

A COMPARISON OF THE TRANSOBTURATOR AND RETROPUBIC MID-URETHRAL SLING PROCEDURES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE

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ABSTRACT

Introduction: We compared the outcomes of transobturator and retropubic mid-urethral sling procedures for female stress urinary incontinence (SUI) in the light of our experience and recent literature data.

Materials and Methods: Between 2004 and 2007, 122 patients underwent mid-urethral sling surgery. Transobturator route was used in 68 patients [IVS04™ in 26, polypropylene mesh in 42 (TOT)] and retropubic procedures were performed in 54 patients [IVS02™ in 24, polypropylene mesh in 30 (TVT)]. Patients were compared for postoperative cure and incidences of various complications.

Results: Cure was achieved in 86% and 87% of the patients after IVS04™ and IVS02™, respectively. Likewise, 88% and 86% of the patients were cured following TOT and TVT procedure, respectively. Operation time was significantly shorter in transobturator procedures. Bladder injuries were seen in 2 cases with retropubic procedures while none occurred during transobturator surgeries. Urethral injury was evident in 1 patient during IVS02™ procedure. Obstructive urinary symptoms were significantly higher following retropubic as compared to transobturator procedures. The incidence of vaginal erosion was not significantly different between either routes, however, the incidences were higher with the IVS™ tape. Urethral erosion, hematoma or wound infection was not observed. The incidences of de-novo urge symptoms were similar between retropubic and transobturator techniques.

Conclusion: Transobturator techniques are as effective as retropubic techniques in the management of SUI with the advantages of shorter operation time and reduced risks of major adverse events.

Key words: Tension-free vaginal tape, Transobturator tape, Surgery, Urinary stress incontinence

ÖZET

Bu çalışmanın amacı kadında, stres tip idrar kaçırma (STİK) tedavisi için uygulanan transobturator ve retropubik gevşek orta üretral askı ameliyatlarını güncel yayınlar ve deneyimlerimizle ışığında kıyaslamasıdır.

2004-2007 yılları arasında gevşek orta üretral askı ameliyatı uygulanan 122 hasta çalışmaya alındı. Bu hastaların 68 tanesinde transobturator yöntem [26 hastada IVS04™, 42 hastada polipropilen mesh (TOT)] ve 54 tanesinde retropubik yöntem [24 tanesinde IVS02™, 30 tanesinde polipropilen mesh (TVT)] kullanıldı. Hastalar ameliyat sonrası dönemde başarı oranları ve istenmeyen yan etki oranları açısından kıyaslandı.

Ameliyat başarısı IVS04™ uygulanan hastalarda %86 olarak, IVS02™ uygulanan hastalarda ise %87 olarak saptandı. Benzer şekilde TOT sonrası başarı %88 iken TVT sonrası başarı %86 olarak bulundu. Transobturator yöntemde ameliyat süresinin anlamlı derecede kısa olduğu gözlemlendi. Retropubik yöntemin kullanıldığı 2 olguda mesane yaralanması gözlenirken transobturator yöntemde böyle bir problem gözlenmedi. Üretra yaralanması sadece IVS02™ uygulanan 1 hastada gözlemlendi. Obstrüktif üriner belirtilerinin transobturator yöntemine göre retropubik yöntemde anlamlı derecede fazla olduğu gözlemlendi. Vajinal erozyon insidansında her iki yöntem arasında anlamlı bir fark gözlenmezken IVS™ teyp uygulaması yapılan hastalarda vajinal erozyonun biraz daha fazla olduğu gözlemlendi. Üretral erozyon, hematoma ya da yara yeri enfeksiyonu gözlenmedi. De-novo sıkışma tipi belirtileri her iki yöntem içinde benzer oranlarda bulundu.

STİK tedavisinde kullanılan olan transobturator teknik ciddi sorunların daha ender gözlenmesi ve kısa ameliyat zamanı gibi avantajlara sahip olmasının yanında en az retropubik teknik kadar etkili bulunmuştur.

