Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out

Jean de Leval *

Department of Urology, Centre Hospitalier Universitaire de Liège, Bâtiment B35, Bloc Central, Niveau – 1, B-4000 Liége, Belgium

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Abstract

Objectives: To describe a new, simple surgical technique for the treatment of female stress urinary incontinence (SUI) and to evaluate its feasibility.

Methods: We have developed a novel surgical treatment of SUI, the transobturator inside-out tension-free urethral suspension, which uses specifically designed surgical tools, and in which a synthetic tape is passed from underneath the urethra, through the obturator foramens, towards the thigh folds, without entering the pelvic region at any time during the procedure. The tape is positioned without tension under the junction between mid and distal urethra.

Results: The procedure was carried out in 107 consecutive patients (mean age: 62 years) using the same operative protocol in all case subjects, independently of the patient’s size and weight. Mean operative time was 14 min (range: 7–20) in case of isolated SUI treatment. No bladder or urethral injuries and no vascular (hematoma or bleeding) or neurological complications were encountered.

Conclusions: The results of this study indicate that our novel transobturator inside-out surgical technique for treating SUI is feasible, accurate, and quick. This technique avoids damage to the urethra and bladder and, therefore, makes cystoscopy not necessary. Further prospective studies are currently ongoing to determine the efficacy of our new surgical approach for treating SUI.

* Tel. +32-4-366-7251; Fax: +32-4-366-7258.
E-mail address: jeandeleval@ulg.ac.be (J. de Leval).

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1. Introduction

Understanding of the physiopathological concepts of female stress urinary incontinence (SUI) has consistently improved over the past decades and their application has lead to the development of numerous surgical techniques aimed at curing this disorder [1,2]. Among these, retro-pubic tension-free vaginal tape (TVT) has probably been the most revolutionary [3–10]. It has been suggested that retro-pubic TVT may stabilize the mid-urethra at the time of an abdominal pressure increase without modifying cervico-urethral mobility [11–14]. The wide use of retro-pubic TVT has been associated with various peri- and post-operative complications, including bladder perforation, temporary or persistent retention, pain, urinary infection, and de novo instability [9]. Other rare but severe—and possibly underestimated—complications have been reported with this approach [5,15,16]. Indeed, the blind passage of the needle in the retro-pubic space can result in injuries to other organs than the bladder, in particular the urethra, vessels, nerves and bowel.

To avoid these complications, alternate approaches with a pre-pubic [17] or transobturator [18–20] passage of the tape have been developed and continence rates obtained with these routes have been roughly similar to those after the ‘classic’ retro-pubic TVT at least on the short term. In the transobturator technique described by Delorme and colleagues, the tape is inserted through the obturator foramens from outside to inside (in extenso from the thigh folds towards underneath the urethra) [18]. Even though the transobturator out-in...
TVT technique is claimed to be a safe procedure, it may occasion urethra and bladder injuries [21].

In this study, we describe a novel surgical technique that allows the passage of a tape through the obturator foramen, from inside to outside, with the use of newly designed specific surgical instruments. Results obtained in a series of 107 consecutive patients indicate that this surgical procedure is feasible, accurate, quick, and simple. In addition, this technique avoids damage to the urethra and bladder and, for this reason, makes cystoscopy not necessary.

2. Material and methods

2.1. Specifically designed surgical instruments

Three specific surgical instruments were created for the procedure: “helical passers”, plastic tubes and an introducer (Fig. 1).

The “helical passers” are pairs of instruments, specific for the left and right sides. They are stainless steel instruments comprising a spirally shaped section and a handle. The spiral section comprises an open circular segment having a 3 cm radius terminated by 2 linear segments. On a horizontal plane perpendicular to the handle’s axis, the gap between the extremities of the spiral section is 2 cm.

The instrument called the “introducer” is a stainless steel device that comprises two segments: a proximal tubular hollow segment and a distal, semi-circular, 7 cm long gutter. The introducer acts as a shoe-horn to ease, without danger, the slipping in of the passer, introduced alongside the gutter, from the perineal space through the obturator foramen.

