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Sub-Urethral Tape Treatment of Female Urinary Incontinence—Morbidity Assessment of the Trans-Obturator Route and a New Tape (I-STOP®): A Multi-Centre Experiment Involving 604 Cases

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Abstract

Purpose: To make an assessment of the morbidity related to using the trans-obturator route (TOT); findings after one year for the 140 first cases and preliminary results of short term morbidity after 604 implants.

Patients and Method: This retrospective, multi-centre study involves the 604 first procedures with a 1–3 month follow-up. The mean patient age was 57 years. 92% of the patients underwent an isolated urinary incontinence cure and 8% had associated surgery. 47.3% of the cases had pure stress urinary incontinence and 52.7% had mixed incontinence. A 12-month minimum follow-up period was applied to the first 140 cases operated between September 2002 and January 2003. Patient assessment was made by a clinical examination in the first three months and their satisfaction rate expressed after 1 year.

Results: Operative complications were very few: 0.5% vesical perforations, 0.3% vaginal perforations, no urethral wounds, 0.8% 200–300 ml haemorrhages, two perineal haematomas (0.33%). The post-operative period was marked by: 1.5% transient retentions, 2.3% transient pain, 2.5% urinary infections, 1.3% transient dysuria.

The 1–3 month follow-up of 572 patients shows a 5.2% rate of de novo symptoms. Patient assessment of 131 subjects after one year revealed an encouraging satisfaction rate of 85.5% with a 1.5% rate of de novo dysuria and urgency. To date there have been no serious or specific complications attributable to the surgical route adopted. The morbidity is not affected by associated surgery.

Conclusion: The trans-obturator route combines low morbidity with a low rate of de novo symptoms on a large series. These results will have to be corroborated by further studies.

Keywords: Trans-obturator route; Sub-urethral tape; Stress urinary incontinence; Morbidity

1. Introduction

Stress urinary incontinence surgery has been revolutionised by the arrival of the tension free vaginal tape technique (TVT) first described in 1995 by Ulmsten

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[1]. Follow-up assessments of over 5 years currently make it the ''gold standard'' technique [2,3].

Delorme's preliminary work on the use of the trans-obturator route for sub-urethral tape implantation (the TOT technique) [4] has opened up an interesting perspective simplifying the surgical procedure and making it more innocuous. The TOT technique appealed to us from the outset and we decided to put it to the test of a multi-centre series trial. For the purpose we chose a new implant, whose characteristics match the ideal specification currently required for prosthetic sling materials [5,6] perfectly.

2. Equipment and method

Six centres and seven surgeons including four gynaecologists and three urologists took part in this multi-centre experiment. The first 140 patients underwent surgery between 1 September 2002 and 15 January 2003. They were then studied retrospectively to assess the morbidity of the technique and the implant. The encouraging results made us enlarge our series. We report the data concerning the 604 first and consecutive procedures performed to date. The aim of this retrospective study is to assess the surgical morbidity of the trans obturator route in the first 3 months following surgery.

2.1. Surgical technique

It is based on Delorme's descriptions [4,7] and primarily differs in the device used. The prosthetic implant is placed under the mid-urethra and passes through the obturator foramen. Surgery commences with an anterior, vertical 15 mm vaginal incision at a point 10 mm below the urethral meatus. Dissection of the para-urethral spaces is then made laterally, with scissors, towards the ischiopubic ramus on either side. The resulting detachment leaves enough room for the index finger to pass. The external needle entry point is made in the genito-femoral fold by a short cutaneous incision made slightly above a horizontal line passing through the clitoral hood. The needle of the device is introduced through this orifice, initially in a direction perpendicular to the cutaneous plane. Once the obturator membrane has been crossed, it is orientated downwards and inwards in an oblique direction to reach the finger inserted in the para-urethral detachment space. It is then wound round the ischiopubic ramus, while the protecting finger remains in contact with the needle until it is exteriorised by the sub-urethral incision. The tape is then ''clipped'' to the needle tip and exteriorised via the genito-femoral fold after withdrawing the needle. The same procedure is carried out on the opposite side, and then tension-free adjustment is made to the tape under the mid-urethra. Vaginal closure is made with interrupted sutures using slow absorption thread to avoid premature wound dehiscence. Cutaneous closure is made with fast absorption thread. Cystoscopy is hardly ever performed. We feel it is essential to check the vaginal fornices for transfixion during surgery. During the course of our experiment the incision entry point was modified. At the beginning of the experiment the genito-femoral fold incision was made at the level of a horizontal line running over the urethral meatus. Gradually this point was raised above a horizontal line going through the clitoral hood. This modification became obvious to each surgeon, independently, without any consultation. Its effect is to increase the tape angulation to obtain an angle of 45° to the horizontal.

