

An inexpensive mid-urethral sling for treating female stress urinary incontinence: the use of renal pedicle clamp and prolene mesh strips

Kadın stres tip idrar kaçırmasının tedavisinde ucuz bir orta üretral askı yöntemi: renal pedikül klemp ve kesilmiş prolene meş kullanımı

Fikret Fatih Önel¹, Osman Köse², Şinasi Yavuz Önel²

¹Sakarya Training and Research Hospital, Clinic of Urology, Sakarya

²Vakıf Gureba Training and Research Hospital, Clinic of Urology, İstanbul

Abstract

Objective: Transobturator vaginal tape (TOT) is a widely used procedure for the management of female stress urinary incontinence (SUI). We reviewed our TOT results with the use of a polypropylene mesh strip and a renal pedicle clamp.

Materials and methods: Between 2004 and 2007 TOT was performed in 132 patients. Forty-nine patients with associated prolapse surgery were excluded from analysis. A 1-cm-wide polypropylene mesh strip was placed midurethrally via a renal pedicle clamp introduced through the transobturator route in 46 patients (Group 1). IVS04™ Tunneler was used in 37 patients who served as the control group (Group 2). Groups were compared for perioperative and postoperative complications, and continence outcomes. Follow-up studies included history, cough test, post-voiding residual urine volume (PVR), and International Consultation on Incontinence Questionnaire (ICIQ-SF) scores obtained at 1, 6, 12, 18, and 24 months.

Results: With a mean follow-up of 22.8 and 24.7 months, cure (defined as elimination of the need to wear protection, and the absence of stress leakage during a cough test) was achieved in 84% and 85% of the patients in Groups 1 and 2, respectively. There was no significant difference between the groups in terms of perioperative complications, or in incidence of postoperative urinary retention, vaginal erosion, or de novo urgency. Urethral erosion, hematoma, or wound infection was not observed.

Conclusion: TOT with the use of surgical polypropylene mesh strip and renal pedicle clamp is an inexpensive and effective procedure for the treatment of female SUI.

Key words: Stress; surgical mesh; tape; transobturator; urinary incontinence.

Özet

Amaç: Transobturator vajinal teyp (TOT) kadın stres tip idrar kaçırmasının (STİK) tedavisinde kullanılan yaygın bir yöntemdir. Bu çalışmada renal pedikül klemp ve kesilmiş polipropilen meş kullanılan TOT olgularımızın sonuçları değerlendirilmektedir.

Gereç ve yöntem: 2004 ve 2007 yılları arasında 132 hastaya TOT uygulandı. Eş zamanlı prolapsus cerrahisi geçiren 49 hasta değerlendirme dışı bırakıldı. Bir cm eninde kesilen polipropilen meş bantı 46 hastada transobturator yoldan uygulanan renal pedikül klemp yardımıyla orta-üretral askı olarak yerleştirildi (1. grup). Kontrol grubu seçilen 37 hastada IVS04™ Tunneler kit kullanıldı (2. grup). Gruplar perioperatif ve postoperatif komplikasyonlar ile kontinans durumu açısından karşılaştırıldı. İzlem 1, 6, 12, 18 ve 24. aylarda alınan hikaye, öksürük testi, işeme sonrası kalan idrar tayini ile Uluslararası İnkontinans Sorgulaması kısa formu (ICIQ-SF) ile yapıldı.

Bulgular: Ortalama 22.8 ve 24.7 aylık izlemde gruplara göre hastaların %84 ve %85'inde (önlem olarak konulan pet ihtiyacının ortadan kalkması veya öksürük testinde idrar kaçırmanın gözlenmemesi olarak tarif edilen) şifa sağlandı. Gruplar arasında perioperatif komplikasyon oranları, postoperatif idrar retansiyonu, vajinal erozyon ve de novo sıkışma semptomları açısından anlamlı fark saptanmadı. Hiçbir hastada üretral erozyon, hematoma veya yara enfeksiyonu gelişmedi.

Sonuç: Kesilmiş polipropilen meş ve renal pedikül klemp yardımıyla uygulanan TOT yöntemi kadın STİK tedavisinde ucuz ve etkili bir yöntemdir.

Anahtar sözcükler: Cerrahi meş; stres; stres tip idrar kaçırma; teyp; transobturator teyp.

Introduction

The introduction of tension-free vaginal tapes (TVTs) more than a decade ago has revolutionized the surgical management of female stress urinary incontinence (SUI) because of their simplicity, efficacy, and minimal invasiveness.^[1] Although these tapes have proven to offer long-term efficacy,^[1-3] a number of serious complications, such as bladder perforation and vascular or bowel injuries, have been reported.^[4,5] In 2001, a transobturator approach, in which the tape is inserted through the obturator foramina from the thigh folds toward the urethra, was introduced with the goal of avoiding the retropubic space and associated complications.^[6] Since then, many surgeons have performed this technique to verify the efficacy and to assess the morbidity of the transobturator route.