2.2. Surgical technique

The surgical procedure is generally carried out under spinal anesthesia but may also be performed under general or local anesthesia.

Two grams of third-generation cephalosporin are administered intravenously at the time of anesthesia induction, followed by 1 gram repeated 8 and 16 hours after the procedure.

The patient is first placed in the gynecological position, legs on stirrups and thighs in hyperflexion. The patient’s buttocks reach the edge of the table. The operative field is cleaned with a standard antiseptic agent and draped with multiple drapes rather than a single trousers-shaped drape, with care being taken to keep the groin folds in the operative field. Labia minor are suspended by fixation to the skin with nylon suture a few centimeters above the vulvar ostium, inside the thigh folds, in order to expose the vulvar vestibulum. A 16 Fr Foley catheter is inserted into the bladder.

The points where the needles will exit at the skin level are identified by tracing a horizontal line at the level of the urethral meatus. The exit points are located 2 centimeters above this line and 2 centimeters outside the thigh folds (Fig. 2A). A 5 mm skin incision is made at each exit point. The anterior vaginal wall is suspended with two Allis clamps on either side of the midline, 1 cm proximally to the urethral meatus. A median sagittal incision of the vaginal wall is started at this level and is continued proximally (towards the vaginal pouches) over a 1 cm distance (Fig. 2B). Both vaginal mucosal and sub-mucosal tissues are incised. Minimal para-urethral sub-vaginal dissection is then carried out laterally with the blade, over a few millimeters distance, on either side (Fig. 2C). One Allis clamp grasps right minor and major labia while another Allis clamp holds the left margin of the sub-urethral vaginal incision, to clearly expose the most posterior aspect of the right vulvar vestibulum. Fine dissection scissors are introduced through the blade-initiated dissection path, and then further (Fig. 3A), on a horizontal plane with a 45° angle relatively to the urethral sagittal plane, towards the upper part of ischio-pubic ramus (Fig. 3B). It is important to correctly expose the vulvar vestibulum and to respect the specific direction of the dissection in order to avoid any perforation of the vaginal wall.

Once the upper part of the ischio-pubic ramus is reached—a bone contact is perceived—the right obturator membrane is perforated with the tips of the scissors, which are then slightly opened. During the dissection, bleeding can occur but is never important and only occasionally requires a blood-aspirating device. The introducer is then pushed in the pre-formed dissection pathway until it reaches and perforates the obturator membrane. The open side of the introducer’s gutter must be facing the operator (Fig. 3C). The distal end of the tube is mounted onto the spiral segment of the needle and the assembled device is gently slipped along the gutter.
of the introducer so as to pass through the obturator foramen (Fig. 4A). The introducer and Allis clamps are removed. At this step, the handle of the passer must be aligned in a parallel manner with the sagittal axis of the vulvar slit (Fig. 4B). Then, thanks to a rotational movement of the passer (Fig. 4C and D), the pointed tip of the tube appears at the previously incised skin exit points at the level of the thigh folds (Fig. 4E). The tube is pulled from the supporting passer, which is removed by a backwards-rotational movement, until the first centimeters of the tape become externalized (Fig. 4F). The same technique is applied to the left side. It is important to take care not to twist the tape. When both tubes have been extracted through the skin incisions, the ends of the tape are cut. The tape is then aligned under the junction between the mid and distal urethra and the tension of the tape is adjusted by exerting a traction on its two ends and by interposing a pair of scissors between the tape and the urethra so as to leave a space avoiding any tension of the tape. The plastic sheaths are then removed simultaneously. An alternative procedure for correctly aligning the tape under the urethra is to grasp the tape at its middle with Babcock forceps so as to create a small, 5 mm-long tape loop (Fig. 5A). As described above, traction is exerted on the distal ends of the tape, which brings the Babcock forceps in contact with the urethra. Plastic sheaths (Fig. 5B) and then Babcock forceps are removed and a small sub-urethral space is thus created between the tape and the ventral aspect of the mid-urethra. The tape ends are cut in the subcutaneous layer and the incisions are closed.

