75 mg diclofenac slow release (class III analgesics) was administered orally. If administration of these painkillers was still unsatisfactory to control pain, morphine was administered.

Patients were asked to assess the intensity of the groin pain they experienced on each side using a visual analog scale (VAS) graded from 0 to 10 (0 corresponding to the absence of pain and 10 corresponding to the worst pain). Groin pain was assessed on the evening of the day of surgery (D0), on the morning of the day after surgery (D1), and at the 1-, 6-, and 12-month follow-up visits. Pain reported at other locations (e.g., lumbar pain, sciatica) was not incorporated in the VAS assessment but was recorded.

Postoperative evaluation

Follow-up evaluations at 1, 6, and 12 months included physical examination with a cough test (5), uroflowmetry with PVR measurement, and scoring of urinary symptom, QoL, and pain scales. Postoperative complications were recorded, including urinary retention, the need for tape release/section, hematoma, sepsis, vaginal or urethral erosion, and neurologic complications.

Cure of SUI was defined as the disappearance of subjective and objective SUI as assessed by SUI symptom scale scoring (no SUI reported by the patient) and by physical examination (negative non-standardized cough test) [24]. To perform the cough test (in the semilithotomy position), patients were invited to present to the follow-up visits with a full bladder [24]. Symptom severity was arbitrarily considered as improved or worsened when the symptom scale score had decreased or increased by at least 50%, respectively [24]. Severe groin pain was arbitrarily defined as a VAS score of 5 or higher.

Statistical analysis

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 (24) and that a 14% decrease in success rates would be clinically important.

