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Peri-Operative Complications and Pain After the Suburethral Sling Procedure for Urinary Stress Incontinence: A French Prospective Randomised Multicentre Study Comparing the Retropubic and Transobturator Routes[☆]

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Abstract

Objective: To compare peri-operative complications, pain, and the immediate functional results of the sub-urethral sling procedure for urinary stress incontinence by the retropubic and transobturator routes, using a non-elastic polypropylene sub-urethral sling.

Patients and Methods: This prospective, multicentre study involved 88 women undergoing the sub-urethral sling procedure for stress urinary incontinence (SUI). The retropubic route (RPR) and the transobturator route (TOR) were used in respectively 42 and 46 cases. The characteristics of the women in the RPR and TOR groups were as follows: mean age (±standard deviation) 56.8 ± 12 years and 53.4 ± 10 years, respectively; mean BMI: 25 ± 4 and 26 ± 4; mean parity: 2.1 ± 0.9 and 2 ± 1 children; post-menopausal status: 66.7% and 58.7%; prior surgery for SUI: 7.1% and 6.5%; and prior hysterectomy: 21.4% and 26.1%. None of these characteristics differed significantly between the groups. Likewise, pre-operative urinary functional status (SUI stage, and pollakiuria, nocturia and urgency rates) was similar in the two groups.

Results: Mean hospital stay and overall morbidity rate were not significantly different between the RPR and TOR groups. Mean operating time was longer in the RPR group. Bladder injury was significantly more frequent in the RPR group and vaginal injury was significantly more

frequent in the TOR group. Pain scores were significantly lower in the TOR group. The objective functional results at one month did not differ between the groups. Quality of life, evaluated with questionnaires and numerical rating scales, was similarly improved in the two groups.

Discussion: The suburethral sling procedure was less painful by the TOR route than by the RPR route. Bladder injury, haematomas and abscesses were only observed in the RPR group, while vaginal injury only occurred in the TOR group. The immediate functional results of the two approaches were similar.

1. Introduction

Since the first description of the tension-free vaginal tape (TVT) procedure by Ulmsten et al. in 1996, using an elastic polypropylene tape (TVT^{TM}, Gynecare) for the treatment of female stress urinary incontinence (SUI) [1], TVT has become one of the most popular procedures worldwide for the treatment of SUI, owing to its high long-term success rate [2]. However, potential immediate surgical complications include bladder perforation [3], and injury to the pelvic vessels [4], bowel [5,6] and ilioinguinal nerve [7]. Moreover, *de novo* urge incontinence and voiding dysfunction may occur following over-correction associated with the retropubic approach and/or the use of elastic polypropylene tape [3].

In 2001, Delorme et al. advocated the use of the transobturator route in order to avoid the complications associated with the retropubic route [8]. Insertion through the obturator and puborectalis muscles reproduces the natural suspension fascia of the urethra while preserving the retropubic space. In a preliminary study, Delorme showed that the transobturator route was associated with a high success rate, no bladder injury, and few peri-operative complications in women with urinary incontinence [8]. These results were recently confirmed in a large series of women, using non-elastic polypropylene tape [9]. Salomon et al. [10] also used the transobturator route for anterior vaginal wall prolapse repair, and confirmed its safety in terms of vessel and bladder injury. The retropubic and transobturator approaches to SUI treatment have not been compared using the same polypropylene tape. The aims of this prospective randomised multicentre study were to evaluate post-operative pain, peri-operative complications, and the immediate functional outcome of the TVT procedure for SUI, using the same non-elastic polypropylene tape and comparing the retropubic and transobturator routes.

2. Population and methods

This prospective randomised multicentre study involved three gynaecology units and two urology units, and was conducted in France from March 2004 to May 2005. All the surgeons had lengthy experience with the retropubic route and had performed at least 30 procedures by the transobturator route. Women with SUI were randomised to undergo suburethral sling procedure by either the retropubic route (RPR) or the transobturator route (TOR), by using a predetermined computer-generated randomisation code. The ethics committee approved the study protocol, and all the women gave their written consent after receiving full information on the study.