2.2. Prosthetic implant

The I-STOP® device we are using has been developed in collaboration with a company (CL Médical) based near Lyon (France). In terms of its structure and current composition, the tape matches the ideal specification currently required [5,6]. It presents the following characteristics:

- Exclusively mono filament polypropylene mesh: Ulmsten [6] has demonstrated it and the use of TVT® has confirmed it. Its material and manufacturing technique provide the highest tolerance to date.
- Aerated structure: macro pores of over 75 microns.
- No rope effect: the tape maintains its integrity right across its width despite sustained traction.
- It is supple and has no shape memory: easy to manipulate, so that it can be adapted in harmony with the patients' anatomy.
- Non-aggressive edges: the tape sticks to the tissues without presenting any irritation.
- No particle release: through a specific cutting-out process. Systemic particle migration has been described only during periurethral injections of various materials [8–11]. It has not been possible to link any specific complication to the migration of a polypropylene particle to date. However we consider it important to include this parameter in the specification, to curb a potential risk, as the anatomical area and type of material used are similar in our procedure.
- Low weight per area: specific knit weave, fine thread and little material used.

2.3. Method

All the surgeons had TVT and vaginal surgery experience. In the series, the surgical indications comprised both pure stress urinary incontinence (when stress urinary incontinence is the only one symptom) and mixed or complicated urinary incontinence defined as a combination of incontinence symptoms (when another urinary symptom is associated to stress urinary incontinence). Pre-operative urodynamics was not systematically required by the surgeons when faced with typical pure stress urinary incontinence. However it was always performed in cases of mixed or complicated urinary incontinence. The length of hospitalisation, urinary catheterisation and the type of anaesthesia varied according to the individual centre and surgeon. The patients were assessed on the basis of a clinical examination and questioning before their hospital discharge and during the first 3 months following surgery. Patient assessment after 1 year of the 140 first cases was made subjectively by asking them to establish their satisfaction level and describe any persistent or de novo (new) urinary symptoms. Patient satisfaction expresses how well the functional result achieved matched their expectations of the surgical procedure.

2.4. Patients

The total population figure studied for the 1–3 month follow-up is 604. 140 patients had one-year follow-up. The mean patient age was 57 years. 556 patients (92%) had isolated TOT urinary incontinence treatment and 48 (8%) underwent associated surgery (prolapse surgery or hysterectomy) and were studied separately.

Stress urinary incontinence was pure in 47.3% of cases (34.5% of degree 2 and 11% of degree 3) while 52.7% suffered from mixed incontinence (33% of degree 2 and 17.7% of degree 3).

3. Results

3.1. Peri-operative period (Table 1)

Surgery was possible in all cases. The results of the peri-operative period are listed in Table 1.

3.2. Complications

Surgical complications of 604 procedures were very few (about 2%) as shown in Table 2. Our results on surgical morbidity do not reveal any digestive, vascular or urethral wounds. One of the three cases of bladder perforation occurred during a hysterectomy. The haemorrhages were classically treated simply by tamponage, but in one case of an isolated TOT procedure (0.16%) the tape had to be cut during surgery to control perineal venous bleeding. One perineal haematoma (0.16%) in a patient who underwent associated prolapse surgery required immediate revision surgery. We observed no serious or specific complications attributable to the surgical route adopted.

Post-operative complications were also moderate (7.5%) (Table 3). Transient pains disappeared after a few days' treatment with anti-inflammatory drugs and minor analgesics, except in one case (0.16%) with persistent pain 2 months after surgery (isolated TOT). One case (0.16%) of transient dysuria needed revision surgery on Day 1 to lower the tape and one case (0.16%) of retention required section of the tape on Day 3. No patient had to practice self-catheterisation after hospital discharge. Two cicatrisation faults occurred including one premature wound dehiscence and one secondary exposure of the tape after 2 months. They were simply covered over surgically without complication.

572 patients were assessed by clinical examination and questioning in the 3 months following surgery, the immediate failure rate and the urinary symptoms induced (de novo symptoms) are detailed in Tables 4 and 5.

Of the 140 first cases, nine patients (6.4%) were lost to follow-up after 1 year. The assessment was thus made on 131 patients and presented a satisfaction rate of 85.5% (Table 6). Four of the non satisfied patients required repeat surgery and 1.5%, complained of de novo symptoms (urgency and dysuria). No problems of infection on the tape have been noted.

Table 4
Short term results: 1–3 months follow-up of 572 patients

	Isolated TOT	Associated surgery	Total
Patients: *N*	524	48	572
No improvement	18	–	18 (3.1%)
De novo symptoms (appeared after surgery)	28	2	30 (5.2%)

Table 1
Peri-operative period

Anaesthesia		Length of operation		Hospitalisation		Urinary catheterisation		
General	Loco-regional	<15 min	<30 min	<24 h	<48 h	None	<12 h	<24 h
432 (71.5%)	172 (28.5%)	452 (75%)	545 (90%)	407 (67.4%)	558 (92.4%)	183 (30.3%)	287 (47.5%)	391 (64.7%)

Table 2
Surgical complications

	N	Bladder perforation	Vaginal perforation	Haemorrhage	Haematoma	Immediate section of tape	Other
Isolated TOT	556	2	2	4	1	1	–
Associated surgery	48	1	–	1	1	–	–
Total	604	3 (0.5%)	2 (0.33%)	5 (0.83%)	2 (0.33%)	1 (0.16%)	–