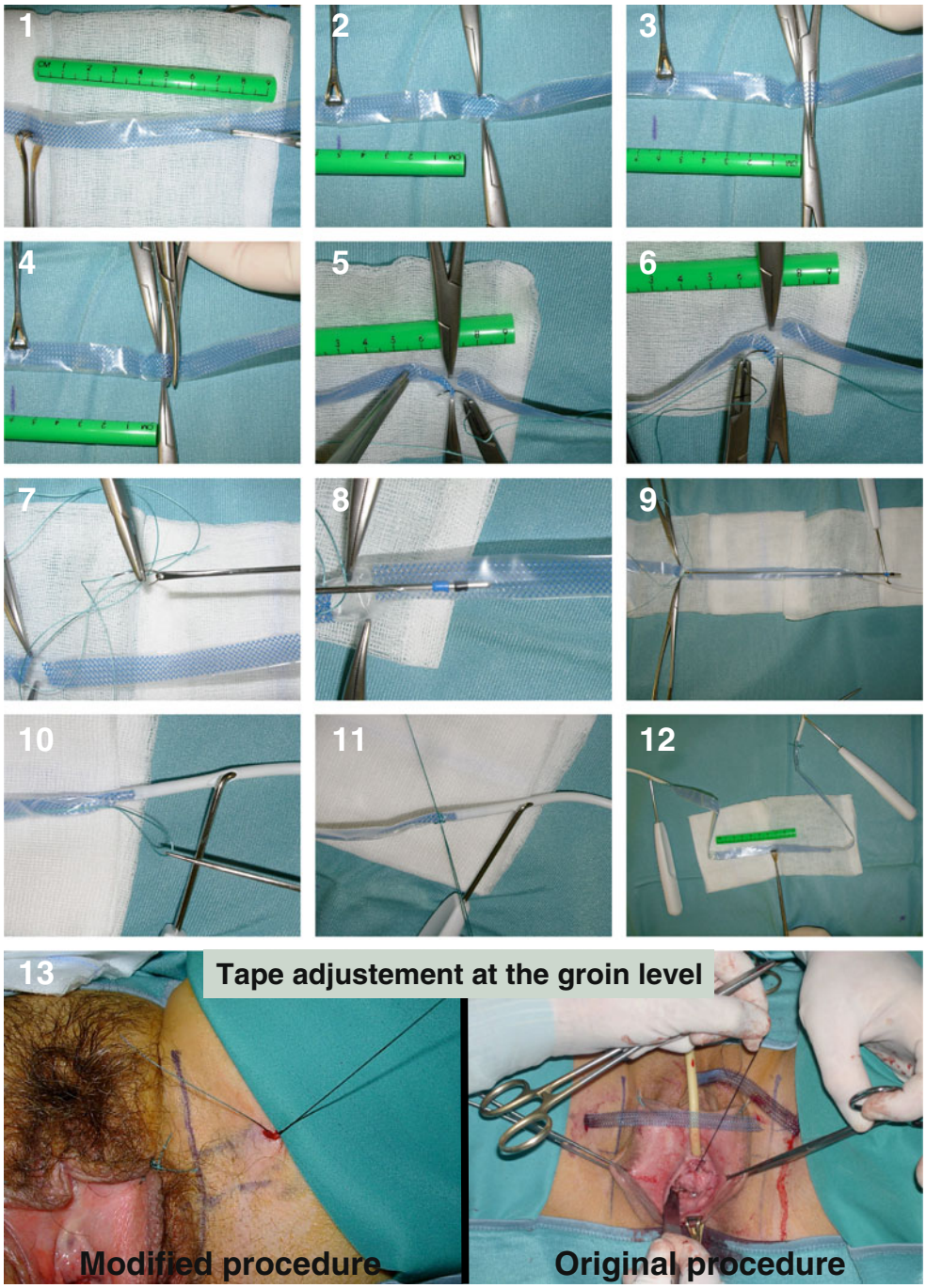


Fig. 1 Modification of the TVT-O device. Panels 1 to 12 describe how the tape was shortened from the TVT-O device in the operating theater immediately prior to the procedure. With the use of a lancet, the plastic sheaths were first opened over a length of 1 cm along their longitudinal axis at a distance of 6 cm from the center of the tape (*panel 1*). The opening of the sheaths allowed cutting the tape with scissors 6 cm laterally to the tape's center (*panels 2 to 4*). A non-absorbable suture was subsequently passed through each tip of the shortened, 12-cm long tape in order to create a loop (*panels 5 and 6*). The two arms of the suture loop were then passed inside the plastic sheaths' lumen using a straight needle's eye and exited through the sheaths close to the proximal portion of the plastic tubes (*panels 7 to 10*). The two arms of the suture loop were then tied to the plastic sheaths (*panel 11*). The modified TVT-O device with its shortened tape is shown in *panel 12*. *Panels 13 and 14* show the final step for adjustment of the tape's tensioning—if required—after removal of the plastic sheaths. In the modified procedure (*panel 13*), section of the plastic sheaths allowed to remove the extra portions of the tape, leaving in place only the two strands of the loop suture. In case the tape was found lying too loose underneath the urethra, traction on the two strands permitted repositioning of the mid portion of the tape in closer contact with the ventral aspect of the urethra. Once final adjustments were done, the suture loops were removed by pulling on only one of their two strands. In the original TVT-O procedure (*panel 14*), as previously described (*2*), removal of the plastic sheaths uncovered the tape, which could be pulled upon if additional tensioning was deemed necessary