The preoperative work-up included a standardised history and physical examination and a urodynamic evaluation. Urinary incontinence was classified as recommended by the International Consultation on Incontinence [11]. All the women completed validated questionnaires on quality of life (urinary distress impact questionnaire: UDI) [12], and on the social and emotional impact of SUI (incontinence impact questionnaire: IIQ) [12], before surgery, at the first post-operative visit (4–6 weeks after surgery), and 3, 6, 12 and 24 months postoperatively. This preliminary report describes only peri-operative complications, pain, and the immediate functional results evaluated at the first postoperative visit.

The I-STOP® device (CL Médical, Lyon, France) was used for both the RPR and the TOR procedure. The tape consists of macroporous (>75-micron pore size) non-elastic monofilament polypropylene mesh.

All the procedures were performed in the modified dorsal-lithotomy position. Blood pressure, the ECG and transcutaneous oxygen saturation were continuously monitored. The RPR procedure was performed as described by Ulmsten et al. [1] and the TOR procedure was performed as described by Delorme et al. [8]. The choice between general and regional anaesthesia was made in each centre. The prosthetic implant was placed under the midurethra. A vertical 15-mm vaginal incision was made 10 mm below the urethral meatus. Dissection of the para-urethral space on each side of the incision was performed with scissors, towards the ischiopubic ramus.

For RPR, ancillary was similar to that use for TVT procedure.

In the TOR approach, the needle of the device was introduced on each side through a 5-mm incision in the

Table 1 – Epidemiological characteristics of the study population

	RPR ($n = 42$)	TOR ($n = 46$)	p
Mean age ± SD (range)	56.8 ± 12 (32–78)	53.4 ± 10.5 (35–75)	0.18
Mean BMI ± SD (range)	25 ± 4 (19–34)	26 ± 4 (18–34)	0.47
Mean parity ± SD (range)	2.1 ± 0.9 (0–4)	2 ± 1 (0–5)	0.55
Nulliparity n (%)	1 (2.4)	3 (6.5)	0.35
Mean weight of first baby (g) ±SD (range)	3115.6 ± 840 (0–5900)	3134.2 ± 1068 (0–4700)	0.91
Macrosomia (≥4000 g) n (%)	5 (11.9)	6 (15.2)	0.53
Post-menopausal status n (%)	27 (66.7)	27 (58.7)	0.44
Prior surgery for SUI n (%)	3 (7.1)	3 (6.5)	0.91
Prior hysterectomy n (%)	9 (21.4)	11 (26.1)	0.45

SD: standard deviation, BMI: Body mass index, SUI: stress urinary incontinence, NS: not significant.

genito-femoral fold, on a horizontal line passing through the clitoric hood and facing the transobturator membrane. Initially, the needle was oriented perpendicularly through the subcutaneous space. Then, once the obturator membrane had been perforated, the needle was orientated downwards and inwards, in an oblique direction, to reach the finger inserted in the para-urethral space. The needle was exteriorised in the vagina and the tape was "clipped" to the needle tip and withdrawn through the genito-femoral incision.

Regardless of the route, tension-free tape adjustment was performed under the midurethra. Cystoscopy was always performed before vaginal and skin closure with resorbable sutures.

The procedure was timed from the vaginal incision to the last skin suture, including cystoscopy.

Intraoperative and immediate postoperative complications, febrile morbidity, pain (numerical rating scale: 0 = no pain, 10 = unendurable pain), and the postoperative hospital stay were systematically recorded. The women were discharged when the residual urine volume was <150 ml, and were seen again 4–6 weeks after surgery.

The power calculation used to estimate study size assumed that the incidence of de novo urge incontinence and immediate and late voiding dysfunction in patients after the sub-urethral sling procedure by retropubic route is 60%, and that this figure would be halved by using the transobturator route, with an α (type I) error of 0.05 and a β (type II) error of 0.2. On this basis it was necessary to recruit at least 40 women to each arm.

