INTERNATIONAL JOURNAL OF UROLOGY

International Journal of Urology (2012) doi: 10.1111/j.1442-2042.2012.03117.x

Original Article

Comparison of two inside-out transobturator suburethral sling techniques for stress incontinence: Early postoperative thigh pain and 3-year outcomes

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Abbreviations & Acronyms
dL = de-Leval
F = Flam
ICS = International Continence Society
NS = not significant
Pts = patients
TVT = tension-free vaginal tape
USI = urinary stress incontinence
UTI = urinary tract infection
VAS = visual analog score

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Received 28 February 2012; accepted 17 July 2012.

Objectives: Inside-out tension-free vaginal tape obturators for the cure of female stress incontinence can cause postoperative thigh pain. The aim of the present study was to analyze and compare the mid-term outcomes of two tension-free vaginal tape obturator procedures.

Methods: Patients diagnosed with urinary stress incontinence were enrolled to undergo a tension-free vaginal tape obturator sub-mid urethral tape operation either by de-Leval's method or by Flam's modification. Peri- and postoperative data were collected by uninvolved researchers and analyzed. Follow up was 36 months.

Results: Overall, 161 patients were included in the study. Cure and complication rates were similar between the two treatment groups. Postoperative thigh pain was significantly more frequent and lasted longer in the de-Leval group compared with the Flam group (31.9% *vs* 10.0%, respectively). Urinary urgency was more frequent in the de-Leval patients (20.3% *vs* 2.8%).

Conclusion: Our findings suggest that both tension-free vaginal tape obturator procedures are effective with few adverse effects. The Flam method provides shorter and decreased levels of postoperative thigh pain, as well as reduced long-term postoperative urinary urgency.

Key words: inside out, suburethral sling, thigh pain, transobturator, urinary stress incontinence.

Introduction

TVT obturator is a surgical procedure for the treatment of female USI. The operation, described by de-Leval in 2003,[1] is based on transobturator placement of a midurethral Prolene supportive tape, and is now accepted worldwide. The TVT-obturator was designed to overcome some operative complications associated with the retropubic TVT,[2–4] the first version of the sub-mid urethral sling procedure. The complications included bladder penetration, postoperative urinary outlet obstruction, bowel penetration, and intraoperative and postoperative bleeding.[5–8] These complications resulted from the retropubic needle passage, proximal to the bladder, bowel and blood vessels. The TVT-obturator was found by some to be less invasive, with high success rates and low complication rates; it therefore became very popular. Nevertheless, some women developed postoperative thigh pain after TVT-obturator surgery.[9–11]

The TVT-obturator Flam[12] modification is a medial deviation of the de-Leval surgical needle pass. Instead of passing tangentially through the central part of the obturator membrane and muscles, it is inserted perpendicularly, through the medial section of these structures (Figs 1,2). This was designed with the purpose of causing less tissue damage, by being remote from the obturator nerve, thereby reducing postoperative thigh pain. The

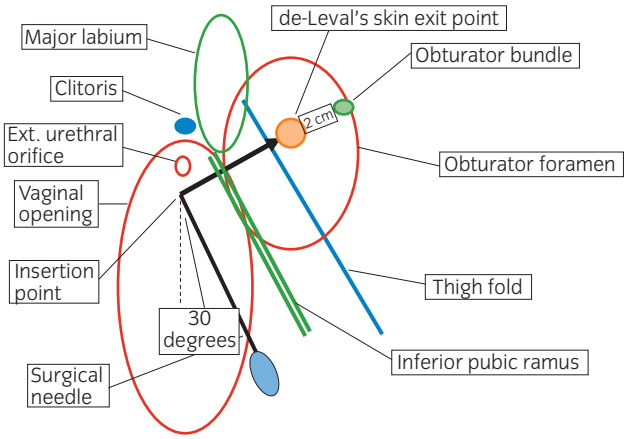

Fig. 1 de-Leval's TVT-obturator technique.

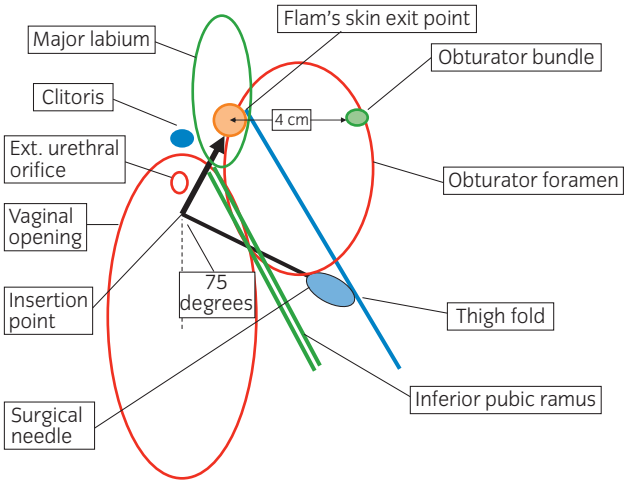

Fig. 2 Flam's TVT-obturator technique.

present study aimed to analyze and compare the mid-term outcomes of two minimally invasive anti-incontinence TVT-obturator procedures.