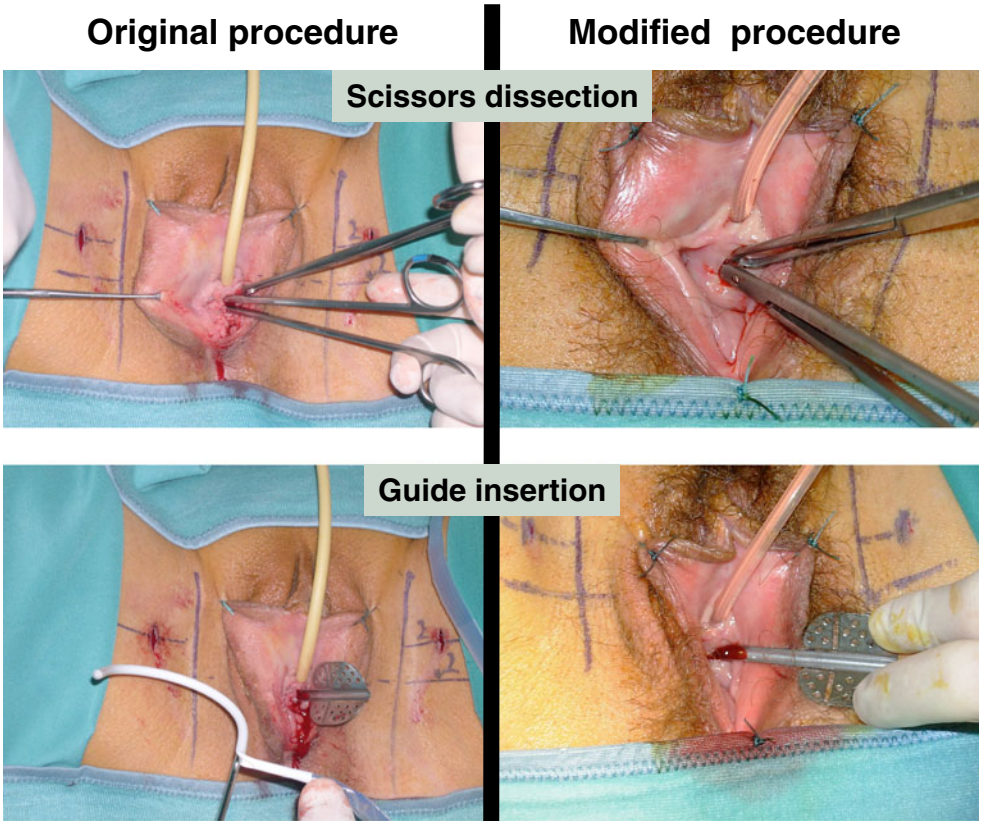


Fig. 2 Modification of the lateral dissection in the modified TVT-O procedure. As compared with the original procedure, neither the scissors nor the guide perforated the obturator membrane in the modified technique. The guide was inserted in the dissected tract and merely brought in contact with the upper edge of the inferior pubic ramus

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 postoperatively (estimated rate of 5%), 84 patients per group needed to be enrolled. For analysis of continuous and nominal variables, Mann–Whitney and Chi-squared tests, respectively, were used to calculate statistical differences between study groups. A p value <0.05 was considered statistically significant.

Results

The progress of the patients through the trial is shown in Fig. 3. One hundred and seventy-five Caucasian women were enrolled and randomized to the original (n=87) or modified TVT-O (n=88) procedure. All patients were blinded to the type of surgical procedure they were to undergo; no patients withdrew from the study prior to their operation. No significant differences in the patient characteristics between both groups were observed (Table 2).

A 1-year follow-up was completed by 170 (97%) women. Two patients were completely lost to follow-up after the 1-month visit and two more after the 6-month visit. One patient died before the 6-month visit; the cause of death was unrelated to the surgery.

Table 3 summarizes the postoperative evolution of urinary symptoms. Overall, cure of SUI was achieved in 91.2% of the patients, with no significant difference between the original and modified TVT-O procedure groups (91.7% and 90.7%, respectively, p=0.824). Onset of urge symptoms was reported by 10.3% of the patients, with no significant difference between the original and modified procedure groups (9.3% and 11.4%, respectively, p=0.752); whereas, approximately 70% of those with preoperative urgency/UUI experienced disappearance or improvement of these symptoms postoperatively, with no significant difference between the two groups (p=0.159). De novo voiding difficulties were reported by less than 10% of the patients in both groups (p=0.571). Comparisons of 1-year postoperative SUI, daytime frequency/nocturia, urgency/UUI, and obstruction symptom scale scores showed no significant difference between the original and modified TVT-O procedure groups (Table 4). Uroflowmetry data demonstrated a similar maximal flow rate (Qmax) and PVR between both groups (p=0.567 and 0.790, respectively). Analysis of the QoL questionnaire showed a similar improvement in QoL (p=0.830).

Adverse events

No intraoperative complication occurred. After catheter removal, two patients presented with a clinically significant