Anahtar kelimeler: Gevşek vajinal teyp, Transobturator teyp, Cerrahi, Stres tip idrar kaçırma

INTRODUCTION

The introduction of tension-free vaginal tape (TVT) procedure in 1996 has revolutionized the

surgical management of female stress urinary incontinence (SUI) in terms of its efficacy and minimal invasiveness¹. Although these tapes have pro-

Date of First Application: 23.05.2008

Accepted: 18.09.2008

ved to offer long-term success¹⁻³, a number of serious complications, such as bladder perforations, vascular or bowel injuries, have been reported^{4,5}. A transobturator approach, in which the tape is inserted through the obturator foramina from the thigh folds toward the urethra, was introduced by Delorme in 2001 with the goal of avoiding the retropubic space and associated complications⁶. Since then, many surgeons have performed this technique to assess the efficacy and morbidity of the transobturator route. A growing body of knowledge suggests that transobturator tape (TOT) provides good intermediate-term results that are comparable toTVT with a reduction in major complication risks⁷⁻⁹. Despite the huge number of TOT and TVT procedures performed world-wide, the number of studies comparing the complications and functional outcome of both techniques is limited. In this study, we aimed to compare our results with both transobturator and retropubic techniques and reviewed the outcomes in the light of recent literature data.

MATERIALS and METHODS

We retrospectively reviewed 122 female patients (age: 31-72 years) who had undergone a mid-urethral sling procedure for SUI between 2004 and 2007 in our clinic. Transobturator route was used in 68 patients and retropubic procedures were performed in 54 patients. All procedures were performed by one of the two experienced surgeons in the field. Preoperative evaluation included detailed history, a validated incontinence questionnaire (International Consultation on Incontinence Questionnaire: ICIQ-SF) which assessed female lower urinary tract symptoms and their impact on the quality of life⁷, stress test with a full bladder, urinalysis, and urinary tract imaging with ultrasound. All patients were free of neurologic diseases, peripheral neuropathies, metabolic disorders, and urinary tract or perineal skin infections. The main criteria for inclusion were visible SUI during cough test and urethral hypermobility (according to the International Continence Society definitions) on physical examination. All of the patients were able to void spontaneously and urodynamic studies were not systematically performed. For the transobturator approach, Obturator IVS04TM Tunneller (Tyco HealthCare, USS, Norwalk, CT, USA) was used in 26 patients (IVS04TM group), whereas, a monofila-

ment polypropylene mesh strip of 1 cm width (cut from Gal-Mesh, Gallini medical devices, Mantova, Italy) was used in 42 patients who could not afford the commercial tape (TOT group). For the retropubic sling procedure, IVS02TM Tunneller (Tyco HealthCare, USS, Norwalk, CT, USA) was used in 24 patients (IVS02TM group) and polypropylene mesh strip was used in 30 patients (TVT group). As summarized in Table 1, patient characteristics between the transobturator and retropubic routes were not significantly different.

Table 1. Preoperative patient characteristics of the transobturator and retropubic sling procedures (values are given as mean ± s.e. of the mean; n(%)).

	Transobturator (n=68)	Retropubic (n=54)	p value
Age at procedure (yr)	49.3±1.2	50.1±2.3	NS*
Parity (n)	3.1±0.2	3.7±0.4	NS*
Body mass index	30.5±0.3	29.1±0.3	NS*
Preoperative ICIQ-SF score	17.1±0.4	18±0.5	NS*
Prior hysterectomy (n), %	5 (7)	7 (12)	NS†
Associated prolapse (n), %	25 (36)	24 (44)	NS†
Prior surgery for incontinence (n), %	4 (6)	5 (9)	NS†

NS: not significant, *: t-test, †: chi-square test

The transobturator technique used was based on Delorme's description⁶. Under spinal anesthesia, an anterior, vertical 15 mm vaginal incision was made at a point about 1 cm below the urethral meatus. Dissection of the paraurethral spaces was then made laterally toward the ischiopubic ramus. The entry point was made on the genitofemoral fold by a cutaneous incision made at the level of clitoris. The tip of the Tunneller IVS04TM device was introduced through this orifice, initially in a direction perpendicular to the lying patient, and then oriented upward and inward in an oblique direction to reach the index finger introduced in the paraurethral space once the obturator membrane had been punctured. The introducer was exteriorized from the suburethral incision, and the tape or the polypropylene mesh strip was transferred from this site to the perineal incision (Figure 1). The same procedure was performed on the contralateral side, and then tension-free adjustment was

made to the tape under the mid-urethra. No cystoscopy was performed during the procedure but urine was checked for hematuria immediately after catheterization.