Methods

The study was designed as an open, non-randomized, two-armed study comparing two inside-out TVT-obturator surgical procedures for the treatment of female USI: the de-Leval (Fig. 1) and the Flam (Fig. 2) methods. The primary outcome measure was the early postoperative pain occurrence. The secondary outcome measures for the present study were the overall cure rates and surgery-related adverse effects for these two operations with 36-month follow up.

Given that the previously reported cure and complication rates with these two surgical procedures were similar, the sample size calculation was based on reports showing 25% significant postoperative pain with the TVT-obturator.[9,10] A total of 80 patients were required in each arm to detect a 20% increase at the postoperative pain rate, with 80% power and 95% confidence (0.05 significance).

The de-Leval patients group was also compared separately with a previous patient group undergoing TVT-SECUR (Ethicon; JNJ, Somerville, NJ, USA).[13] The study was approved by the institutional review board (Helsinki committee). The inclusion criterion was the diagnosis of urinary stress incontinence, based on the patient's personal history and a positive cough test. Exclusion criteria included the patient's refusal to participate, connective tissue disorders or the need for concomitant surgery other than colporrhaphy. The study patients were provided with detailed relevant information before their signing the consent form. They were then asked to choose between either the de-Leval or Flam methods of the TVT-obturator as the anti-incontinence operation. All patients were given 1 g monocef (Cefonicid; Beecham Healthcare, Middlesex, UK) intravenously 1 h before surgery. They all underwent an iodine antiseptic vaginal wash before the surgery. The mode of anesthesia depended on the patient's request. Urinary bladder catheterization, intraoperative cough test or diagnostic cystoscopy were not routinely carried out. Patients presenting with symptomatic vaginal wall relaxation with extra-hiatal bulging had anterior and/or posterior colporrhaphies, concomitant with the anti-incontinence surgery. The TVT-obturator surgical needle was inserted using the technique described by de-Leval[1] for the de-Leval patients group and by Neuman[12] for the Flam patients group. Patients were followed up at 1, 6 and 12 months after surgery, and yearly thereafter. All operations were carried out by a single surgeon at a university hospital and a private hospital; the first 50 operations with each method were not included.

Data were collected from patients' charts, by researchers not involved with the patients' care. Subjective data regarding urgency, frequency, stress and urge incontinence of urine and feces, voiding habits, and bulging were recorded using the validated Urogential Distress Inventory and Incontinence Impact Questionnaire completed by the patients and according with the terminology of the International Continence Society, International Urogynecology Association standardization committee regarding prolapse and incontinence. Postoperative pain was assessed with VAS at the first postoperative month follow-up meeting. Objective outcome was assessed by pelvic examination and cough test with filled bladder according to the standard ICS terminology. Operative outcome was graded as follows: "cure" – when there was no leakage at all; "improvement" – when the leakage was significantly reduced and patients did not request further treatment; and "failure" – when there was inadequate improvement. Normally distributed continuous data were described using the means and standard deviations, resorting to the median and interquartile range for those not fitting a normal distribution. Categorical data were described using numbers and percentages.

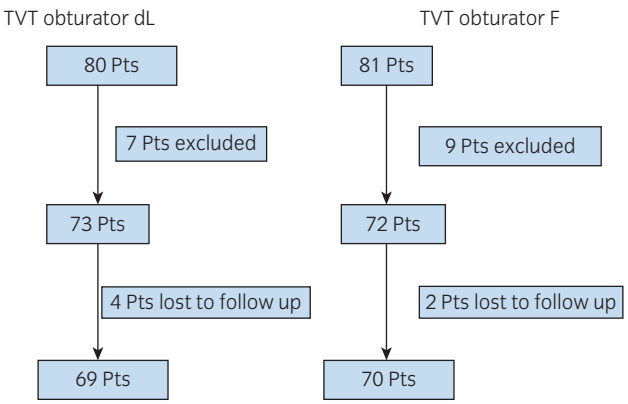

Fig. 3 Patients flowchart.