Table 3
Post-operative complications

	N	Transient retention	Transient perineal pain	Transient dysuria	Urinary infection	Cicatrisation faults	Other
Isolated TOT	556	8	14	8	10	2	–
Associated surgery	48	1	–	–	5	–	–
Total	604	9 (1.5%)	14 (2.3%)	8 (1.3%)	15 (2.5%)	2 (0.3%)	–

Table 5
Details of de novo symptoms after 1–3 months

	Isolated TOT	Associated surgery	Total
Dysuria and urinary urgency	2	–	2 (0.35%)
Dysuria	15	1	16 (2.8%)
Urinary urgency	9	–	9 (1.6%)
Dyspareunia	1	1	2 (0.3%)
Perineal pain	1	–	1 (0.2%)

Table 6
Assessment after one year

Follow-up	1 year
Patients	131
Satisfied	85.5%
Not satisfied	14.5%
De novo dysuria and urinary urgency	2 (1.5%)
Re-operated patients	4 (3%)

4. Discussion

With the benefit of scientific literature and several years' experience of practising TVT we recorded certain points that could lead improving this technique [3,12–17]. This extends to: post-operative dysuria and retention rates, the risk of visceral wounds, de novo symptoms rates and the tape-dependent ''rope'' effect.

The trans-obturator route technique was put forward by Delorme as a useful alternative to the retropubic route. It retains the urethral support principle whose role in stress urinary incontinence treatment is clearly explained by de Lancey's theory [18]. Moreover it enables the pre-vesical space to be preserved as it avoids intra-pelvic and retropubic passage, and consequently seems to limit the risks of not only visceral and vesical wounds, but more importantly digestive and vascular wounds. Anatomic studies rule out the risk of lesion to the obturator pedicle in theory [4]. We were able to observe low surgical morbidity on our first 140 cases. No visceral wounds or serious complications or haemorrhages occurred. This observation enabled us, like others [19], to continue our series in total safety without practising per-operative cystoscopy as a matter of course. The results after 604 procedures confirm the low morbidity. We recall that vesical perforation rate has been assessed at 0–7% as against the French national ANAES report [3] on TVT, which can rise to as much as 21% according to some exhaustive TVT reviews [13,14]. We report two cases of bladder perforation during an isolated TOT procedure. They both occurred in cases of associated major cystocele and were immediately noticed by the surgeon. The first tape was removed and a second tape was placed without any consequences. A cystoscopy was performed at the end of both procedures.

There were also very few post-operative complications in comparison with the literature on TVT. The immediate retention rate, between 2.3 and 27% in scientific literature [13,14] was 1.5% in our series and required section of the tape in one case (0.16%). The cases of immediate post-operative dysuria improved rapidly and no patient needed to practice self-catheterisation after being discharged. The 2.3% of transient perineal pains rapidly receded except in one case in which pain was still present but improving after 2 months. They do not amount to obturator nerve trauma. The cicatrisation fault rate of 0.3% falls within the mean of the publications studied, which give a range of 0.8–2% [3]. In our series premature separation of the cicatrix and secondary exposure occurred. In both cases, the incision was simply closed up and the tape covered. These two cases further bolstered our choice of tape which did not present any infectious development. Probably the most interesting result is the rate of de novo symptoms (urgency and dysuria), which is only 4.7% for the 572 patients assessed after 3 months and 1.5% for the 131 patients assessed after one year. We recall that the literature on TVT records 5–38% of de novo dysuria cases and 1–36% of de novo instability cases [13,14]. Another point is that morbidity does not seem to be affected by associated surgery (prolapse treatment, hysterectomy).

Our results obtained after one year, demonstrate an encouraging satisfaction rate of 85.5%. We chose to assess the patients subjectively by asking them to express their satisfaction level and any urinary symptoms. Our series has not been objectively assessed as the pre-operative and post-operative urodynamics were not systematic and the quality of life was not taken into account.

Our results must be interpreted in the light of the fact that 52.7% of the patients operated presented mixed urinary incontinence sometimes combined with sphincter insufficiency. These operative indications are the same as those retained by surgeons practising TVT, which now extend beyond the treatment of pure stress urinary incontinence.

Our group is quite heterogeneous, firstly in terms of the specialities (urologists and gynaecologists) and the sector of activity (public and private health). The series includes each surgeon's learning curve. These observations enhance the good feasibility and safety results of the trans-obturator technique even more. However the way each centre is run and the practices of each individual surgeon give rise to differences in the type of anaesthetic, the length of the hospitalisation and indwelling catheterisation.

These results are really encouraging in confirming the usefulness of the trans-obturator technique and the quality of the tape used. This study is currently being pursued prospectively, as it is vital that these first results are substantiated on a greater number of cases over a longer post-operative period.

