

The initial experience of a training hospital on TOT

Bir eğitim hastanesinin TOT üzerine ilk deneyimleri

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Abstract

Objective: To evaluate the short term results, reliability and complications of Trans Obturator Tape (TOT) operations in patients with stress urinary incontinence (SUI).

Material and Methods: Of 71 patients with SUI or mixed urinary incontinence, we included 66 patients who had undergone TOT operations due to SUI or mixed urinary incontinence (MUI) in our prospective study. Gynecological and neurological examinations, ultrasonographic evaluations, Q-Tip tests, office cystometry tests, complete urine analysis, and urine culture tests were performed. Patients were evaluated again following an average of 9 months (5-14 months) after the operation.

Results: After an average of 9 months after the operation, 86% of the patients were cured. Although we experienced no major intraoperative complications, 24.2% of patients had reported limb pain, 6.1% had vaginal erosion, 3% developed de novo urgency, 7.6 % had obstruction and 4.5% suffered from dyspareunia.

Conclusion: TOT is an effective operation that is easy to learn with low complication rates.

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Key words: Stress Urinary Incontinence, Trans-Obturator Tape, complication

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Özet

Amaç: Stres üriner inkontinans (SUI) olgularında, transobturator bant (TOT) operasyonunun kısa dönem sonuçlarını, güvenilirliğini ve komplikasyonlarını, değerlendirmek.

Gereç ve Yöntemler: SUI veya Mikst üriner inkontinans (MUI) tanısı alan 71 olgudan, çalışma kriterlerine uyan ve TOT yapılan 66 olgu prospektif çalışmamıza alındı. Olgulara jinekolojik muayene, ultrasonografi, stres test, Q tip test, nörolojik inceleme, ofis sistometri, idrar tetkiki ve idrar kültürü yapıldı. Operasyondan ortalama 9 ay (5-14) sonra tüm tetkikler tekrarlanarak preop parametrelerle karşılaştırıldı.

Bulgular: Operasyon sonrası ortalama 9 ay sonra yapılan değerlendirilmede %86 oranında tamamen kür sağlandı. Her ne kadar majör intraoperatif komplikasyon gözlenmedi de, olguların % 24,2 bacak ağrısı, %6.1 vajinal erozyon, %3 De novo urgency, %4.5 dispareni, %7.6 obstrüksiyon saptadık.

Sonuç: TOT etkin ve düşük komplikasyon oranına sahip, öğrenilmesi kolay bir operasyondur.

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Anahtar kelimeler: Stres üriner inkontinans, Trans-obturator Tape, komplikasyon,

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Introduction

As the average life expectancy has been increasing worldwide, urinary incontinence has become one of the factors affecting the quality of life. The most common urinary incontinence type in women is stress urinary incontinence (SUI), observed during activities that increase intra-abdominal pressure such as laughing, coughing, or weightlifting (1). More than a quarter of women between the ages of 30 and 60 are affected by SUI worldwide; and SUI accounts for 77% of all incontinence cases (2). Biri et al. (3) performed a study in Turkey on 2601 women over the age of 15 years. They reported the SUI prevalence to be 4.7% in women between 15-24 years of age; 21.6% between 35-44 years of age; 25.1% between 55-64 years of age; and 21.9% in women older than 65 years. The estimated cost of SUI for the USA is 12.43 billion dollars annually. The available data is not adequate to calculate its annual cost for Turkey (4).

Many surgical treatment options based on the idea of supporting the urethro-vesical junction by placing a hammock-

like structure under the urethra have been suggested. One of these treatment options is the outside-to-inside trans-obturator tape (TOT) application, suggested by Delorme in 2001 (5). TOT is one of the most popular surgical treatments in SUI due to its safety, efficacy, and ease of learning.

The objective of this study was to observe the average operation duration, efficacy, and possible complications of the TOT operation, which is considered to be a minimally invasive surgical method in SUI treatment.