All statistical analyses were carried out using SPSS 18 (IBM Corporation, Somers, NY, USA). The Student's *t*-test was used for comparison of quantitative variables between groups, whereas the χ^2-test or Fisher's exact test were used to compare categorical variables between groups. The McNemar test was used for longitudinal data comparison. All statistical tests were evaluated at the $P = 0.05$ level of significance.

Results

A total of 161 patients suffering from USI were referred for corrective surgery over a period of 2 years. Seven patients who underwent the TVT-obturator de-Leval procedure (8.8%) and nine patients undergoing the TVT-obturator Flam procedure (11.1%) were excluded from the study because of their refusal to participate, the need for additional operations concomitantly or the presence of connective tissue disorders. The study patients either failed or refused pelvic floor rehabilitation physical therapy.

The patients' personal characteristics preoperatively showed no statistical differences between the two groups. Age, parity, menopause, bladder over-activity, previous anti-incontinence surgery and the presence of chronic illnesses were similar for the two patient groups. There was no difference between the groups with regard to the operative details, including the length of the procedure, the need for concomitant colporrhaphy and the mode of anesthesia: more than 95% required general anesthesia. Operative injuries and cure rates, as well as postoperative complication rates, were similar in the two groups. The only statistically significant differences between the groups were the postoperative pain levels and duration, as well as the occurrence of postoperative urinary urgency (Fig. 3 and Tables 1,2). Thigh pain occurred more frequently and lasted longer with TVT-obturator de-Leval than with Flam (31.9% *vs* 10% and 14.5% *vs* 2.8%, respectively). Thigh pain was self-limited and lasted no longer than 2 weeks. Urinary urgency, according to the ICS terminology, occurred in women who underwent the de-Leval operation more frequently than those who had the Flam operation (20.3% *vs* 2.8%). One patient in the Flam group, suffering from dyspareunia, required segmental tape removal for pain relief; this was carried out under general anesthesia 3 months after the primary operation.

Four patients in the TVT-obturator de-Leval group (5.4%) and two in the Flam group (2.6%) were lost to follow up (Fig. 3). This patient dropout was previously reported not to alter the study's results or the conclusions.[14]

No events of operative bleeding or postoperative surgical field infection were documented. One event of tape exposure in the TVT-obturator de-Leval group was treated successfully in the office by simple removal of the extruded mesh segment. Patients who experienced therapeutic failure were evaluated by urodynamic tests, ultrasound scan and cystoscopy, and were then offered to undergo tape tightening by a TVT readjustment[15] procedure. Early postoperative partial urinary outlet obstruction, leading to increased residual bladder volume (>150 mL), occurred in six patients – four in the TVT-obturator de-Leval group (5.5%) and two in the Flam group (2.8%). This was treated with intermittent bladder catheterization for up to 1 week. Complete obstruction occurred in three patients (two from the de-Leval group and one from the Flam group), and was treated up to 1 week after primary surgery in the operating theater by release of the tape tension (Tables 3,4).[16]

Discussion

The main finding of the present study was that both the TVT-obturator de-Leval and the TVT-obturator Flam techniques achieved similar urinary incontinence mid-term cure rates and similar rates of adverse effects. The study was open with two comparable patient groups and 36-month follow up.

However, the primary outcome measure, namely the incidence and duration of postoperative thigh pain, differed significantly between the two patient groups. The incidence of postoperative pain in the TVT-obturator de-Leval group was statistically significantly higher and lasted longer than in the Flam group. The pain was located in the thigh, lasted for up to 2 weeks, responded well to oral analgesics and resolved spontaneously. There is no clear explanation for the TVT-obturator de-Leval-related pain and its subsequent disappearance, as there is usually no overt nerve injury. It might possibly be as a result of tissue damage at the central obturator region radiating to the thigh, with subsequent spontaneous healing and recovery. This is thought to be more frequent with the inside-out approach, yet it might also occur with the outside-in method. The here reported findings are in accordance with previous publications reporting up to 18% postoperative thigh pain in TVT-obturator de-Leval patients. The pain usually lasted for up to 1 week and was

Table 1 Patient characteristics

	TVT-obturator dL ($n = 73$)	TVT-obturator F ($n = 72$)	*P*-value
Age (mean and standard deviation)	55 (11.8)	59 (10.2)	NS
Parity (mean and standard deviation)	2.8 (1.0)	3.1 (1.7)	NS
USI duration (mean and standard deviation)	3.8 years (4.8)	2.9 years (3.1)	NS
Urgency	28 Pts (38.4%)	14 Pts (19.4%)	NS
Frequency	24 Pts (32.9%)	16 Pts (22.2%)	NS
Nocturia	19 Pts (26.0%)	9 Pts (12.5%)	NS
Cystocele	51 Pts (69.9%)	57 Pts (79.2%)	NS
Rectocele	35 Pts (47.9%)	51 Pts (70.8%)	NS
Previous USI corrective surgery	3 Pts (4.1%)	5 Pts (6.9%)	NS
Previous hysterectomy	8 Pts (11.0%)	11 Pts (15.3%)	NS
Background chronic Illness†	9 Pts (12.3%)	13 Pts (%)	NS

†Diabetes mellitus, hypertension, bronchial asthma, breast cancer.