5. Conclusion

Our approach is part and parcel of our determination to improve a technique and product that have already been giving very good results. Stress urinary incontinence surgery must meet the demands of functional surgery with low operative risk and low de novo morbidity. The trans-obturator route appears to achieve gains in terms of morbidity and safety combined with a low rate of de novo symptoms. In our view this result is due to combining a pertinent surgical technique with an implant that matches the specific constraints of this surgery. Corroboration on the basis of a larger series is required. This calls for further studies to make an objective and prospective assessment of patients and a comparison with the ''gold standard'' technique (TVT).

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Editorial Comment

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The authors described the morbidity after three months follow-up in a large series of 604 patients with stress urinary incontinence who have been operated by a sub-urethral tape using the trans-obturator route. Hopefully the 48 patients who had associated procedures have been separated from those with isolated procedures. This data confirms that trans-obturator route avoids digestive or iliac vessels lesions and dramatically limits bladder perforation. But trans-obturator route also considerably limits de novo symptoms including acute retention, chronic retention, dysuria or urgency. Why is it so? One explanation is the following. Both procedures are tension-free ones. But experience has proven that some TVT could be placed anyway with too much tension and needed to be secondarily released. In trans-obturator route, as the tape is placed horizontally between the two ischiopubic ramus the urethra is sustained and no more tension is

possible. It is not the case with TVT. The tape could be placed just at the level of the mid urethra but more tension is always available (by retraction of the tape or technical fault for example). Concerning the angle of the tape under the urethra I don't agree with the authors. The angle is given by three points. The mid urethra and the two points under the ischiopubic ramus. Maybe when you enter the skin at the level of a line crossing the clitoris hood it is more easy to reach these points in a proper manner so that the angle is around 45° but it could also be possible to reach these points by entering the skin in a lower level. So the skin entering point is not as important as the position under the ischiopubic ramus.

So trans-obturator route is now enthousiasming surgeons by its low morbidity rate. But one must be cautious because what has made the success of TVT is also the results concerning continence with time. Sub-urethral tape by trans-obturator route has to prove the same efficacy and the same functional results. We are waiting for such large series with functional results nicely documented.

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Female Urology-Incontinence

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 retropublic 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

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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™, 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 post-operatively (Table 4).

Table 3 – Pre-operative urodynamic parameters

Urodynamic parameters	RPR (n = 42)	TOR (n = 46)	p
UCP (cmH_2O)	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 transobturator 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 transobturator 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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An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency

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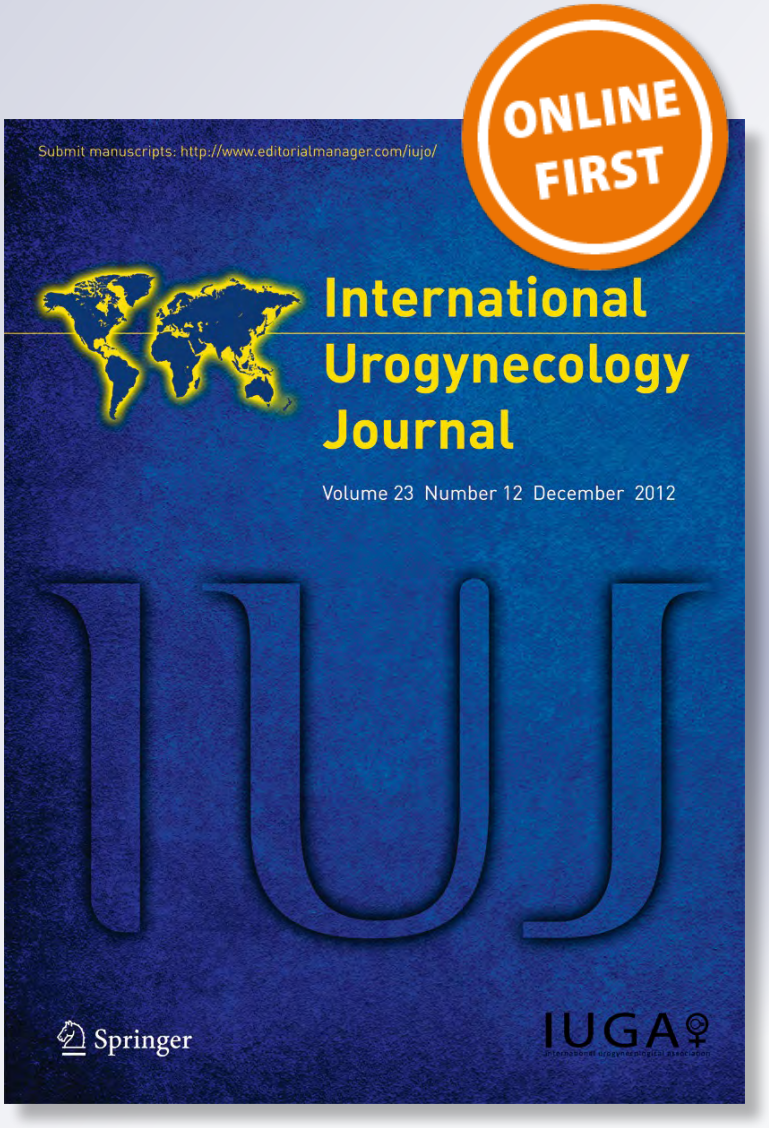