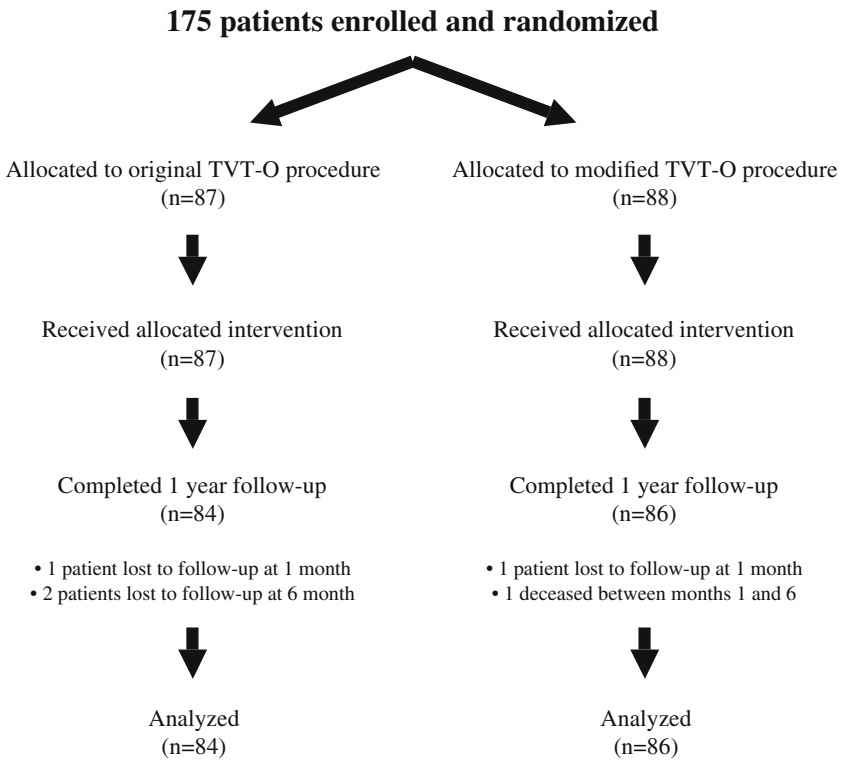


Fig. 3 Flow diagram showing the progress of patients throughout the trial

PVR. One of the patients in the original procedure group underwent placement of a suprapubic catheter. Another patient, who had undergone the modified procedure, underwent an immediate tape release procedure. At the 1-year visit, these two patients were cured of SUI without any PVR and with no de novo urge symptoms. One patient who had undergone the original procedure developed a sub-urethral vaginal exposure of the mesh, requiring partial tape excision. No other complications were observed during follow-up. One hundred and sixty eight patients (96%) were discharged, as planned, on the day after surgery. Seven patients were discharged later (range, day 2–4 postoperatively) for reasons not related to the surgical procedure in three patients and because of a significant postoperative PVR in four patients.

Postoperative pain

Postoperative evolution of groin pain is shown in Fig. 4. Overall, the percentage of patients who reported postoperative groin pain (either unilateral or bilateral) differed significantly between the two procedures on day 0 and day 1 ($p=0.003$ and $p=0.011$, respectively), but not thereafter (Fig. 4, panel a). On day 0, 65.9% and 42.0% of the patients in the original and modified procedure groups experienced groin pain, respectively. One day postoperatively, respectively 59.1% and 39.8% of the patients in the two groups reported such symptoms. These differences were observed at both the left and the right groin on day 0 and day 1 (Fig. 4, panel b). The percentage of patients with severe groin pain, arbitrarily defined as a VAS score$\geq$5, was also significantly higher in the original procedure group than in the modified procedure group on day 0 and day 1 while no severe groin pain was reported at the 6- and 12-month visits (Fig. 4, panel c). At the 12-month visit, approximately 3–4% of the patients in each group still reported groin pain, which was scored $\leq$3 on the VAS in all cases. It must be noted that none of these patients were complaining of this pain spontaneously, only after inquiring about it. Overall, mean groin pain intensity at either groin side was significantly higher after the original procedure than after the modified procedure on day 0 and day 1, but it did not differ during the follow-up visits at month 1, 6, and 12 (Fig. 4, panel d).

A greater portion of patients who had undergone the original TVT-O procedure required increased analgesia in the immediate postoperative period as opposed to those who had had the modified procedure (Fig. 5). A significant difference could only be found for class I analgesics (oral paracetamol), however (Fig. 5, panels a and b). Less than 20% of the patients required class II and less than 10% class III analgesics. None of the patients required morphine.

Regarding pain symptoms at other sites than groins, ten (11.5%) and nine (10.2%) patients who had undergone the original and modified procedure, respectively, experienced pain at different locations, including the lumbar spine, the hips, and vaginally.

Table 2 Baseline patients' characteristics

	Original TVT-O	Modified TVT-O	*P* value
Age (years)	60.0±11.7 (33–82)	57.2±12.7 (32–85)	0.097
BMI (kg/m^2)	26.4±4.8 (20.2–42.9)	26.8±5.3 (18.6–48.3)	0.753
Parity	2.1±1.3 (0–7)	2.5±1.4 (0–9)	0.099
Previous surgery			
For SUI	4 (4.6%)	4 (4.5%)	0.987
For POP	4 (4.6%)	2 (2.3%)	0.398
Hysterectomy	21 (24.1%)	20 (22.7%)	0.826
Previous pelvic irradiation	1 (1.1%)	2 (2.3%)	0.567
Previous physiotherapy	40 (45.9%)	43 (48.9%)	0.702
Patients reporting sport activities	30 (34.5%)	28 (31.8%)	0.708
Symptom scale scoring			
SUI (/8)	6.6±0.9 (4–8)	6.5±1.0 (4–8)	0.460
Urgency/UUI (/8)	2.8±2.6 (0–8)	3.0±2.8 (0–8)	0.521
Daytime frequency/nocturia (/8)	0.9±1.4 (0–8)	1.2±1.5 (0–5)	0.273
LUTS suggestive of bladder outlet obstruction (/4)	0.1±0.3 (0–1)	0.0±0.1 (0–1)	0.429
Urodynamic parameters			
Qmax (mL/s) #	25.7±11.6 (8.0–67.4)	29.1±12.5 (9.1–81.0)	0.140
Qmax≤10 mL/s	5 (5.7%)	3 (3.4%)	0.496
MUCP (cm H_2O)	58.1±28.6 (18–222)	61.1±25.0 (13–133)	0.329
MUCP≤20 cm H_2O	3 (3.4%)	3 (3.4%)	0.989
MUCP≤30 cm H_2O	9 (10.3%)	6 (6.8%)	0.405
PVR (mL)	11.8±24.4 (0–100)	7.4±18.5 (0–100)	0.147
Quality of life scale scoring			
Impact of urinary symptoms on QoL (from 10 to 50)	32±8 (15–48)	30±7 (14–46)	0.146
Type of anesthesia			
Spinal	62 (71.3%)	60 (68.2%)	0.657
General	25 (28.7%)	28 (31.8%)	