Recent literature suggests that transobturator tape (TOT) provides good long-term results that are comparable to those of TVT, with reduced major complications.^[7-9] Nonetheless, the cost of commercial TOT kits ranges from 500 to 800 US Dollars (USD), which may not be affordable to all patients, or be covered by all insurance plans. Therefore, we have begun to use a new technique for the midurethral sling procedure that entails the placement of a standard polypropylene mesh strip with the aid of a renal pedicle clamp via the transobturator route. In this report, we review our mid-term results.

Materials and methods

One hundred and thirty-two women (age range, 31-75 years) underwent TOT implantation for SUI between 2004 and 2007. Pelvic organ prolapse (cystocele, rectocele, or uterine or vault prolapse) requiring surgical intervention was evident in 49 patients, and these patients were, therefore, excluded from the study. 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 life,^[7] physical examination with a stress test, urinalysis, uroflowmetric studies and urinary tract imaging with ultrasound. Each of the patients was able to void spontaneously. Detailed cystometric studies were not systematically performed. All patients were free of neurologic disease, peripheral neuropathy, metabolic disorders, and urinary tract or perineal skin infection at the time of surgery.

The main criteria for inclusion were the diagnosis of SUI and urethral hypermobility on physical

examination. Patients were fully informed regarding the technique and the postoperative course and written consent was obtained from all patients. In 46 patients who could not afford a commercial tape, and whose insurance plan did not pay for the kit (Group 1), a 1-cm-wide macroporous monofilament surgical polypropylene mesh strip cut from a 30x30 cm Gal-Mesh (Gallini Medical Devices, Mantova, Italy), was placed suburethrally with the outside-in advancement of a vascular pedicle clamp that had the appropriate curvature for transobturator passage. The entire 30x30-cm mesh costs approximately 33 USD. The remaining 37 patients, who received TOT implantation with Obturator IVS04™ Tunneler (Tyco HealthCare, USS, Norwalk, CT, USA) during the same study period served as the control group (Group 2). As summarized in Table 1, preoperative patient characteristics were not significantly different between the two groups.

The technique used was based on Delorme's description.^[6] 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 performed laterally toward the ischiopubic ramus. The entry point was established on the genitofemoral fold by a cutaneous incision at the level of clitoris. Depending on the type of procedure, the tip of the Tunneler IVS04™ device or the pedicle clamp was introduced through this orifice, initially anterior to posterior in the recumbent patient, and then cephalad and inward in an oblique direction to reach the index finger introduced in the paraurethral space once the obturator membrane had been punctured (Fig. 1). The pedicle clamp was exte-



Figure 1 Introduction of the vascular pedicle clamp from the perineal incision to the suburethral space, with index finger guidance.

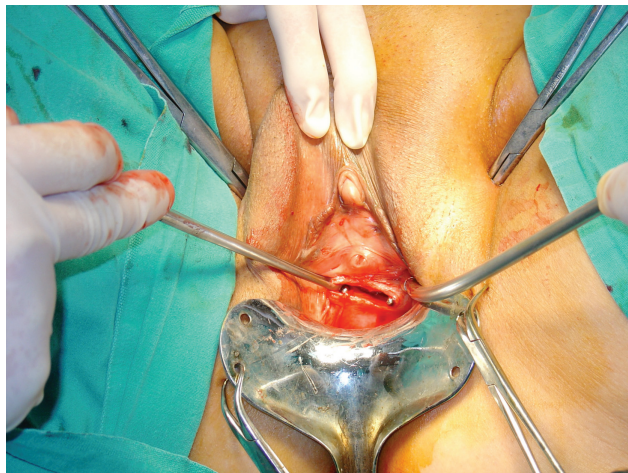


Figure 2 The tips of vascular pedicle clamps, shown to be exteriorized bilaterally from the vaginal incision.