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ORIGINAL ARTICLE

An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency

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Abstract
Introduction and hypothesis We evaluated outcomes of an inelastic retropubic sling in patients with intrinsic sphincteric deficiency (ISD).
Methods This is a retrospective review of women diagnosed with ISD according to urodynamic parameters who underwent a retropubic suburethral sling surgery using a tape with minimal elasticity. All patients in the study where followed up at 2, 6, and 24 weeks and yearly. Outcome measures included self-assessed satisfaction, daily incontinence episodes and pad usage, standardized stress test, postvoid residual volume, and surgical complications.
Results Two hundred and forty-seven patients were involved in this study, with a median follow-up of 43 [interquartile range (IQR) 22–77] weeks and a minimum of 12 weeks. Two patients (0.008 %) had a positive stress test postoperatively. There was a decrease in daily incontinence events (median 1.5–0) ($p<0.001$) and pad usage per day (median 1.5–0) ($p<0.001$). Two hundred and sixteen (87.4 %) patients reported subjective improvement in symptoms. Urinary retention was found in 18 (7.2 %) patients, and 19 (7.7 %) patients required reintervention, mostly with bulking agent injections for persistent incontinence. No tape-related mesh exposures were reported.
Conclusion Retropubic suburethral inelastic slings represent a good option for treating patients with ISD, with satisfactory continent rates and low postoperative complications.

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Introduction

Although intrinsic sphincter deficiency (ISD) is a commonly used phrase, it is not consistently defined in the urodynamic literature [1]. What is clear, however, is that as the name states, the urethral sphincter fails to hold urine, producing involuntary leakage [2]. Approximately 30 years ago, McGuire defined ISD as the worst form of stress urinary incontinence (SUI) (type III), in which sphincter impairment was so significant that a minimal increase in abdominal pressure could lead to urine leakage [3]. Maximal urethral closure pressure (MUCP) of ≤20 cm H_2O and/or Valsalva leak-point pressure (VLPP) of ≤60 cm H_2O, a urodynamic measure described by McGuire, remain the accepted diagnostic criteria despite the controversy that exists about the definition of this condition [4].

Urodynamic parameters are the most objective means of assessing urethral function, although data available on the value of these parameters in predicting sling success, short- or long-term, is limited. However, women with a VLPP or MUCP in the lowest quartile are nearly twofold more likely to experience SUI 1 year after transobturator or retropubic midurethral sling placement [5].

There have been substantial improvements in the treatment of female SUI (SUI). However, ISD is still associated with a high incidence of surgical failure [2]. Success rates with transvaginal tape (TVT) or transobturator sling (TOT), the most commonly used slings in ISD patients, range between 50 % and 86 % in long-term follow-up studies [6–9]. In an attempt to improve outcomes, several

novel slings have become available with different tape characteristics (elasticity, flexibility, variation in material), as well as different implantation techniques (adjustable, helical, etc.), each one with its touted benefits and risks. Reduction in elasticity may be beneficial because unlike high elasticity slings that deform under strain, an inelastic sling allows individualized tensioning in patients in whom some tension may be beneficial due to poor urethral function.

We performed a retrospective study to evaluate outcomes of patients diagnosed with ISD who underwent suburethral sling procedures with an inelastic [10] type I polypropylene sling [11] placed at the proximal urethra via a retropubic approach.

Materials and methods

Patients with urodynamically proven SUI with ISD who underwent a suburethral sling procedure with an inelastic monofilament, macroporous sling with looped edges (Fig. 1) (I-STOP, CL Medical, Lyon, France) between February 2007 and November 2011 at the Cleveland Clinic, Florida, USA, with a minimal follow-up of 12 weeks, were reviewed. The institution's comprehensive urogynecological database was queried for patient data after obtaining Institutional Review Board approval.

Inclusion criteria for sling placement were based on urodynamic parameters with a MUCP of ≤40 cm H_2O and/or a VLPP at ≤60 cm H_2O capacity and urethral hypermobility [4]. These urodynamic parameters were chosen because MUCP and VLPP are commonly used tests to assess urethral function. MUCP of 40 cm H_2O was chosen based on our center's data on a higher failure rate of transobturator slings with MUCP ≤40 cm H_2O and/or VLPP at capacity ≤60 cm H_2O [4]. Self-reported pad usage per day was not used as a study inclusion criterion, as it is an unreliable measure of incontinence severity with a significant age bias [12]. Older patients have been previously reported to have a higher gram per pad urinary loss into fewer total pads [12].