Values are given as mean±SD (range) and *n* (%)

BMI body mass index, *SUI* stress urinary incontinence, *UUI* urge urinary incontinence, *MUCP* maximal urethral closure pressure, *PVR* post void residual, *Qmax* maximal flow rate, *QoL* quality of life, *LUTS* lower urinary tract symptoms

Table 3 Postoperative evolution of urinary symptoms at the 1 year follow-up visit

Symptom	SUI		Urgency/UUI		Frequency[a]		Obstruction[b]	
	Original TVT-O	Modified TVT-O	Original TVT-O	Modified TVT-O	Original TVT-O	Modified TVT-O	Original TVT-O	Modified TVT-O
Disappearance	91.7% (77/84)	90.7% (78/86)	70.7% (29/41)	66.7% (28/42)	77.8% (8/9)	82.3% (14/17)	85.7% (6/7)	100.0% (2/2)
Improvement	3.6% (3/84)	7.0% (6/86)	4.9% (2/41)	2.4% (1/42)	11.1% (1/9)	0.0% (0/17)	0.0% (0/7)	0.0% (0/2)
No change	4.8% (4/84)	2.3% (2/86)	24.4% (10/41)	31.0% (13/42)	11.1% (1/9)	17.6% (3/17)	14.3% (1/7)	0.0% (0/2)
Worsening	0.0% (0/84)	0.0% (0/86)	0.0% (0/41)	0.0% (0/42)	0.0% (0/9)	0.0% (0/17)	0.0% (0/7)	0.0% (0/2)
Onset	Not applicable	Not applicable	9.3% (4/43)	11.4% (5/44)	4.0% (3/75)	2.9% (2/69)	9.1% (7/77)	8.3% (7/84)

[a] Includes daytime frequency and nocturia

[b] Represents lower urinary tract symptoms suggestive of bladder outlet obstruction

Table 4 Comparison of 1-year postoperative urinary symptom scores, voiding parameters, and quality of life scale scores 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
Daytime frequency/nocturia (/8)	0.4±1.0 (0–5)	0.4±0.9 (0–4)	0.400
LUTS suggestive of bladder outlet obstruction (/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/s)[a]	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