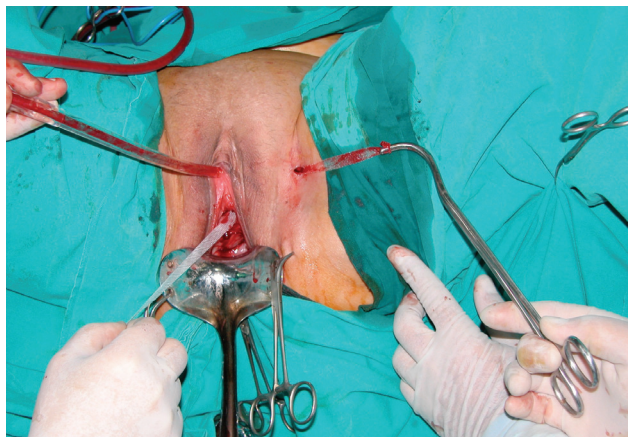


Figure 3 A 1-cm-wide macroporous polypropylene mesh strip has been grasped with the vascular pedicle clamp from the vaginal incision, and pulled from the perineal incision.

riorized from the suburethral incision (Fig. 2) and the pre-prepared mesh strip was grasped and transferred from this site to the perineal incision (Fig. 3). The same procedure was performed on the contralateral side, then tension-free adjustment was made to the mesh under the mid-urethra. The tape was not fixed to any point during surgery in patients where “home-made” polypropylene mesh was used. No cystoscopy was performed during the procedure. Peri-operative blood loss was estimated from the volume aspirated during the procedure.

Urethral catheter was removed within the first 24 hours. Postoperative follow-up included an initial visit seven days after surgery. Additional visits were scheduled at 1, 6, 12, 18, and 24 months, and yearly thereafter. During the visits, patients provided interval history and self-assessment with ICIQ-SF questionnaire, and underwent physical examination and post-voiding residual urine (PVR) determination. Cure was defined as elimination of the need for wearing any protection, and absence of stress leakage or leakage during a cough test with a full bladder.

With the aid of computer software, the incidences of various variables between the 2 groups were compared by using the two groups by using the chi-square test. Values for nominal variables were given as mean \pm standard deviation. Comparisons were performed 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

Both procedures revealed similar operative times and perioperative complication rates (Table 2). Urethral laceration (0.5 cm) was recognized in one

Table 1. Preoperative characteristics of patients in the renal pedicle clamp group (Group 1) and Obturator IVS04TM Tunneler group (Group 2). Values are given as mean \pm standard deviation or n (%).

	Group 1 (n=46)	Group 2 (n=37)	p value
Age at procedure (year)	49.1 \pm 8.6	46.7 \pm 9.8	0.809 ^a
Parity (number)	2.9 \pm 1.3	3.1 \pm 1.2	0.918 ^a
Body mass index	31.1 \pm 1.2	29.8 \pm 2.7	0.087 ^a
Preoperative ICIQ score	17.2 \pm 2.2	18.1 \pm 2.4	0.959 ^a
Pads used/day (number)	3.1 \pm 1.3	2.4 \pm 0.9	0.07 ^a
Associated urge incontinence	14 (30%)	10 (27%)	0.57 ^b
Uroflowmetric parameters			
Max. flow rate (mL/s)	28.1 \pm 10.8	31.4 \pm 12.3	0.59 ^a
Voiding time (seconds)	38.3 \pm 13.6	32.6 \pm 11.8	0.41 ^a
Postvoid residual (mL)	29.6 \pm 15.4	22.3 \pm 13.8	0.13 ^a
Prior hysterectomy	4 (9%)	3 (8%)	0.11 ^b
Prior surgery for incontinence	2 (4%)	2 (5%)	0.11 ^b

a: t-test, b: chi-square test

Table 2. Perioperative and postoperative outcomes in the renal pedicle clamp (Group 1) and Obturator IVS04™ Tunneler (Group 2) groups. Values are given as mean \pm standard deviation or n (%).

	Group 1 (n=46)	Group 2 (n=37)	p value
Peroperative outcomes			
Mean operation time	16.8 \pm 10.9 (range: 14-31)	14.7 \pm 8.3 (range: 12-28)	0.45 ^a
Blood loss (>70 mL)	0 (0%)	0 (0%)	NA
Hematoma	0 (0%)	0 (0%)	NA
Vaginal injury	0 (0%)	0 (0%)	NA
Urethral injury	0 (0%)	1 (3%)	0.156 ^b
Postoperative outcomes			
Mean follow-up (months)	22.8 \pm 14.9 (range: 4-36)	24.7 \pm 18.3 (range: 6-38)	0.245 ^a
Cure	39 (85%)	31 (84%)	0.11 ^b
ICIQ score at 12th month	5.8 \pm 7.6 (n=42)	2.7 \pm 3.4 (n=33)	0.156 ^a
Obstructive voiding	1 (2%)	2 (5%)	0.159 ^b
De novo urgency	4 (9%)	3 (8%)	0.987 ^b
Vaginal erosion	1 (2%)	2 (5%)	0.559 ^b
Urethral erosion	0 (0%)	0 (0%)	NA
Wound/pelvic infection	0 (0%)	0 (0%)	NA

a: t-test; b: chi-square test, NA: not applicable.

patient in Group 2, and the procedure was successfully completed after primary closure without any complications during follow-up. All patients were discharged from the hospital within 24 hours of surgery. Mean follow-up for Groups 1 and 2 was 22.8 \pm 14.9 and 24.7 \pm 18.3 months, respectively. Cure was achieved in 85% of patients in Group 1, and 84% of patients in Group 2 ($p=0.11$, Table 2). Similarly, ICIQ scores obtained at postoperative month 12 were not significantly different between the two groups ($p=0.156$, Table 2).