Table 2 Operative details

	TVT-obturator dL ($n = 73$)	TVT-obturator F ($n = 72$)	*P*-value
Sling operative time (mean and range)	17 min. (12–27 min.)	18 min. (11–23 min.)	NS
Total operative time (mean and range)	31 min. (25–42 min.)	29 min. (23–37 min.)	NS
Concomitant Anterior colporrhaphy	51 Pts (69.9%)	37 Pts (51.4%)	NS
Concomitant Posterior colporrhaphy	35 Pts (47.9%)	25 Pts (34.7%)	NS

Table 3 Intraoperative and early postoperative complication rates

	TVT-obturator dL ($n = 73$)	TVT-obturator F ($n = 72$)	*P*-value
Bladder, bowel and/or urethral injury	0 Pts (0.0%)	0 Pts (0.0%)	NS
Operative bleeding >100 mL	0 Pts (0.0%)	0 Pt (0.0%)	NS
Vaginal mesh protrusion	1 Pt (1.4%)	0 Pts (0.0%)	NS
Operative field Infection	0 Pts (0.0%)	0 Pts (0.0%)	NS
Early voiding difficulties	4 Pts (5.5%)	2 Pts (2.8%)	NS
Postoperative UTI	1 Pt (1.4%)	1 Pt (1.4%)	NS

rarely permanent.[9,10] The TVT-obturator Flam surgical needle has previously been shown to be remote from the obturator nerves on cadaver studies,[12] which might go some way to explaining the reduction in pain.

Urinary urgency occurred more frequently in patients having the de-Leval operation than in patients treated with the Flam operation; we were unable to account for this finding.

Common complications of former retropubic open operations for the treatment of USI, such as pelvic and abdominal organ injury and bladder penetration, are rare with the use of the TVT-obturator,[8] as the tape introducers do not cross the retropubic area.

The operative times, need for concomitant colporrhaphy, and early and late postoperative complications were similar in the two study groups. The 3-year follow-up data presented here for both the TVT-obturator methods agree in general with the previously reported efficacy, in terms of cure, and intra- and postoperative complication rates.[8] Although diagnostic cystoscopy was not used in the study patients, we assumed that no bladder perforation occurred in these study patients, as no signs suggestive of bladder perforation (e.g. urinary leakage through surgical vaginal cuts) were recorded. Neither the TVT-obturator de-Leval nor the TVT-obturator Flam were associated with postoperative field infection nor significant intraoperative

Table 4 Operative outcome

	TVT-obturator dL (n = 69)	TVT-obturator F (n = 70)	P-value
Early postoperative thigh pain			<0.014
VAS >3	22 Pts (31.9%)	7 Pts (10.0%)	
VAS >6	0 Pts (0.0%)	0 Pts (0.0%)	
Pain duration >10 days	10 Pts (14.5%)	2 Pts (2.8%)	<0.001
USI cure	60 Pts (87.0%)	60 Pts (85.7%)	NS
USI marked improvement	2 Pts (2.9%)	2 Pts (2.8%)	NS
Operative failure	7 Pts (10.1%)	4 Pts (5.6%)	NS
Postoperative urgency	14 Pts (20.3%)	2 Pts (2.8%)	<0.006
Postoperative frequency	9 Pts (13.0%)	4 Pts (5.6%)	NS
Postoperative nocturia	14 Pts (20.3%)	6 Pts (8.6%)	NS
Postoperative dyspareunia	0 Pts (0.0%)	1 Pt (1.4%)	NS

bleeding. The present study was markedly weakened because of being non-randomized.

The data reported here show that both procedures have satisfactory cure rates and low complication rates. Stress urinary incontinent patients might benefit from the TVT-obturator Flam operation because of the low incidence and durability of postoperative thigh pain, as well as for the reduced rate of postoperative urinary urgency.

Conflict of interest

Menahem Neuman was a consultant to Gynecare. All other authors have no conflict of interest.

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