Figure 1. Transobturator tape procedure with “home-made” mesh: Polypropylene mesh strip has been shown to be transferred from the vaginal through the perineal incision



Figure 2. Placement of the mid-urethral sling material with the aid of retropubic IVS02™ Tunneller kit

Retropubic sling procedures were performed under spinal anesthesia through a 15 mm sagittal

incision made in the vaginal wall, at the level of the mid-urethra, followed by a periurethral dissection plane which was extended laterally toward the ischiopubic rami. Two stab incisions were made in the suprapubic region at the upper rim of the pubic bone, 2 cm lateral from the midline. Then, the IVS02™ Tunneller was placed within the periurethral tunnel with the tip of the device between the index finger and the lower rim of the pubic ramus. The device was pushed upwards with controlled pressure to exit the suprapubic incision, keeping the tip of the tunneler in close contact with the pubic bone. After confirmation of secure entry with cystoscopy, the procedure was repeated on the contralateral side. Either the tape or the polypropylene mesh strip was transferred from the suburethral incision to the skin incisions on each side followed by tension-free adjustment (Figure 2).

In all patients the urethral catheter was removed within the first 18 hours. Postoperative follow-up included an initial visit 7 days after surgery. Additional visits were scheduled at 1, 6, and 12 months, and yearly thereafter. During the visits, patients underwent history, self-assessment with ICIQ-SF questionnaire, physical examination, and post-voiding residual urine (PVR) determination. Cure was defined as eliminated need for wearing any protection, absence of stress leakage, and no leakage during a cough test with a full bladder. With the aid of a computerized software, the incidences of various non-parametric variables between the IVS04™ and IVS02™ as well as TOT and TVT groups were compared by using the chi-square test. Results were considered statistically significant when *Pearson* coefficient was less than 0.05. Values for nominal variables were given as mean±standard error of the mean and comparisons were done by independent-samples t-test where a *p* value of less than 0.05 was considered statistically significant. All reported *p* values were 2-tailed.

RESULTS

Peroperative and postoperative outcomes with respect to IVS04™ and IVS02™ groups are presented in Table 2 and a comparison of the TOT and TVT groups are presented in Table 3. The procedure was significantly shorter in patients who received a transobturator sling ($p < 0.05$, Tables 2 and 3). The transobturator and retropubic approaches were found to yield comparable cure rates with

the use of both IVS™ tape and monofilament polypropylene mesh ($p>0.05$, Tables 2 and 3). Likewise, ICIQ scores obtained at postoperative 12th month were not significantly different between the 2 routes ($p>0.05$, tables 2 and 3). One patient in the IVS04™ group who failed initial surgery underwent urethrolisis with a repeat TOT procedure, and was eventually improved. In 2 patients who did not benefit from mid-urethral sling procedure, a concomitant genitourinary fistula was diagnosed and successfully treated with Martius flaps. Preoperative cystoscopy in these patients was negative.

Table 2. Per- and postoperative outcomes in the IVS04™ and IVS02™ groups (values are given as mean \pm s.e. of the mean; n(%))

	IVS04 (n=26)	IVS02 (n=24)	p value
Follow-up (months)	12,9 \pm 1,3 (range: 4-28)	16,8 \pm 1,8 (range: 6-37)	NS*
Operative time (min)	18,4 \pm 3,4	35,6 \pm 10,8	<0,05
Cure (n), %	22 (86)	21 (87)	NS†
ICIQ score at 12th month	4,4 \pm 1,0	3 \pm 1,5	NS*
Obstructive urinary symptoms	2 (7)	4 (16)	<0,05
Vaginal injury (n), %	0 (0)	0 (0)	NS†
Vaginal erosion (n), %	1 (4)	2 (8)	NS†
Urethral injury (n), %	0 (0)	1 (4)	NS†
Urethral erosion (n), %	0 (0)	0 (0)	NS†
Bladder injury (n), %	0 (0)	1 (4)	NS†
Hematoma (n), %	0 (0)	0 (0)	NS†
Wound infection (n), %	0 (0)	0 (0)	NS†
De-novo urgency (n), %	2 (7)	3 (12)	NS†

NS: not significant, *: t-test, †: chi-square test

Bladder injury was seen in 1 patient in both groups with the retropubic approach. Both of these cases had a prior history of abdominal colposuspension surgery. The tape was removed and the patient was scheduled for a TOT procedure on both occasions. Urethral injury was encountered in one case during IVS04™ placement. The procedure was completed following primary repair of the urethra without any consequences.