3. Results

A total of 107 patients were consecutively operated on using the transobturator inside-out surgical procedure between March 2002 and February 2003. Informed consent was obtained from all patients before the operation. Surgery was carried out under spinal, general, and local anesthesia in 82, 24, and 1 cases, respectively. Mean age of the patients was 62.0 ± 12.6 years (median: 62.2 years; range: 29–88) and mean parity was 2.5 ± 1.7 (median: 2.5; range: 0–9). Seventeen patients (15.9%) had been operated previously for incontinence and/or vaginal prolapse.
Among the 107 patients, 74 of these suffered from typical symptoms of SUI, documented by detailed history, physical examination, endoscopic assessment and urodynamic testing. Ulmsten’s test was positive in every case. The remaining patients (n = 33) had pelvic organ prolapse requiring surgical treatment. In these patients, the transobturator vaginal tape inside-out was carried out after prolapse surgical correction (during the same anesthesia) for treating associated SUI (n = 15) or for prophylactically preventing secondary SUI (n = 18).

The procedure was carried out independently of the patient’s size and weight, in all case subjects. Each of the 214 needles was passed through the obturator foramen and exited at the skin level exactly where it had been marked and incised.

Mean operative time was 14 min (median: 13; range: 7–20) in case of isolated SUI treatment. Patients with transobturator inside-out operations only were hospitalized for a mean of 1.8 days (range: 0.5–8 days).

No peri-operative complication was encountered. No injury to the urethra, bladder, nerves or bowel was noted. Significant (>100 ml) intra-operative bleeding did not occur. In none of the cases was the vaginal wall perforated during the operation. No ecchymose or hematoma was noticed after the procedure.

All patients had a follow-up visit at one month after surgery, including detailed interview by the surgeon, clinical examination, urine analysis, and postvoid residual determination. During this short follow-up time, only few post-operative complications were observed. Minor vaginal erosion was noted in one patient. Three patients (2.8%) had complete retention; two of them had undergone associated prolapse surgical treatment. In these patients, a tape release procedure was carried out in the immediate post-operative period with local anesthetic injection and intravenous sedation as needed. No tape required to be sectioned. None of the patients who underwent a tape release procedure developed incontinence or fistula.

Twenty-seven patients (15.9%) complained directly after the procedure that they had moderate pain or discomfort in the thigh folds. This symptom usually abated within 2 days and was in all cases controlled by non-opioid analgesics. In 2 patients (1.9%), more severe pain persisted for one week and was associated
with hip arthralgia, probably as a result of the gynecological position during the procedure. Pain was not reported by any of the patients one month after the operation.

Superficial vein thrombosis occurred in one patient at day 8 after surgery, with secondary development of an abscess that required drainage. Evolution of this patient was favorable. Despite the sepsis was not in contact with the operative field (the abscess developed approximately 10 centimeters below the skin exit point of the passer), further to this adverse event, care was taken to prophylactically administer powerful antibiotics in all patients undergoing the surgical treatment.

4. Discussion

The main goal of surgical treatment for SUI is to render patients completely continent without generating significant morbidity. Until the advent of retro-pubic TVT, Burch’s colposuspension has been considered the gold standard surgical procedure for SUI.

Accumulating reports have indicated the efficacy of tension-free sub-urethral tapes, which are currently widely utilized [4–10]. The results of a prospective randomized multicenter trial comparing retro-pubic TVT with colposuspension have recently shown that continence rates were similar at six months of follow-up, with more operative complications for retro-pubic TVT and more frequent post-operative complications and longer recovery for colposuspension [22,23]. Retro-pubic TVT procedure required much less operative time, had much shorter hospitalization time, with significantly less post-operative pain and faster return to normal daily activities than Burch’s colposuspension [22,23].