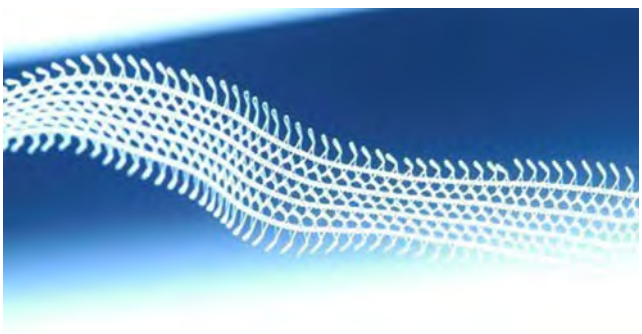

Fig. 1 Mesh used for the I-STOP sling

All patients were examined by the primary surgeon prior to surgery and evaluated at the postoperative follow-up visits by one of five clinicians, including postgraduate fellows. Patient data consisted of demographic variables such as age, body mass index (BMI), gravidity, parity, menopausal status, and tobacco use. Urogynecologic symptomatology, including incontinent events and pad usage per day and past urogynecologic procedures was recorded. Preoperative evaluation included physical examination to determine vaginal support anatomy and degree of urethral mobility via a Q-tip test, urinalysis and culture, and empty supine stress test (ESST). Multichannel urodynamic testing was performed using air-charged catheters and routine technique in all patients [13]. All surgical procedures were performed by two experienced urogynecologic surgeons. Perioperative factors considered were type of anesthesia, blood loss, concomitant procedures, and complications.

Follow-up visits where scheduled at the 2, 6, and 24 weeks postoperatively and then yearly. At each visit, data collected included reporting of subjective satisfaction, incontinent events and pad usage per day, standardized stress test, pelvic examination, postvoid urine residual measured by ultrasound (US), urinalysis, and sexual activity symptoms. The standardized stress test was performed with 250 cc of urine in the bladder in supine and standing (if no leakage when supine) positions. Incontinence events and pad usage were reported. Bladder diaries were not routinely completed, and quality of life questionnaires were not used routinely. However, patients completed a 5-point standardized global improvement scale comprising cured, greatly improved, improved, not improved, worsened, which was administered on intake by a clinic nurse. Subjective success was defined as cured or greatly improved. Outcome measures analyzed were daily incontinence episodes and pad use, stress test results, the 5-point standardized global improvement scale, postvoid residual urine volume, and perioperative and postoperative complications.

Statistical analysis was performed using PASW STATISTICS 18 (SPSS, Chicago, IL, USA). Continuous variables were tested for normality using Shapiro–normality test. Normal continuous data was described as mean and standard deviation (SD), with 95 % confidence interval (CI), and abnormal continuous data was described as median and interquartile range (IQR). Normal continuous variables were analyzed with paired t test, and abnormal data was analyzed with Wilcoxon signed rank test. Categorical data was analyzed using the chi-square test. Fisher's exact test was used if the value of any cell in the 2 × 2 contingency table was <5. A p value<0.05 was considered significant.

Operative technique

Proximal urethral placement of the sling was based on previously reported pubovaginal sling techniques, which have been described as indicated for severe SUI or ISD. This technique is designed to mimic the mechanism of such traditional pubourethral slings [14]. The surgical approach for I-STOP sling is similar to other retropubic slings. Two small (1-cm) incisions were made 2 cm above and lateral to the pubic symphysis for later passage of the sling needles. The anterior vaginal wall was infiltrated with 1 % lidocaine with epinephrine and incised vertically suburethrally for a length of 3 cm. The endopelvic fascia was dissected off the vaginal mucosa bilaterally to the vaginal sulcus and urogenital diaphragm. This allowed sufficient bladder-neck mobility such that the desired sling tension could be achieved by the surgeon. The sling needles were guided ipsilaterally through the urogenital diaphragm and space of Retzius and through the suprapubic incisions. Cystoscopy was performed to rule out injury to either urethra or bladder. A suprapubic catheter was placed under cystoscopic visualization, if required. The ends of the sling tape were then connected to the needles, and both needles were pulled upward through the suprapubic incisions. The sling was secured by a suture to the proximal urethra. Sling tensioning was performed using a 21-F cystoscope held in a 45° angle to the horizontal plane [15]. The excess tape was cut just below the skin line. Closure of the suprapubic and vaginal incisions was accomplished with surgical glue and 2-0 Vicryl suture, respectively.

Results

Our query yielded 247 patients who had undergone I-STOP sling surgery for ISD during the study period. Table 1 displays patient demographic data. The vast majority were menopausal, with 75 % being older than 60.5 years and 25 % older than 78.0 years; 68.4 % were overweight (BMI >24.9), with 27.9 % categorized as obese (BMI >29.9). Thirty-three patients had undergone previous anti-incontinence surgery, with three having undergone more than one.