Statistical analysis was based on Student's t test and the Mann-Whitney test for parametric and non-normally distributed continuous variables, respectively, and the chi square test or Fisher's exact test, as appropriate, for categorical variables. $p < 0.05$ was considered to denote statistical significance.

3. Results

3.1. Epidemiological and urodynamic characteristics of the RPR and TOR groups

The epidemiological characteristics and surgical histories of the women in the RPR and TOR groups were not significantly different (Table 1). The preoperative SUI grades, and urinary symptoms

Table 2 – Pre-operative urinary symptoms and

Clinical parameters	RPR ($n = 42$)	TOR ($n = 46$)	p
Stage 1 (%)	8 (19)	6 (13.6)	
Stage 2 (%)	30 (71.4)	33 (72.7)	0.71
Stade 3 (%)	4 (9.5)	7 (13.6)	
Pollakyuria n (%)	19 (45.2)	19 (41.3)	0.71
Nocturia n (%)	17 (40.5)	14 (30.4)	0.52
Urgency n (%)	25 (59.5)	18 (39.1)	0.06

are shown in Table 2. Urodynamic parameters in the two groups are summarised in Table 3. There were no significant differences between the groups as regards the SUI grade distribution or the frequency of mixed incontinence, pre-operative pollakiuria, or nocturia. Pre-operative urinary urgency tended to be more frequent in the RPR group ($p = 0.06$). Pre-operative urodynamic parameters, including the urinary residual volume and bladder capacity, were similar in the two groups. Urethral closure pressure was lower in the RPR group ($p = 0.02$).

3.2. Operating time and peri-operative complications

The mean operating time was significantly longer in the RPR group. No difference in the postoperative urinary residual volume was noted. None of the women required bladder self-catheterisation postoperatively (Table 4).

Table 3 – Pre-operative urodynamic parameters

Urodynamic parameters	RPR ($n = 42$)	TOR ($n = 46$)	p
UCP (cmH$_2$O)	46 ± 22 (6–90)	60 ± 31 (23–144)	0.02
Residual urine volume (mL)	13 ± 40 (0–200)	11 ± 46 (0–300)	0.80
Bladder capacity (mL)	424 ± 99 (100–600)	436 ± 124 (150–811)	0.62
Mixed incontinence (%)	5 (11.9)	6 (13)	0.91

UCP: urethral closure pressure

Table 4 – Type of anaesthesia, operating time, and post-operative outcomes

	RPR (n = 42)	TOR (n = 46)	p
General anaesthesia n (%)	18 (42.9)	18 (39.1)	0.61
Mean operating time (min) ± SD (range)	21 ± 9.5 (10–50)	17 ± 6.6 (8–40)	0.03
Mean length of bladder catheterisation (days) ± SD (range)	1 ± 1 (0–5)	0.8 ± 0.5 (0–2)	0.07
Mean residual urine volume (mL) ± SD (range)	23 ± 45 (0–150)	28 ± 49 (0–150)	0.12

Table 5 – Intra- and post-operative complication and pain

Complications	RPR (n = 42)	TOR (n = 46)	p
Overall morbidity n (%)	8 (19)	5 (10.9)	0.28
Bladder injury n (%)	4 (9.5)	0	0.03
Vaginal injury n (%)	0	5 (10.9)	0.03
Haemorrhage (>200 ml) n (%)	2 (4.8)	0	0.13
Retropubic haematoma n (%)	2 (4.8)	0	0.13
Pelvic abscess n (%)	1 (2.4)	0	0.28
Post-operative pain (NRS)	2 ± 2 (0–7)	0.8 ± 1.4 (0–6)	0.0005

NRS: numerical rating scale

Intra- and postoperative complications and post-operative pain intensities are shown in Table 5. The overall complication rate was similar in the two groups. Vaginal injury was significantly more frequent in the TOR group than in the RPR group ($p = 0.02$), whereas the bladder injury rate was significantly higher in the RPR group ($p = 0.03$). No vascular, nervous or intestinal injuries occurred.

