

Long-Term Surgical Outcomes of Transobturator Tape Procedure in Women With Mixed Urinary Incontinence

Miks Üriner İnkontinansı Olan Kadınlarda Transobturator Band Uygulamasının Uzundönem Cerrahi Sonuçları

Tarık Yonguç¹, Özgü Aydoğdu¹, İbrahim Halil Bozkurt¹, Salih Polat¹, Bülent Günlüsoy¹, Volkan Şen¹, Tansu Değirmenci¹, Burak Arslan²

¹ İzmir Bozyaka Training and Research Hospital, Urology Clinic, İzmir
² Haseki Training and Research Hospital, Urology Clinic, İstanbul

Objective: To evaluate postoperative outcomes and complications of transobturator tape (TOT) procedure in the treatment of patients with mixed urinary incontinence (MUI).

Materials and methods: We analyzed 193 consecutive female patients who underwent TOT procedure. Among these patients 75 women with MUI were the subjects of this study. All patients were evaluated with the International Consultation on Incontinence Questionnaire-Short form (ICIQ-SF) preoperatively and at the postoperative follow-up visits. Patient satisfaction was evaluated with Visual analog scale. On the postoperative 15th day, all patients were routinely evaluated with urine culture and possible early postoperative complications were examined. Patients were evaluated on the postoperative 3rd, 12th months and annually with pelvic examination, VAS, cough stress test (CST) and ICIQ-SF. Surgical outcomes were evaluated and data of subjective and objective cure rates, any complications related to the procedure were registered. Statistical analyses were performed with SPSS 17.0 (SPSS version 17.0, Chicago, IL, USA).

Results: A total of 67 women who met the requirements for inclusion and who had available records for analysis were included in the study. Objective cure, subjective cure and patient satisfaction rates were 89.6, 53.7 and 70.1% respectively. The mean score for 29 patients with a postoperative 5th year ICIQ-SF score >0 was 12.2 (SD ± 4.2). Of the 67 patients, the urgency urinary incontinence (UUI) component of 12 patients (17.9%) had improved postoperatively. Fifty-five (82%) patients with persistent UUI postoperatively were treated with antimuscarinic drugs. None of our patients experienced intraoperative complications. Two (3%) patients required re-operation for recurrent stress urinary incontinence (SUI) in the follow-up.

Conclusion: TOT procedure is successful for surgical treatment of MUI with predominant SUI in long-term follow-up. The operation was satisfactory for the most of the women. Persistence of UUI was the main reason for dissatisfaction.

Key Words: TOT, mixed urinary incontinence, stress urinary incontinence

Amaç: Miks üriner inkontinansı (MÜİ) olan hastalarda transobturator bant (TOT) işlemine ait postoperative sonuçlar ve komplikasyonların değerlendirilmesi.

Gereç ve yöntem: TOT yapılan 193 kadın hasta değerlendirildi. Bu hastalardan MÜİ olan 75 kadın hasta incelendi. Tüm hastalar preoperatif dönemde ve postoperatif kontrollerde International Consultation on Incontinence Questionnaire-Short formunu (ICIQ-SF) ile değerlendirildi. Postoperatif hasta memnuniyet visual analog scale (VAS) ile değerlendirildi. Tüm hastalar postoperatif 15. günde idrar kültürü ile ve olası postoperatif erken komplikasyonlar açısından değerlendirildi. Hastalar postoperatif 3. ve 12. aylarda ve yıllık olarak pelvik muayene, VAS, öksürük stress testi (CST) ve ICIQ-SF ile değerlendirildi. Cerrahi sonuçlar, subjektif ve objektif iyileşme oranları ile işleme ilişkili komplikasyonlar not edildi. İstatistiksel analizler SPSS 17.0 programı (SPSS version 17.0, Chicago, IL, USA) kullanılarak yapıldı.

Bulgular: Çalışma kriterlerine uygun olan toplam 67 hasta çalışmaya dahil edildi. Objektif iyileşme, subjektif iyileşme ve hasta memnuniyet oranları sırasıyla %89,6, %53,7 ve %70,1 olarak bulundu. Postoperatif 5. yıl ICIQ-SF skoru >0 olan 29 hastanın ortalama skoru 12,2 (SD ± 4,2) idi. 67 hastadan, 12 hastanın (%17,9) urge üriner inkontinans (UUI) şikayeti postoperatif dönemde iyileşti. Postoperatif dönemde UUI şikayeti devam eden 55 (%82) hastaya antimuskarinik ilaç tedavisi başlandı. Hiçbir hastada intraoperatif komplikasyon izlenmedi. Takip sırasında iki hasta (%3) rekürren stres üriner inkontinans (SUI) nedeniyle tekrar opere edildi.