In one patient in each arm who did not benefit from the TOT procedure, genitourinary fistula was diagnosed postoperatively. These patients were treated successfully with Martius flaps. One patient in Group 1, who failed initial surgery, underwent urethrolisis with repeat mesh placement and was significantly improved. In this patient, the number of pads used per day dropped from 3 to 1. Transient obstruction was observed in one patient in Group 1 following removal of the Foley catheter. Similarly, urinary obstructive symptoms were observed in two patients in Group 2, one of whom required mesh incision on postoperative day 16, and remained continent during follow-up. Significant PVR (>50 mL) was not evident in any case. Vaginal erosion was seen in two patients in Group 1, and in one patient in Group 2 ($p=0.559$, Table 2). Urethral erosion, hematoma, or wound infection was not observed in any case. *De novo* urge symptoms were seen in 4 (9%) and 3 (8%)

patients in Groups 1 and 2, respectively ($p=0.987$, Table 2) which improved with anticholinergics following exclusion of urethral obstruction with uroflowmetric studies.

Discussion

The main goal of surgical treatment for SUI is to render patients completely continent without generating 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 efficacy.^[1-3] Nevertheless, the TVT procedure has not been free of complications. Bladder perforation has occurred in 0% to 23% of 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, also have been reported.^[1,5]

To minimize complications of TVT while maintaining the same results for treatment of 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 space.^[6] Recent data have revealed that this procedure is a useful alternative to the TVT procedure.^[7-9] For example, evaluation of continence in two studies with a follow-up of longer than two years has demonstrated a cure rate of >80% with fairly low complication rates.^[7,8]

The cost of materials is a major factor contributing to the cost of a TOT procedure.^[10] The aim of this work was to investigate the efficacy of an inexpensive TOT procedure with the use of a macroporous polypropylene mesh strip and a vascular pedicle clamp. This “home-made” modification was used in patients who could not afford the commercial kit and whose insurance system did not pay for the kit. Commercial transobturator kits cost 500 to 800 USD in Turkey, and are not paid by all insurance plans. In the present setting, the cost of the transobturator kit included only a monofilament polypropylene mesh strip as the tape material, which was only 2 USD per patient. As many as 15 separate strips of 1.5 cm width can be obtained from a 33 USD 30 x 30 -cm Galmesh, and can be re-sterilized for use in other patients.

With a mean follow-up of two years, this system achieved continence, and resulted in complication rates which were comparable to those obtained with the use of a commercially proven tape. To the best of our knowledge, this is the first study to report the outcome of a “home-made” TOT system, despite its limitations. The use of “home-made” polypropylene mesh strips for mid-urethral SUI procedures has been reported in a limited number of studies. A similar cost-effective procedure that did not perforate the obturator foramen was introduced by Foglia et al.^[11] In their series of 12 patients, they placed an 8 x 1.5-cm monofilament prolene mesh strip under the mid-urethra, and bilaterally in the perforated endopelvic fascia. With the use of this the transfascial vaginal tape, they reported a cure rate of 83% at one year without any evidence of infection, erosion, fistula, or voiding problems. “Home-made” prolene mesh strips may be used further to salvage mid-urethral sling procedures that have failed following tape protrusion.^[12]

The type of the biomaterial is an important factor determining the success of the procedure, and tape-related complications. Polypropylene materials have been shown to be well tolerated by the body, with little risk of infection or vaginal or urethral erosion.^[8,9,13] In this regard, the multifilament intravaginal slingplasty (IVS™, Tyco HealthCare) polypropylene tape has proven efficacy and safety in the treatment of female SUI.^[14-17] We obtained an 84% cure rate with this material, with minimal complications. Our vaginal erosion rate was 5% with the IVS tape, which is slightly higher than that reported in the literature.^[14-17] This complication was evident in 2% of the patients in the “home-made-tape” group, but this rate was not statistically significantly different from that of the

IVS group. The materials used in each group are different (monofilament versus multifilament polypropylene), which constitutes the major limitation of the present study. Nonetheless, we observed good tissue integration without evidence of any infection following the use of a surgical monofilament polypropylene mesh material. It is also noteworthy that we did not fix the mesh to any point during surgery. This did not result in any malpositioning of the mesh, and cure was achieved in 85% of cases. The incidence of *de novo* urge symptoms during follow-up was not significantly different between the two groups.