Preoperative urodynamic parameters were as follows: median (IQR) MUCP was 28 (20.5), VLPP at capacity 42 (27.5) cm H_2O, peak flow 14.6 (7.05) ml/min, mean flow 6 (4.45) ml/min, and detrusor pressure at maximal flow 10.2 (4.6) cm H_2O. Median blood loss was 100 ml (IQR 50), with no events of postoperative hemorrhage or blood transfusion. One hundred twenty-eight patients (51.8 %) underwent spinal anesthesia, 118 (47.8 %) general anesthesia, and one (0.004 %) both. One hundred ninety-seven (79.8 %) patients had concomitant procedures; specific surgeries are listed in Table 2. There were few complications associated with surgical procedures or during the immediate recovery period. One patient developed a vaginal hematoma, which required drainage 6 weeks after the procedure, and one developed a rectovaginal fistula unrelated to the sling, which required reintervention. One bladder laceration with a sling needle was recognized during cystoscopy and required suturing during surgery without having any later consequences or affecting the patient's continence. There were no vaginal or bladder tape exposures reported during the follow-up period.

Median follow-up was 43 (IQR 22–77) weeks. Median number of postoperative visits was four (IQR 3–6). Table 3 shows subjective and objective outcomes after surgery; 87.4 % of patients reported being cured or improved; >71 % reported being cured at the last follow-up recorded; 12.4 % stated they did not improve or got worse.

Median number of incontinence events per day and pad usage revealed a significant decrease from preoperative to the postoperative values. Occult incontinence was reported in 85 (34.4 %) patients who had concomitant prolapse. The

Table 1 Demographic data (N=247 patients)

Variable	Value
Age[a]	69.4 (17.5)
Weight (kg)[a]	68.2 (15.3)
Height (m)[a]	1.60 (0.1)
BMI[a]	27.01 (6.0)
Parity[a]	2.00 (1.00)
Menopausal status	
Postmenopausal	221 (89.5 %)
Premenopausal	26 (10.5 %)
Smoker	
Never	187 (59.5 %)
Past + current	135 (40.5 %)
Previous surgeries	
TAH	76 (30.76)
TVH	31 (12.55)
Anti-incontinence surgery	33 (13.4)
Pelvic repair surgery	27 (10.9)

[a] Median (Interquartile range)

Table 2 Concomitant procedures

	Number	Percent
Hysterectomy	39	15.79
Anterior repair	108	43.72
Posterior repair	150	60.73
Abdominal apical suspension	8	3.24
Vaginal apical suspension	109	44.13

Table 3 Outcomes

Objective	Preop	Postop	*P* value
Incontinent events per day[ab]	3.5 (1.5–5.5)	0 (0–1.5)	<0.001
Pads per day[ab]	1.5 (1.5–3.5)	0 (0–1.5)	<0.001
Stress test positive	162 (65.5 %)	2 (0.008 %)	
Subjective			
Postoperative self-assessment satisfaction			
Cured/improved		216 (87.4 %)	
Not improved		17 (6.8 %)	
Worsened		14 (5.6 %)	

[a]Median (interquartile range)

[b]85 patients were excluded because of occult stress incontinence

remaining 162 (65.5 %) patients had a positive stress test during pelvic examination. All had urodynamically documented ISD. One hundred and twenty-five patients had mixed urinary incontinence (MUI) prior to surgery, of whom 40 had significant bother at 6 weeks following surgery and were given anticholinergic medication. Four patients developed de novo urge following surgery, of whom two reported symptoms 12 weeks following surgery but did not require medication; two developed urge 2 years after surgery and were given anticholinergic medication. Eighteen (7.2 %) patients had postvoid residual urine volume >100 ml at the last follow-up visit; 12 (66.7 %) of them were asymptomatic, and six (33.33 %) reported having voiding abnormalities (slow, interrupted, dribbling). The number of sexually active patients decreased from 100 (40.5 %) before to 80 (32.4 %) after the surgery. The proportion reporting dyspareunia among sexually active women remained similar, with 35 (35 %) prior to surgery and 30 (33.8 %) after surgery. Nineteen (7.7 %) patients required reintervention: 11 underwent bulking agent injection for persistent incontinence; five underwent sling takedown or transection for urinary retention. Sling transection was performed at least 3 months postoperatively to allow full integration of the sling arms and reduce the likelihood of recurrent SUI.

Discussion

The principal focus of our study was to evaluate the use of an inelastic suburethral sling in patients with ISD, a challenging, severe form of SUI. The I-STOP sling is a type I polypropylene, monofilament, macroporous, mesh tape [16] similar to the traditionally used synthetic slings except that it is woven to be much less elastic. It is now well known that monofilament tapes decrease the risk of infection compared with multifilament meshes [17]. Multifilament slings do not allow white blood cells to enter interstices between filaments <10 um, making infection more likely [18]. Monofilament slings have less risk of producing healing abnormalities (i.e., mucosal exposures) compared with multifilament slings (1.3 % vs. 6 %, respectively) [19]. I-STOP tapes are macroporous, which means that the pore size is >75 μm [17]. This allows fibroblasts, mononuclear phagocytes, and polymorphonuclear neutrophils to infiltrate through pores and create a better environment to permit tissue incorporation into the tape material [18].