Material and Method

This prospective study was conducted in the gynecology department of our hospital between March 2006 and February 2008. In the study 71 patients with complaints related to stress urinary incontinence or stress plus urge urinary incontinence (mixed incontinence) were included. Informed consent was obtained from all participants and the approval of the Ethics Committee of our hospital was obtained.

The detailed medical histories were obtained from each patient and their physical examinations were performed. Complete urine analysis and urinary culture was obtained from each patient. Patients diagnosed to have urinary infection were given appropriate treatments. All patients underwent stress test, Q tip test, preoperative urogynecological examination that includes simple cystometry, and neurological evaluation of clitoris, anus, and cough reflexes. Their pad use was questioned. All participants were asked to keep a urinary diary for at least 3 days.

Patients with complaints related to stress urinary incontinence or stress and urge urinary incontinence were included in the study. Urogynecological examinations supported their case. Patients with grade three genital prolapse, chronic diseases such as Diabetes Mellitus, or detrusor instability demonstrating urge urinary incontinence rather than SUI, were excluded from the study.

As IV antibacterial prophylaxis, 2g cefazolin was given to each patient 12 hours prior to the operation and Biocadin vaginal suppositories were applied 24 hours before surgery. 43 patients (65.2%) underwent general anesthesia, and the remaining 23 patients (34.8%) received epidural anesthesia. The operations were performed by 3 different surgeons working in our clinic according to the technique suggested by Delorme (5). A 2 cm long horizontal incision was made at the midurethral level of the anterior vaginal wall. Then, a 1 cm long incision was made at the clitoral level on the lateral side of each labium majus. The tape was placed at the midurethral level. We used multifilament polypropylene tapes (IVS 04, Surgipro tape, Covidien USA) in 18 of our cases, and monofilament polypropylene tapes (IVS 04, Surgipro tape M, Covidien USA) in 48 of our cases. Cystoscopy was not performed on any patient following surgery.

In the follow-up examinations, the patient was considered to be "cured" if no complaints of urinary incontinence were present, residual urine was less than 100 ml, and the stress test was negative. If the residual urine was less than 100 ml, and the patient reported only one episode of urinary incontinence per day, the patient was considered to have "recovered". If the patient did not feel any improvement in her incontinence, residual urine was more than 100 ml, and the patient reported more than one episode of urinary incontinence per day, the result was considered to be a "failure". The operation was considered "successful" if the patient was cured or had recovered. Operation durations, preoperative and post operative hemoglobin levels, intra operative and post operative complications and the length of stay in the hospital were recorded for each patient. In order to determine the efficacy of TOT, the patients were re-evaluated in

5 to 14 months (an average of 9 months) after being discharged from hospital. The results of their preoperative and postoperative gynecological evaluations were compared.

Statistics

The SPSS (Statistical Package for Social Sciences) for Windows 15.0 program was used to analyze data obtained in the study. Definitive statistical methods (average, mean, rate, standard deviation, frequency) and quantitative statistical methods such as Paired sample t test and Wilcoxon sign test were used to evaluate the data. To compare qualitative data, the Mc Nemar test was used. Statistical significance was considered achieved at $p < 0.05$, with a 95% confidence level.

Results

We conducted this prospective study in 66 patients (93%) who met the inclusion criteria. Of the 5 patients (7%) excluded from the study, 2 had Diabetes Mellitus; 2 were considered to have only detrusor instability; and 1 did not show up for her post operative evaluation. The ages of the 66 patients ranged from 30 to 67 and the mean age was 48.1 ± 8.2 . All patients were multiparous. Their average body mass index was $29.2 \pm 4.6 \text{ kg/m}^2$. 36 of the participants (54.5%) were premenopausal, while 30 of them (45.5%) were postmenopausal. The average duration of menopause for postmenopausal patients was 8.1 ± 6.4 years. 2 of these patients had a history of hormone replacement therapy; however, they both reported having abandoned this 2 years previously. All of the participants had some degree of pelvic organ prolapse. 47 patients (71.2%) suffered from SUI only, whereas 19 of them (28.8%) had stress plus urge urinary incontinence.