Sonuç: Uzun dönemde TOT, baskın komponenti SUI olan MUI hastalarının cerrahi tedavisinde başarılı bir yöntemdir. Çoğu kadın için operasyon tatmin edicidir. UUI'nin devam etmesi hasta memnuniyetsizliğinin temel nedenidir.

Anahtar Sözcükler: TOT, miks üriner inkontinans, stres üriner inkontinans

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Corresponding Author

Özgü Aydoğdu
GSM: 0 532 672 10 12
E-mail: ozgucan@yahoo.com
İzmir Bozyaka Training and Research Hospital, Urology Clinic
Karabağlar, İzmir

Mixed urinary incontinence (MUI) is the coexistence of stress and urgency urinary incontinence and is defined as involuntary loss of urine associated with the sensation of urgency and

also associated with exertion, effort, sneezing or coughing (1). In a community based study, it was reported that 36% of women with urinary incontinence had MUI (2).

The lack of clarity awareness regarding the real clinical picture makes diagnosis and management extremely difficult (3). MUI is considered more difficult to treat due to the need of mutually managing stress urinary incontinence and overactive bladder symptoms, with the latter often being unpredictable with evidence of flaring and remission of symptoms over time (4).

In the treatment of female stress urinary incontinence (SUI), minimal invasive surgical procedures such as transobturator tape (TOT) and tension-free vaginal tape (TVT) are most popular techniques. Both TOT and TVT have short operative and hospitalization times with acceptable complication rates. Most studies comparing TOT and TVT have not found significant differences between these two techniques concerning objective and subjective efficacy in SUI (5,6). However postoperative complications including bladder and bowel perforation, pelvic hematoma seems to be less common in patients who underwent TOT (7).

There are variable data available regarding cure rate of MUI following midurethral sling surgery of both the stress and urge components. In a recent systematic review and meta-analysis Jain et al (1) examined the effectiveness of MUS in women with MUI. The authors showed that MUS is associated with reasonable overall subjective cure rates in women with MUI. However, there was a wide variation in the cure rate of urgency and urgency urinary incontinence (UUI). The cure rate for overactive bladder (OAB) was lower than for SUI and decreased with time. TOT is theoretically more advantageous in women with MUI compared to TVT due to the more horizontal insertion and less obstructive nature (1).

There is ongoing discussion for the best treatment approach to the patients with MUI. Without results of long-term follow-up comparative studies, it is not possible to conclude the efficacy of surgical procedures in

MUI. In the current study, our aim is to evaluate the success and complications of TOT procedure in the treatment of patients with MUI.

MATERIALS AND METHODS

We analyzed 193 consecutive female patients who underwent TOT procedure for SUI in two institutions from March 2005 to March 2009. Among these patients 75 women with MUI were the subjects of this study. All MUI patients had predominant SUI. All patients underwent standard outside-in TOT procedure as Delorme (8) described and data of the patients were retrospectively documented. All operations were performed using two brands which have the same characteristics (Heine Medizin® urethral support system, Düsseldorf, Germany and I-STOP® CL Medical, Lyon, France). Both of them are macropore monofilament polypropylene meshes. Eligible women were at least 21 years old and had documented SUI or MUI (shown by urodynamic studies (UDS) and/or preoperative evaluation) and had completed the 5 years follow-up period. Patients with neurological disorder history, previous urethral reconstruction, morbid obesity and pelvic organ prolapse (POP) greater than stage 1 were excluded from the study. None of the patients experienced incontinence and/or gynecological surgery previously and underwent concomitant vaginal surgery. Preoperatively all patients filled in the informed consent form explaining the possible outcomes and complications of the procedure in detail.

All patients were preoperatively evaluated with history, pelvic examination in lithotomy position, urinary system ultrasound scan (US) and cough stress test (CST). Patients' characteristics including age, body mass index (BMI), the number of postmenopausal women, parity, the number of pads used daily, follow-up

time, previous surgery and post voiding residual urine volume (PVR) were noted. All patients filled in the International Consultation on Incontinence Questionnaire-Short form (ICIQ-SF) preoperatively and at the postoperative follow-up visits. Visual analog scale (VAS) was used to evaluate postoperative patient satisfaction. In VAS, a score of 0 represented very dissatisfied / intolerable urinary complaints and 100 represented very satisfied / no urinary problems (1,9). The patient was accepted as satisfied if the VAS score was ≥ 80 . POP was described during a maximal Valsalva maneuver using the POP quantification system (POP-Q). All patients underwent UDS evaluation (cystometry, pressure-flow study).