Two women had haematomas, complicated by an abscess in one case; all these complications occurred in the RPR group. The woman with the abscess was re-admitted and was treated with antibiotics; further surgery was not necessary.

Postoperative pain was less severe in the TOR group than in the RPR group ($p = 0.0008$) (Table 5).

The mean hospital stay in the RPR and TOR groups was $1.8 ± 1.7$ (1–8) and $1.4 ± 0.5$ (1–2) days, respectively (no significant difference).

3.3. Functional results and quality of life

The impact of surgery on urinary status at one month is shown in Table 6. The cure rate was similar in the two groups. Likewise, the rates of post-operative pollakiuria, nocturia and urinary urgency were not different between the groups.

The UDI questionnaire (Table 7) showed a significant improvement in both groups. The post-operative UDI scores did not differ between the groups.

Table 6 – Cure rates and voiding problems at the one-month postoperative visit

Symptoms n (%)	PRP (n = 42)	TOR (n = 46)	p
Dry	39 (92.9)	43 (93.5)	
Improved	2 (4.8)	1 (2.2)	0.71
Failed (unchanged or worsen)	1 (2.4)	2 (4.3)	
Post-operative pollakyuria	11 (26.2)	10 (21.7)	0.56
De novo pollakyuria	5 (11.9)	4 (8.7)	0.59
Post-operative nocturia	9 (21.4)	5 (10.9)	0.16
De novo nocturia	3 (7.1)	1 (2.2)	0.16
Post-operative urgency	13 (31)	11 (23.9)	0.42
De novo urgency (%)	2 (4.8)	4 (8.7)	0.48

Table 7 – Pre- and postoperative quality of life scores (UDI questionnaire) and social and emotional status (IIQ questionnaire)

	Pre-operative score Mean ± SD (range)	Post-operative score Mean ± SD (range)	p
UDI			
RPR	64.2 ± 54.3 (0–217)	5.4 ± 20.3 (0–127)	<0.0001
TOR	62 ± 53 (0–172)	5.7 ± 25.2 (0–133)	<0.0001
IIQ			
RPR	32 ± 57.6 (0–251)	0.6 ± 3.2 (0–20)	0.0006
TOR	25.7 ± 43.5 (0–168)	6.1 24.6 (0-153)	0.0002

The IIQ questionnaire (Table 7) also showed a significant improvement, with no significant difference between the groups.

4. Discussion

This prospective randomised study shows that the suburethral sling procedure by the transobturator route (TOR) is associated with less postoperative pain but a higher risk of vaginal injury than the retropubic route (RPR). In contrast, bladder injury was more frequent in the RPR group. The RPR and TOR routes gave similar rates of immediate success in the treatment of urinary incontinence.

The most striking finding is the lower post-operative pain scores among the women in the TOR group compared to those in the RPR group. These are the first comparative data on postoperative pain after the two procedures. In a study of 450 women, Duckett and Jain [13] reported that 1% of women had groin pain after the suburethral sling procedure by the retropubic route. In a series of 235 retropubic suburethral sling procedures, Bourrat et al. [14] found that post-operative pain impaired the quality of life of 30% of patients. Tsivian et al. [15]

reported that the most common complaint after the TVT procedure was persistent urethral pain. Barrington et al. [16] suggested that suprapubic pain directly over the iliopectineal ligaments ("post-colposuspension syndrome") after the TVT sling procedure was related to dense adherence to the iliopectineal ligaments. Persistent pain can be controlled by local injections of steroids plus local anaesthetics, but some women nonetheless require sling excision [14]. Few data are available on pain after the suburethral sling procedure by the trans-obturator route. In a preliminary study, Delorme et al. [8] reported no pain among women undergoing the transobturator procedure. Using I-stop tape and the transobturator route, Krauth et al. [9] observed cases of transient pain requiring anti-inflammatory drugs or minor analgesics, and also pain lasting two months after the procedure, but it should be noted that postoperative pain was not systematically evaluated. There is no clear explanation for the lower incidence of pain associated with the trans-obturator route. It is conceivable that differences in the nervous and venous anatomy lead to a lower risk of nerve injury and compression (due to haematomas) with the transobturator approach [17].