TOT is a simple, safe, and effective technique for the treatment of SUI. The continence rates are comparable to those reported with TVT, with a lower rate of adverse events. Our mid-term results suggest that reimplantation of a standard surgical polypropylene mesh strip via a transobturator route by using a vascular pedicle clamp is an effective procedure with minimal risk of complications. Whether the use of “home-made” prolene mesh strips may substitute for industrial kits in health systems with a high burden of female SUI cases should be evaluated with future studies.

References

1. Atherton MJ, Stanton SL. The tension-free vaginal tape reviewed: an evidence-based review from inception to current status. *BJOG* 2005;112:534-46.
2. Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U. Long-term results of the tension-free vaginal tape (TVT) procedure for the surgical treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunc* 2001;12(suppl):S5-8.
3. Nilsson CG, Falconer C, Rezapour M. Seven year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. *Obstet Gynecol* 2004;104:1259-62.
4. Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol Scand* 2002;81:72-7.
5. Zilbert AW, Farrell SA. External iliac artery laceration during tension-free vaginal tape procedure. *Int Urogynecol J Pelvic Dysfunc* 2001;12:141-3.
6. Delorme E. Transobturator urethral suspension: a minimally invasive procedure in the treatment of stress urinary incontinence in women. [Article in French] *Prog Urol* 2001;11:1306-13.
7. Al-Singary W, Shergill IS, Allen SE, John JA, Arya M, Patel HR. Trans-obturator tape for incontinence: a 3-year follow-up. *Urol Int* 2007;78:198-201.

8. Giberti C, Gallo F, Cortese P, Schenone M. Transobturator tape for treatment of female stress urinary incontinence: objective and subjective results after a mean follow-up of two years. *Urology* 2007;69:703-7.
9. Grise P, Droupy S, Saussine C, Ballanger P, Monneins F, Hermieu JF et al. Transobturator tape sling for female stress incontinence with polypropylene tape and outside-in procedure: prospective study with 1 year of minimal follow-up and review of transobturator tape sling. *Urology* 2006;68:759-63.
10. Castellón Vela IT, Redondo González E, Linares Quevedo AI, Vallejo Herrador J, Ríos González E, Sáenz Medina J et al. Outpatient female stress urinary incontinence surgery: budget impact study. [Article in Spanish] *Arch Esp Urol* 2007;60:267-72.
11. Foglia G, Mistrangelo E, Lijoi D, Alessandri F, Ragni N. Transfascial vaginal tape for surgical treatment of stress urinary incontinence. *Urology* 2006;68:423-6.
12. Lo TS, Lee SJ. Simple sling resection and a second, intermediate polypropylene mesh for treatment of vaginal tape protrusion concurrent with recurrent urinary stress incontinence after TVT procedure. *J Obstet Gynaecol Res* 2007;33:739-42.
13. Delorme E, Droupy S, de Tayrac R, Delmas V. Transobturator tape (Uratape): a new minimally-invasive procedure to treat female urinary incontinence. *Eur Urol* 2004;45:203-7.
14. Adamiak A, Jankiewicz K, Miotla P, Rechberger T. Tape erosion--local process or general reaction of the organism. The erosion rate and localization of implanted polypropylene tape in female pelvis. *Ginekol Pol* 2007;78:210-3.
15. Basok EK, Yildirim A, Atsu N, Gurbuz C, Tokuc R. The surgical results of the pubovaginal sling procedure using intravaginal slingplasty (IVS) for stress urinary incontinence. *Int Urol Nephrol* 2006;38:507-12.
16. Önel SY, Önel FF, İnal H, Onur S, Köse O. A comparison of the results of intravaginal suburethral sling and transobturator tape procedures in the surgical treatment of stress urinary incontinence. *Urology* 2006;68(Suppl):250.
17. Pariente JL, Villars F, Bram R, Ibarboure E. Mechanical evaluation of various suburethral tapes used for the treatment of stress urinary incontinence. [Article in French] *Prog Urol* 2005;15:1106-9.

Correspondence (Yazışma): Uzm. Dr. Fikret Fatih Önel. Sakarya EAH, Üroloji Kliniği, Korucuk Kampüsü 54290 Sakarya, Turkey
Phone: +90533-514 10 99 e-mail: ffonol@yahoo.com