Nevertheless, retro-pubic TVT has not been free of complication, as indicated by Boustead [9] and Sanjurjo et al. [10] in recent reviews on retro-pubic TVT. Bladder perforation occurred in 0%–23% of the patients, de novo urgency in 2.5%–25%, retention in 1.5%–12.9%, and hematoma in 0.8%–3.3%. Severe complications such as vascular and bowel injuries, as well as deaths, have been reported [9].

The outside-in transobturator technique proposed by Delorme [18,20] may present several advantages, amongst which the occurrence of immediate complications may be less frequent. In particular, the author stated that there might be no risk to damage the bladder or the urethra, or to cause de novo urgency [17]. The concept that there is no risk of bladder or urethral perforation with Delorme’s technique is not shared by everyone. Such complications have indeed been recently reported in 3 patients [21]. We have also recently treated 3 patients who had undergone outside-in transobturator TVT in other institutions and who had subsequently developed urethral fistula (de Leval J., unpublished observation). In addition, Delmas et al. [24] have performed dissection studies in cadavers and their results have indicated that the risk of nerve or vessel injury is nearly absent. However, they have concluded that a risk of vagina, bladder and urethra damage is present. For this reason, the authors have proposed that a large opening should be carried out at the level of the vaginal dissection and have advised to use the tip of the index to pick up the end of the ‘tunnelisateur’.

We have recently performed anatomical studies using cadavers to identify the exact passage of the needles and tape with our transobturator inside-out procedure (manuscript in preparation). We observed that the pelvic region was completely outside of the dissection field. Indeed, the tubes were immediately passed in a virtual space located in the most anterior part of the ischio-rectal fossa. This triangular space was limited in its internal region by the external plane of the levator ani muscle. Its inferior limit corresponded to the median perineal aponeurosis and its external boundary was constituted by the internal obturator muscle. The terminal end of the pudendal nerve was located below the median perineal aponeurosis. These anatomical observations demonstrated that there is no danger to generate neurological complications.

The passage of the tapes with our procedure and surgical devices was extremely accurate, as testified by the systematic exit location of the tubes at the predefined skin exit points. Our passage was different from the one described by Delorme [18] and Delmas [19,24], since our anatomical studies have revealed that the levator ani muscles and the pelvic fascia were not perforated at any time during the procedure. In addition, our transobturator passage was carried out largely above the pudendal nerve landmark. Therefore, we herein claim that cystoscopy is not necessary, provided that our procedure is performed according to the proposed guidelines. Mean operative time should be consequently reduced.

In this study, no hematoma was observed after the procedure. This may be partly explained by the minimally carried out dissection, which, in addition, may reduce the risk of tape migration. It is also noteworthy that our dissection is performed in a space that is devoid of large vascular structures. Our dissection was performed under sight control with large exposure of the vulvar vestibulum, thus reducing the risk of vaginal wall perforation.
On the physiopathologic level, high continence rates obtained with the transobturator, retro-pubic or pre-pubic tapes share a common denominator, which is the restoration of the fixed bearing point at the junction between the middle and the distal third of the posterior urethra. Our previous works have indeed identified a fixed point, which is a genuine pivot of rotation, from which two urethral segments—inferior and superior—can be distinguished [25]. The anatomical correspondence of this point of confluence is the median perineal aponeurosis [25,26]. We thus believe that the tape may restore this aponeurotic structure that is underdeveloped in women [26] and that may be altered by pregnancy/delivery.

This preliminary analysis mainly focused on the feasibility and immediate complication rates associated with our newly developed surgical procedure. Continence and de novo urgency rates are not provided due to the short follow up time (one month) in this study. In addition, the population of patients analyzed in this study was not homogenous since it incorporated patients with isolated SUI, patients with SUI and associated prolapse, and patients with prolapse without urgency. Rates of de novo urgency are not provided.

In conclusion, we propose the transobturator inside-out tension-free urethral suspension as a novel surgical procedure for treating SUI. This technique is feasible, accurate, quick, and simple, and avoids urethra, bladder, bowel, neurological and vascular injuries. Further ongoing studies will help determine the efficacy of this new surgical technique.

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