All patients were routinely evaluated on the postoperative 15th day with urine culture and possible early postoperative complications were examined. Patients were evaluated on the postoperative 3rd, 12th months and annually with pelvic examination, VAS, CST and ICIQ-SF. Surgical outcomes were evaluated and data of subjective and objective cure rates, any complications related to the procedure were registered. Objective cure was defined as a negative CST, no need for pads and no reoperation for SUI. The criteria for subjective cure included a score of 0 point from ICIQ-SF, no need for pads and no operation for SUI. All other outcomes were defined as failure. Cure of UUI was evaluated according to the patients' stating on ICIQ-SF and no need for antimuscarinic treatment. Statistical analyses were performed with SPSS 17.0 (SPSS version 17.0, Chicago, IL, USA).

RESULTS

A total of 67 women met the requirements for inclusion and had sufficient records for analysis. TOT procedure performed under spinal anesthesia in 65 (97%) patients and under general anesthesia in 2 (3%).

Patients' characteristics were shown in table 1. According to electronic records UDS had revealed detrusor over-activity (DO) in 32 women (47.7 %) and urodynamic SUI (USUI) in 59 women (88 %) among 67 women with MUI. 24 women (35.8%) had showed both USUI and DO.

Table 2 summarizes objective cure, subjective cure and patient

satisfaction rates at the end of 5 year follow-up. The mean score for 29 patients with a postoperative 5th year ICIQ-SF score >0 was 12.2 (SD ± 4.2).

Of the 67 patients, the UUI component of 12 patients (17.9%) had resolved postoperatively. Fifty-five (82%) patients with persistent UUI postoperatively were treated with antimuscarinic drugs.

Overall, postoperative complication rate was 8.9 % (Table 3). Table 3 summarizes the surgical complications reported according to modified Clavien classification. None of our patients experienced intraoperative complications. Two (3%) patients required re-operation for recurrent SUI in the follow-up.

Table 1: Patients' demographic and preoperative characteristics

Number of patients (n)	67
Age (year) mean ±SD	52.7±8.4
BMI (kg/m²) mean ±SD	29.2±2.5
Number of postmenopausal women n (%)	31 (46.3)
Parity median (range)	2 (0-5)
Daily pad use median (range)	4 (2-9)
Follow-up time (month) mean ±SD (range)	69.67±11.1 (60-96)
Preoperative ICIQ-SF score mean ±SD	17.13±3.4

SD, standard deviation;
BMI, body mass index;
ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form

Table 2: Outcomes of the patients at the postoperative 5th year

Total, n (%)	67 (100)
Objective cure, n (%)	60 (89.6)
Subjective cure, n (%)	36 (53.7)
Patient satisfaction (VAS score ≥80), n (%)	47 (70.1)

VAS, visual analog scale
n, number of patients

Table 3: Postoperative complications listed according to modified Clavien classification system

Total complication rate	6 (8.9%)
Grade 1	1 (16.7%)
Dyspareunia/sexual discomfort	1
Grade 2	4 (66,6%)
De novo urgency	-
Severe groin and/or leg pain	2
Urinary tract infection	1
Vaginal mesh extrusion, local estrogen application	1
Grade 3a	1 (16,7%)
Urinary retention, prolonged urethral catheterization	1
Grade 3b	
Urinary retention, mesh incision	-
Vaginal mesh extrusion, mesh removing	-

DISCUSSION

MUI, which is considered as a combination of SUI and UUI, is highly prevalent in everyday practice (3). Semantic definitions of urge

predominant MUI or stress predominant MUI were introduced to facilitate practical use and orient treatment (3). There is a paucity of primary research in this area and management of women with urodynamic MUI remains a subject

of debate (9). MUI treatment consists of conservative management, pharmacotherapy and surgery. For women with predominant SUI, surgery is the most preferred treatment option but patients should be closely informed about possible

postoperative additional treatments. Also before deciding for surgery, all treatment alternatives should be explained to the patient. The best approach has not been defined yet (3). In the current study, our aim is to evaluate our TOT surgery results in patients with MUI. Our study represents long term follow-up, high patient compliance, use of validated questionnaire to evaluate subjective and objective cure rates.