Postoperative obstructive urinary symptoms were significantly higher with the retropubic route

with both sling materials ($p<0.05$, Tables 2 and 3). In the majority of the cases, transient intermittent catheterization of 7 to 10 days duration was sufficient to alleviate the symptoms, whereas, the tape had to be divided in 1 patient who received TOT and 3 patients who received a retropubic sling (1 IVS, 2 TVT) due to persistent obstructive symptoms. The release procedure was performed between postoperative days 16 and 21, and the patients remained continent during follow-up. Significant PVR (>50 ml) was not evident in any case. Vaginal erosion was seen in 1 patient after transobturator sling (IVS04™ tape) and 3 patients following retropubic approach (1 TVT, IVS02™ tapes). Urethral erosion, hematoma or wound infection was not observed in any case. De-novo urge symptoms were observed with similar incidences following both transobturator and retropubic slings ($p>0.05$, Tables 2 and 3), and were significantly improved with anticholinergics.

Table 3. Per- and postoperative outcomes in the TOT and TVT groups (values are given as mean \pm s.e. of the mean; n(%))

	TOT (n=42)	TVT (n=30)	p value
Follow-up (months)	14,8 \pm 1,4 (range: 4-32)	12,6 \pm 0,8 (range: 6-28)	NS*
Operative time (min)	18,4 \pm 2,8	38,6 \pm 9,4	<0,05
Cure (n), %	37 (88)	26 (86)	NS†
ICIQ score at 12th month	2,7 \pm 0,9	5,8 \pm 1,7	NS*
Obstructive urinary symptoms (n), %	2 (4)	5 (17)	<0,05
Vaginal injury (n), %	0 (0)	0 (0)	NS†
Vaginal erosion (n), %	0 (0)	1 (3)	NS†
Urethral injury (n), %	0 (0)	0 (0)	NS†
Urethral erosion (n), %	0 (0)	0 (0)	NS†
Bladder injury (n), %	0 (0)	1 (3)	NS†
Hematoma (n), %	0 (0)	0 (0)	NS†
Wound infection (n), %	0 (0)	0 (0)	NS†
De-novo urgency (n), %	4 (9)	5 (17)	NS†

NS: not significant, *: t-test, †: chi-square test

DISCUSSION

The main goal of surgical treatment for SUI is to render patients completely continent without ge-

nerating significant morbidity. The minimally invasive TVT procedure as described by Ulmsten more than a decade ago has replaced most colposuspensions. The cure rate for SUI for TVT has ranged from 84% to 95%, with proven long-term efficacy¹⁻³. However, the TVT procedure has not been free of complications. Bladder perforation occurred in up to 23% of the patients, de novo urgency in 2.5%-25%, retention in 1.5%-12.9%, and hematoma in 0.8%-3.3%^{1,2,4}. Severe complications such as vascular and bowel injuries, as well as deaths, have also been reported^{1,5}. To minimize the TVT complications while maintaining the same results for incontinence, the TOT technique presents a novel approach for the route of the tape. The perineal approach reproduces the natural support of the urethra while preserving an intact retropubic space⁶. Recent data has revealed this procedure as a useful alternative to the TVT procedure⁷⁻⁹. For example, evaluation on continence in 2 studies with a follow-up of longer than 2 years has demonstrated a cure rate of more than 80% with fairly low complication rates^{7,8}. Nonetheless, the number of studies comparing the efficacy and complications of both techniques are few.