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

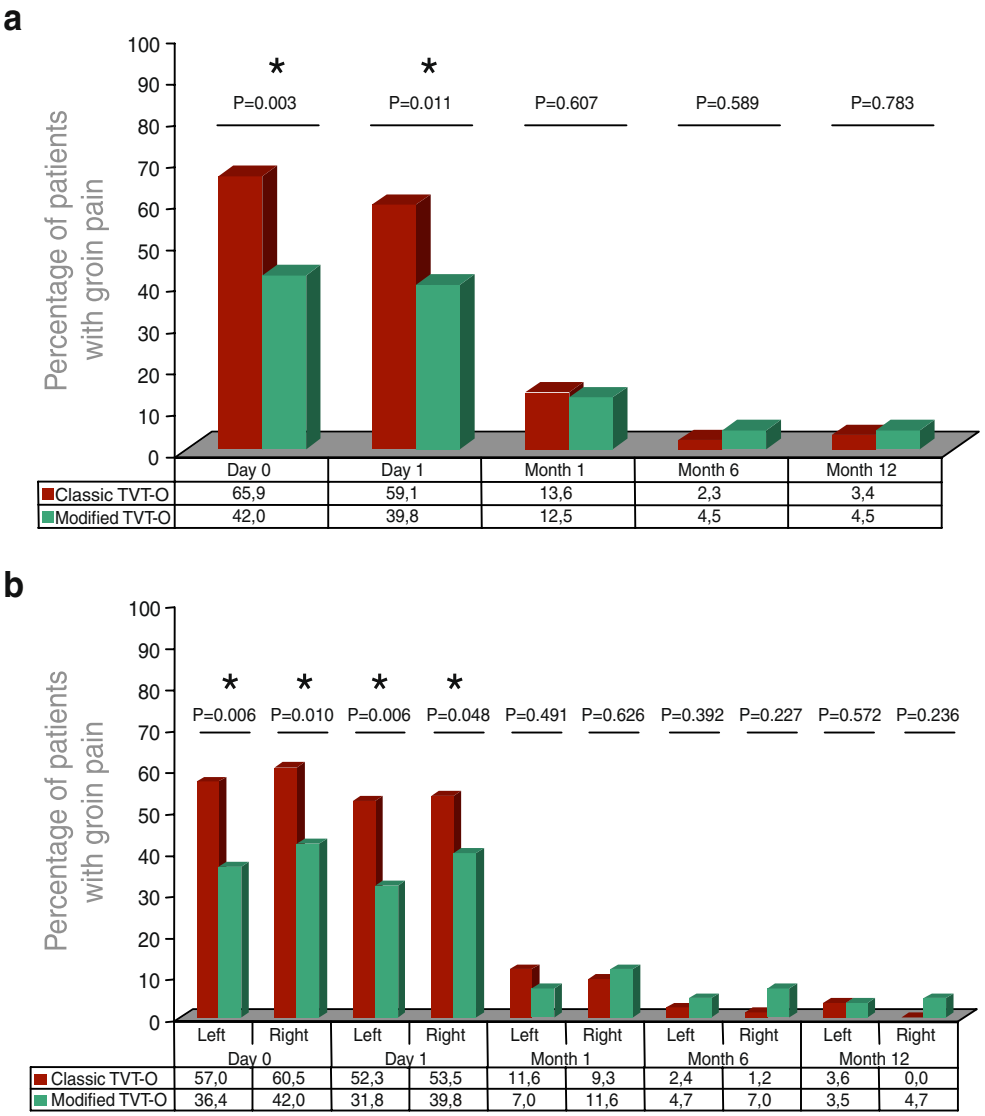
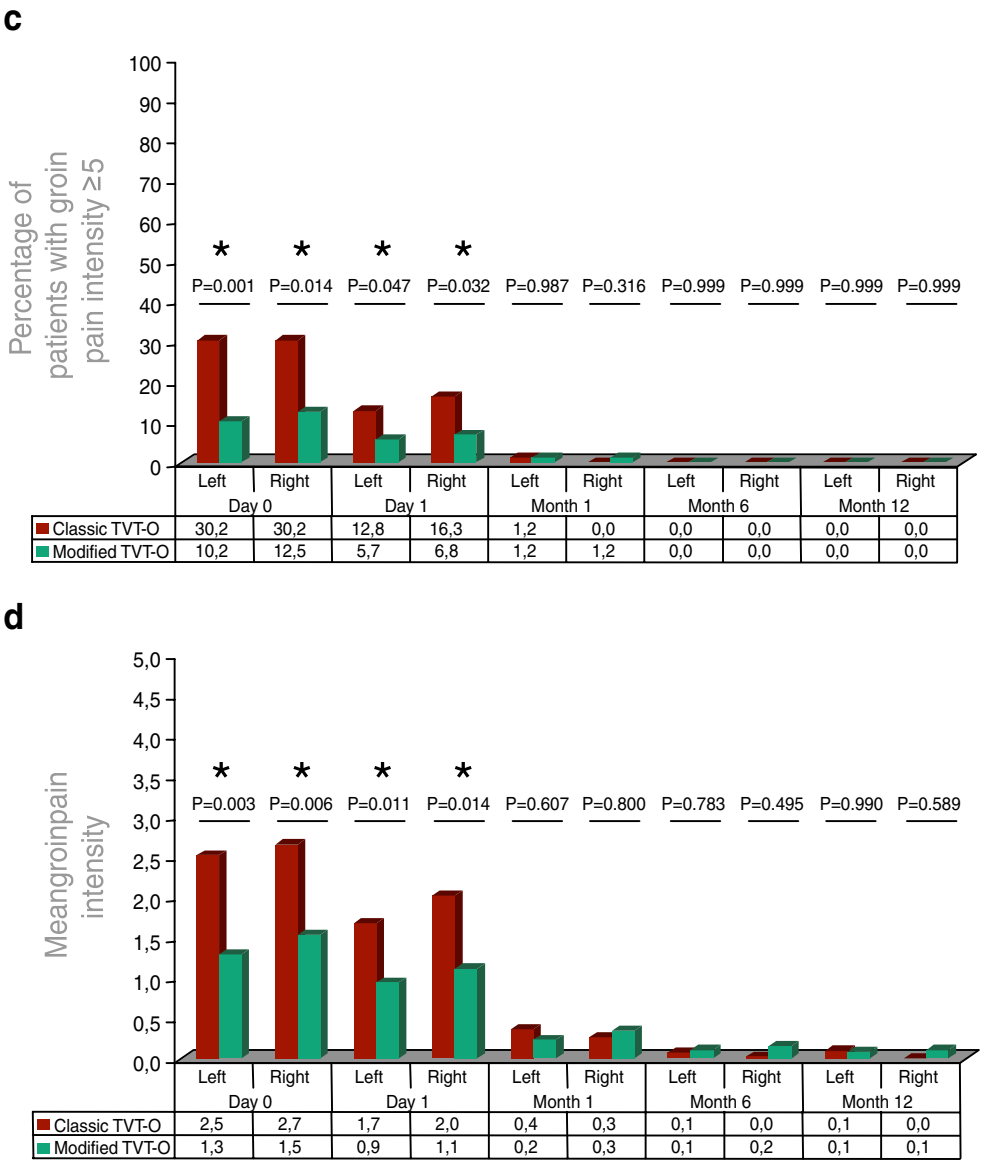