The overall complication rates associated with the TOR and RPR routes were similar in this study. Vaginal injuries were always located in the lateral fornix and only occurred in the TOR group. They were treated by simple suturing and healed without further consequences. Delorme et al. [8] did not report observing this complication. In contrast, Krauth et al. [9] reported a vaginal injury rate of 0.3% in a retrospective multicentre study. The high incidence of vaginal injury in our study may have been due to inadequate lateral dissection, needed to introduce the finger through vaginal incision and thus to guide the needle. Another potential explanation is the use of an outside-in transobturator procedure, requiring a downwards then inwards orientation of the needle in an oblique direction. In contrast, the inside-out procedure, beginning with needle placement behind the ischiopubic ramus, avoids initial vaginal perforation. Although Bonnet et al. [17] found that the tape placed by the inside-out route remained far from the dorsal nerve of the clitoris and from the obturator nerve and vessels in a study of 12 cadavers, further clinical studies are needed to evaluate the specific risks associated with this approach.

Bladder injury is the main concern when using the retropubic route for suburethral sling placement, with an incidence of up to 24% during TVT and SPARC procedures [3,18]. This complication is not always recognised during initial cystoscopy [19] and can be a source of late complications such as chronic pain and urinary tract infection requiring further surgery. No bladder injury occurred with the transobturator route in our study, tending to confirm that routine cystoscopy is not needed during the outside-in TOR procedure [20,21]. Nevertheless, bladder injury was recently reported after TOR suburethral sling placement [9,22].

The RPR route, contrary to the TOR route, was associated with complications such as haemorrhage, retropubic haematoma and pelvic abscess. Our data are in keeping with those of previous outside-in and inside-out TOR studies showing no bladder or urethral injuries and no vascular or neurological complications [23,24]. Our results for the retropubic route are also compatible with reported incidence rates of haemorrhage, suprapubic infection and haematoma of respectively 2.1% [25], 0.4% and 1.9% [26]. In contrast, in the largest published series of transobturator sling procedures [8], the incidence of haemorrhage and perineal haematoma was only 0.8% and 0.33%, respectively.

No cases of immediate postoperative dysuria or urinary retention were observed in our study, regardless of the route used. This was probably due to the non-elastic nature of the slings. Previous studies of TOR using non-elastic polypropylene slings also showed a low incidence of dysuria and retention (1.3% and 1.5%, respectively) [9,24]. In recent studies using elastic slings and the retropubic route, urinary retention occurred in up to 12.9% of cases [26,27]. Using elastic slings and the transobturator route, de Leval et al. [23] observed a retention rate of 2.8%, although voiding disorders were not routinely analysed.

The main aims of this study were to document pain, peri-operative complications and immediate functional results, and further follow-up is clearly required to determine long-term outcomes. However, it is noteworthy that the immediate cure rate was similar with the two approaches, and was in keeping with previously reported rates observed with suburethral slings [1,8]. Likewise, the rates of postoperative pollakiuria, nocturia and urinary urgency, and quality of life, were similar in the TOR and RPR groups. Previous studies of TVT procedures have shown high rates of de novo dysuria and urinary urgency (5% to 38% and 1% to 36%, respectively) [28,29]. Like us, Krauth et al. [9] observed low rates of de novo urinary urgency and dysuria, and suggested that these good results were attributable to the use of the transobturator route. In contrast, we consider that the main factor influencing immediate postoperative outcome is the use of non-elastic slings rather than the choice of route.

In conclusion, this prospective study shows that TOR is less painful than RPR. Bladder injury, haematoma and abscess formation were only observed in the RPR group, while vaginal injury only occurred in the TOR group.

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