In a prospective randomized study comparing TVT and TOT in patients with SUI or MUI, Nyssönen et al (10) showed that a large proportion of patients with MUI found the operation beneficial for urge symptoms. In a median follow-up of 46 months, the subjective and objective cure rates in TOT group were 81% and 74%, respectively. Urge symptoms were relieved in 70% of patients in MUI subgroup. In another study, Gamble et al (11) assessed the efficacy of transobturator, retropubic or bladder neck sling in 305 women with MUI and concluded that transobturator slings had the lowest rate of persistent DO. Paick et al. (12) reported on 144 women with MUI who underwent TVT, SPARC or TOT and found similar cure rates in all three groups for SUI (96%, 90%, and 94%, respectively) and UUI (urge urinary incontinence) (82%, 86% and 82%, respectively). They also reported that preoperative low maximum urethral closure pressure and DO were both associated with increased likelihood of treatment failure of UUI. In a prospective, multi-centre, randomized study comparing TVT and TOT procedures for MUI, Kocjancic et al. (13) analyzed 116 women with SUI or MUI and randomized to TVT or TOT. They reported de novo urgency as the most frequent late complication. The storage symptom cure rate was 31% after TVT and 55% after TOT. In the current study, although objective cure and patient satisfaction rates were high, the subjective cure rate was relatively

low. This can be explained by the considerable effect of persistent UUI on subjective cure rates. Aging process directly affects the prevalence of UUI so the subjective cure rate decreases in the long-term follow-up (14). In addition to long-term follow-up, the definition of cure in our study was also responsible from low subjective cure rate. Definition of cure varied between different studies may be the possible reason for the variable success rates in different studies (1,15). In a study with large number of patients, observed subjective cure was 60% at 7 months and 53.8% at 38 months when cure rate was defined as stress and urge indices of two or less episode of incontinence one to four times a month or less. However when cure was defined as complete dryness, the subjective cure rate dropped to 35.9% at 7 months and 28.4% after 38 months. In our study we found approximately 20% subjective cure rate at minimum 5 year follow-up (16). The prevalence rates of urinary incontinence subtype varied with responders' age, ethnicity, how the question was asked, and how the subtype was defined (17,18). We use the definition of cure in patients with UUI or MUI only in women who were completely dry. An available explanation why UUI may improve after surgery is that midurethral slings prevent urine from entering into the upper posterior urethra with increase in intra-abdominal pressure thereby avoiding reflex urine leak (19). In fact, tape is located under midurethra or distal urethra instead of proximal urethra in a successful TOT procedure (20).

Coyne et al (21) assessed the impact on health-related quality of life of stress, urge and MUI. The authors found that patients with MUI and UUI scored worse than those with SUI but no significant differences were found in quality of life (QoL) scores in patients with MUI and UUI. These findings were interpreted as urgency in mixed incontinence had a greater impact on quality of life than stress.

Patient satisfaction showing the effect of surgical treatment on the patients' QoL should be a matter of discussion in a study examining the results and efficacy of incontinence surgery. In a recent trial by our study group, patient satisfaction after TOT at the postoperative 1st and 5th year was found to be 92% and 73%, respectively (22). It is hard to evaluate patient satisfaction objectively due to several factors including surgical outcomes or complications which have direct impacts on the patients' expectations. Postoperative incontinence of any kind reduces patient satisfaction (23). In the present study, persistence of UUI was the main reason for dissatisfaction of the patients.

UDS are generally recommended before invasive procedures and surgery in MUI patients. UDS is an invasive and distressing procedure with a significant cost. Nager et al. (24) proved that preoperative UDS is not superior to office evaluation of UUI before surgery in terms of treatment success and patient satisfaction. UDS failed to identify SUI in eight (11.9%) patients, but we have done TOT because of positive CST and SUI history. Also we could not confirm DO in 21 (31.3%) patients who had incontinence with strong urge. When there is a disagreement between the UDS and the patient's symptoms, UDS findings are not superior to the patient's symptoms. Failure to demonstrate DO or SUI on UDS does not exclude the importance of patient's symptoms (25).

In our study, overall complication rate of 8.9% was comparable to other studies with the complication rates ranging 10.5% to 31.3% (22,26). It has been advocated that de novo urgency rate is lower in TOT compared to other midurethral sling procedures (26). None of the patients experienced worsening of UUI. Also we had one vaginal erosion and one urinary retention. We did not remove the sling in both of the cases. In the patient with vaginal erosion, local

estrogen application was enough and the other patient with urinary retention is treated with transient bladder catheterization.

Our study has some limitations. There was little data on daily pad use after surgery. If the patient was accepted as failure, questioning the daily pad use was omitted in most of the

patients. Also postoperative UDS were performed only in case of worsening for UUI, not in all of the patients.

CONCLUSION

TOT procedure is successful for surgical treatment of MUI with predominant SUI in long-term follow-up. The

majority of women found the operation satisfactory. Persistence of UUI was the main reason for dissatisfaction. Long-term comparative studies are needed to assess the efficacy of TOT in patients with MUI.

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