Fig. 4 Postoperative groin pain incidence and intensity after the original and modified TVT-O procedures. Patients were asked to self-evaluate groin pain intensity at either side using a VAS graded from 0 to 10, with 0 corresponding to the absence of pain and 10 corresponding to the worst pain. Groin pain was assessed on the evening of the day of surgery (D0), on the morning of the day after surgery (D1), and at month 1, 6, and 12. *Asterisks* show significant *p* values (<0.05)

Fig. 4 (continued)



Discussion

In the current study, a modified inside-out transobturator procedure was compared with its original version for the surgical treatment of SUI. Shortening of the tape to a length of 12 cm was based on preclinical anatomical works using cadavers to determine the trajectory of the shortened tape in the various muscular/aponeurotic structures at the obturator/groin level (Bonnet P. et al., manuscript submitted). The shortened tape was found to be consistently traversing all relevant tissue planes that are thought to be critical for providing initial fixation force, namely the internus and externus obturator muscles together with the obturator membrane, with no or only a minimal amount of tape lying in the adductor magnus muscle. The 12-cm length of the tape seemed sufficient to overarch the distance between both obturator membranes, taking into account the variability in the bony architecture of the obturator foramen and pubic arch of the female pelvis [26]. Since the shortened tape traversed less muscular structures (i.e., adductor muscles), we felt it was mandatory to reduce the depth of the lateral dissection by avoiding perforation of the obturator membrane with the scissors or the guide, hypothesizing that this would lead to an increased securing of the tape within the obturator membrane and muscles.

The most important finding of this study was the equivalent cure rate for SUI after 1 year between patients who had undergone either the original or the modified TVT-O procedure. In addition, the favorable evolution observed for other urinary symptoms, including urgency and dysuria, was similar in both groups. There were no differences in QoL scores and uroflowmetry data. These