In this study, we aimed to review the surgical outcomes of transobturator versus retropubic techniques in the light of our experience and recent literature data. For each route, 2 different tapes (ie. multifilament IVS™ tape and monofilament polypropylene mesh strip) were used in our clinical setting, and the results were compared for each sling material. With a mean follow-up of at least 1 year, the transobturator route provided cure rates that were comparable to those obtained with the retropubic procedures. Our findings are consistent with other publications¹⁰⁻¹². To the best of our knowledge no previous study had compared TVT and TOT cure rates in Turkey. But TOT and TVT operations were discussed in separate papers. Cetinel B had reported a cure rate of 89% for TVT operation and Citgez S had reported a cure rate of 85% for TOT operation^{13,14}. In a recent multicentre randomized trial Porena et al reported cure (defined as no leakage during stress test and/or reported by patients) in 71% and 77% for TVT and TOT, respectively¹². When satisfactorily improved but leaking patients were considered, the rates increased to 90% with both techniques. Likewise, Fischer et al achieved cure (leakage <2 g in 1 h pad test) in 81% of TOT

patients and 76% of TVT patients in their series¹¹. The difference between the definitions for cure causes a discrepancy between reported success rates. Furthermore, the inclusion criteria in terms of mixed versus genuine SUI, presence or absence of vaginal prolapse, and presence or absence of previous surgeries for incontinence and/or prolapse varies between the studies. In a recent meta-analysis, Latthe et al concluded that the two techniques of inserting vaginal tape by obturator or retropubic route were not significantly different in effectiveness but their complication profiles were different; for example, bladder injuries and voiding difficulties were lower, but the risk of vaginal erosions and groin pain were higher with TOT¹⁵.

Despite providing similar success rates, the route of the tape is different in TOT from TVT. The more horizontal path of the TOT may lead to a less lateral wall support and obstruction of the urethra. The consequence of this horizontal position of the tape is two-fold: First, TOT may not give optimal results in patients with a low urethral resistance. In this regard, Miller et al have recently demonstrated a significantly higher failure rate with TOT in subjects with a preoperative maximum urethral pressure of 42 cm H₂O or less as compared to TVT¹⁶. Therefore, the selection criteria for choosing between either route in patients presenting with the same symptomatology and physical examination findings should be defined with further studies. Second, TOT is less likely to cause obstructive symptoms and de-novo urgencies due to the difference in sling axis. Although postoperative obstructive symptoms and urinary retention were found to be significantly higher with retropubic techniques in our study, the incidence of de-novo urge symptoms was not significantly different between either type of procedures, the findings of which are shared by most large series^{11,12}. In the light of these contradictory results, it may be reasonable to prefer TOT implantation in women with borderline urinary flow rates^{11,15}.

Our results showed different complication profiles for the transobturator and retropubic sling procedures. The two bladder perforations and one urethral injury in our series occurred during retropubic surgery, all of which occurred in a secondary surgery setting. These observations may indicate TOT as an option of choice in women who have

had previous operations such as colposuspension and/or pelvic organ prolapse repair. Lateral vaginal perforation in the lateral cul de sac of the vagina described in some reports did not occur in our series. The incidence of vaginal erosion was not different between the 2 techniques in the present study. However, an erosion rate of up to 8% was encountered with the IVS™ tape in contrast to one vaginal erosion out of 72 patients (1%) where a monofilament polypropylene mesh was used. The type of biomaterial seems to be an important factor determining the success and tape-related complications. Polypropylene materials have been shown to be well tolerated by the body, with little exposure of the patient to infection and vaginal or urethral erosion^{8,9}. The multifilament intravaginal sling-plasty (IVS™, Tyco HealthCare) polypropylene tape has proven efficacy in the management of female SUI and pelvic organ prolapse¹⁷⁻¹⁹. However, the literature data regarding the safety of this material in terms of erosion and recommendations for its use are conflicting^{17,19-21}. We have used monofilament polypropylene mesh strip in addition to the IVS™ tape with comparable efficacy, and apparently a lower risk of vaginal extrusion. Furthermore, the tape was prepared from a 30x30 cm mesh costing 25 USD, which can yield more than 10 strips for mid-urethral sling placement. The place for such “home-made” slings should be addressed with further studies of long-term follow-up.

In summary, TOT is a simple, safe and effective technique for the treatment of female SUI. The continence rates are as good as those reported for TVTs, with a lower incidence of major adverse events and a shorter duration of the procedure. Future studies should aim at identifying the prognostic factors for choosing between either technique in order to achieve the best possible results.

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