As the I-STOP sling has lower elasticity [16], the surgeon may be able to apply tension more precisely. Its construct minimizes tape deformability, which may provide a more predictable postimplantation behavior [20]. It was initially thought that in order to prevent urinary retention, sling tapes had to have high elasticity, but new studies have proven otherwise [10]. Being inelastic, there may be less likelihood of tape shrinkage, which can lead to progressive retention and irritative bladder symptoms, possibly requiring sling revision. Another important characteristic of this tape is its high flexibility compared with other type I tapes, which have medium flexibility. This means it may have the capacity to bend, making it more malleable during surgery [20]. As a result, it may be more accurately tensioned and may lay flat without deformation suburethrally. Another unique characteristic of this tape is the presence of looped tape edges [20]. This may help decrease mucosal exposure into adjacent tissue and may improve tissue fixation. There were no vaginal exposures in our study, whereas in other studies in which TVT or TOT tapes were used, exposure rates were reported between 1.4 % and 3.8 % [6, 7, 21]. However, our median follow-up of 43 weeks was too short to make any definite conclusions regarding mesh exposure following I-STOP sling surgery. Also, the potential benefits of low elasticity and high flexibility need to be assessed in comparative studies.

Results of our study are encouraging when compared with other published articles on the use of suburethral slings for ISD treatment. Gungorduk et al. reported an overall cure rate of 52.5 % with TOT and 78.3 % when using TVT [7]. Similarly, Choo et al. reported a success rate of 76.6 % after

a minimum follow-up of 3 years in ISD patients using TVT [6]. In both those studies, however, the mean age was 50.6 and 58.7 years, respectively. Doo et al. found an overall cure rate of 50 % after 5 years of follow-up in a retrospective study of 134 patients with VLPP of ≤60 cm H_2O treated with TVT [8]. A retrospective study by Jeon et al. found that cure rates following TVT in ISD patients decreased from 86.94 % to 55.09 % between the 2- and 7-year follow-up [22]. On the other hand, Rezapeur et al. reported an overall improvement of 86 % using TVT in a prospective study [9]. However, the majority of patients in whom TVT failed were >70 years of age. It must be noted that almost 50 % of patients in our study were >70. This supports the fact that the incidence of ISD increases as women age, as does SUI severity.

In a randomized controlled trial of 164 patients, Schierltz et al. compared the efficacy of TVT and TOT in patients with ISD. They reported a 45 % and 21 % failure rate 6 months after surgery in TOT and TVT, respectively. Similarly, when an intention-to-treat analysis was undertaken, they found that one of every six patients with TOT and one of every 16 patients with TVT would have required surgical reintervention for further correction [23]. Sling tensioning with a cystoscope at a 45 ° angle was based on a study by Ostermann et al., in which the MUCP was measured intraoperatively while performing the sling tensioning procedure. The authors reported that using this technique for tensioning, there was a normalization of MUCP when the scope was held at a 45° angle without excessive tensioning, which could lead to urinary retention [15].

There were 19 (7.7 %) patients who required reintervention in our study. In contrast, Araco et al. reported a 17 % reoperation rate: 12 for bladder obstruction and 17 for failure to cure incontinence [24]. Intervention was uncommon in our patients. We were very careful during tensioning to avoid overcorrection. That may explain the need to perform bulking agent injections in patients with persistent SUI.

Urinary retention is the most frequent complication in sling surgery for SUI [25]. In our study, 18 (7.2 %) patients had urinary retention at the last recorded visit, with five (1.6 %) patients requiring sling takedown with simple transection. Studies involving TVT slings have reported a similar or higher retention rate and sling removal. Wang et al. reported a 26 % rate of voiding dysfunction after undergoing a TVT procedure for SUI or MUI [26]. Similarly, Abouassaly et al., in a retrospective study using TVT sling, reported a 32 % rate of retention longer than 48 h, 20 % requiring intermittent catheterization and 4.5 % required sling takedown or transection for urinary retention [27]. Guezzi et al. reported voiding difficulties in 25.7 % of patients, with 5.7 % of the patients requiring sling takedown [28].

Our study is not exempt from weaknesses. It was a retrospective study without comparison to a control group or the use of validated questionnaires. Inclusion criteria were based on urodynamic parameters, and hence, a proportion of our study patients had occult incontinence. However, a previous study that established that poor urethral function, as determined by urodynamic parameters, is associated with sling failure also included 20 % with occult incontinence. Thus, the presence of occult incontinence in our study population may not be a confounding factor for assessing the efficacy of the I-STOP sling. Median follow-up was 43 weeks. This could be considered a short-term follow-up, and there should be a delayed analysis performed of the same group of patients to determine long-term outcomes of this sling.

Conclusion

From the results of this investigation, we can conclude that an inelastic retropubic suburethral sling is effective for patients with ISD. Further research is necessary using this type of sling in a randomized, prospective, comparative trial to corroborate these findings.

Conflicts of interest GW Davila: honoraria, American Medical Systems, CL Medical, Astellas, Warner-Chilcott; consultant, American Medical Systems, Coloplast, CL Medical, Astellas; research funding, CL Medical. Other authors: No conflict of interest

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