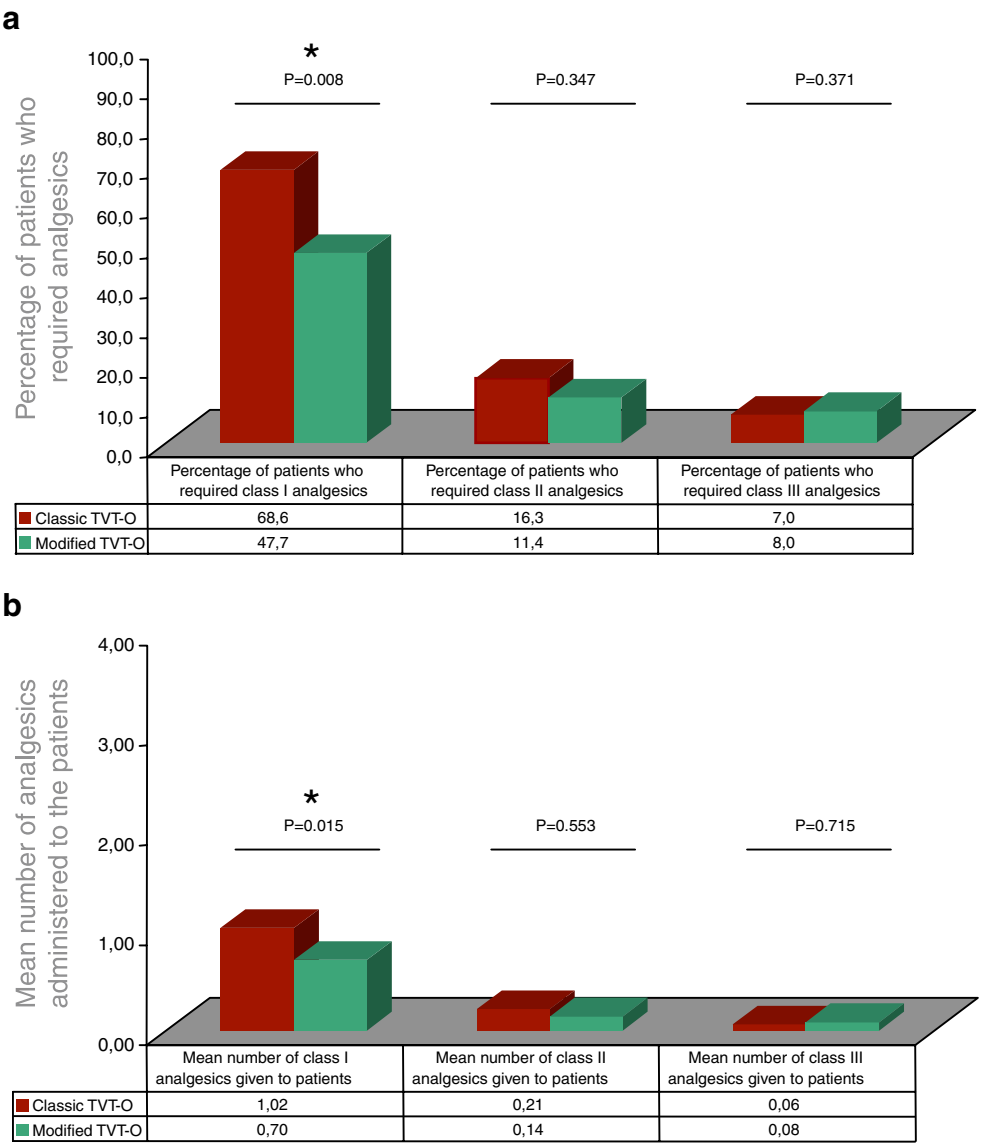


Fig. 5 Postoperative requirement of analgesia after the original and modified TVT-O procedures. Refer to the "Material and methods" section for details on the patient's on-demand analgesia protocol. Class I analgesics: paracetamol, class II analgesics: tramadol; class III analgesics: diclofenac. *Asterisks* indicate significant *p* values (<0.05)

data suggest that bilateral fixation of a shortened tape in the obturator muscles and membrane via a reduced dissection tract has no deleterious effect on the efficacy of the original procedure. Overall, the results of this trial 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. Obviously, our data originating from a single-center, single-surgeon, randomized study should be repeated in a multi-center multi-surgeon context for external validation.

No difference in complication rates was observed between the original and modified TVT-O procedures. It must be acknowledged, though, that since the TVT-O procedure has already been associated with a low rate of postoperative complications, as shown here and in previous studies [3], a much larger population of patients would need to be assessed in order to detect potential differences. Nevertheless, the present data corroborated our preclinical anatomical findings showing an equally safe anatomical trajectory of the tape in the modified technique, as compared with the original one (Bonnet P. et al., manuscript submitted).

It was hypothesized that the reduced dissection and mesh load of the modified TVT-O procedure could decrease postoperative pain sensation at the level of the groins. In the current trial, the incidence and intensity of groin pain was significantly higher in the group of patients who underwent the original procedure, but only on day 0 and day 1, and patients in this group required more analgesics. At this time, the clinical relevance of this finding remains undetermined. Indeed, one may argue that little added clinical value could be expected from a ±20% reduction in the incidence of overall or severe postoperative pain, or

from a reduction of ±1 point in the mean pain intensity score during the first 24 h postoperative. Similarly, even though less analgesia was required by patients in the modified procedure group, this was only the case for class I analgesics, with a mean difference of no more than 300 mg of paracetamol per patient. It is also worth mentioning that postoperative pain severity and incidence may be influenced by the anesthesia and analgesia protocols. In this study, ±70% of the patients were operated upon under spinal anesthesia and a standardized analgesia protocol was followed. Whether the differences in postoperative pain found herein would also be observed in trials incorporating other regimens of analgesia or anesthesia (e.g., local+sedation) or different patient populations (e.g., women with a small pelvis bony frame) will require further trials.

Conclusions

At 1 year follow-up, our modified inside-out transobturator tape procedure was as safe and efficacious as the original TVT-O, but associated with less immediate postoperative groin pain.

Conflicts of interest Jean de Leval and David Waltregny are consultants for Ethicon. The University of Liège owns the TVT-O patent. All authors declare that no funding or other agreement has limited their ability to fairly complete and publish this research study. There has been no extra-institutional funding for this study. David Waltregny had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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