58 patients (87.9%) underwent only a TOT operation. In addition to TOT surgery, 4 women (6.1%) underwent anterior vaginal wall repair, 2 women (3%) underwent posterior vaginal wall repair and 2 women (3%) underwent both anterior and posterior vaginal wall repair.

Preoperative and postoperative urinary symptoms of these 66 patients are summarized in table-1. (Table 2). During the postoperative evaluation, it was observed that 57 patients (86%) had been "cured", 3 (4.5%) patients had "recovered", and 6 patients (9.5%) had experienced "failure". The operation was considered "successful" if the patient was cured or had recovered. The average operative time was 25 minutes, varying from 10 to 60 minutes. The average postoperative catheterization time was 1 day, varying from 1 to 6 days. The average length of hospital

Table 1. Comparison of preoperative urinary symptoms and basic cystometry results with postoperative urinary symptoms and basic cystometry results

Urinary symptoms and basic cystometry results	Preoperative	Postoperative	P
Daytime voiding frequency	7.59±3.05	5.85±1.29	0.001*
Nighttime voiding frequency	2.53±1.40	1.20±1.13	0.001*
Q-tip test (0)	66.06±14.34	29.24±8.19	0.001*
Residual urine (ml)	13.55±17.33	29.91±25.17	0.001†
Bladder capacity (ml)	481.06±65.43	489.24±67.56	0.003†
Pad use	57 (86%)	9 (14%)	0.001•
*Wilcoxon signed-rank test †Paired sample t-test •McNemar test			

stay was 2 days, varying from 1 to 7 days. The average difference in the preoperative and postoperative hemoglobin levels of the participants was 0.18 ± 0.25 mg/dl, which was not statistically significant ($p < 0.05$). The outcomes of the TOT operations and their intra-operative and postoperative complications are summarized in Table 2 (Table 2).

Discussion

The TOT operation has gained worldwide popularity immediately following its introduction. Its short operative time, brief hospitalization period, and ease of application have played a role in its acceptance (6). In our study, the average length of hospital stay was 2 days, and the average operative time was 25 minutes. We noticed a decrease in the operation duration after our 12th case. We consider that the operation duration and hospitalization period can shorten as we gain more experience. Sivaslıoğlu et al. (7) reported the average duration of the TOT operation performed by experienced surgeons to be 13 minutes. After the introduction of the TOT operation, bladder, urethra, and nerve injuries had been reported during the learning stage. Krauth et al. (8) reported the risk of bladder perforation with the TOT technique to be 0.5%. Two cases in their series (3/604) had significant cystocele. Minaglia et al. (9) reported 3 bladder perforations during the TOT operation. Two of these women had histories of prior pelvic organ prolapse surgery. Cystoscopy can be suggested for patients with a history of operation for pelvic organ prolapse or for patients who are programmed to undergo pelvic organ prolapse operations in addition to the TOT operation. In our study, neither the 58 patients undergoing the TOT operation only, nor the 8 patients undergoing TOT plus pelvic organ prolapse operations suffered from bladder, urethra or nerve injuries. The reason for not encountering any bladder injuries in our series may be due to the exclusion of all patients with grade three genital prolapse from the study, and possibly to the experience of surgeons in the field of vaginal surgery. Cys-

toscopy was not applied following surgery in our study. A study evaluating TOT results and complications in the USA reported 173 complications related to TOT. Obturator nerve damage, excessive bleeding, ischioanal fossa abscess, iliac vein injury, and hematoma were some of the complications mentioned in the study (10). In their review of the current literature on TOT, Daneshgari et al. (11) declared a complication rate of 10.5 to 31.3%, including bladder perforations, urethral injuries, hemorrhage, vaginal erosions, de novo urge, urge incontinence, and urinary tract infections. While we did not encounter any major complications, 4 patients suffered from tape erosions, 4 patients had vaginal perforation, 1 patient had a urinary infection, and 2 patients had dyspareunia. The average difference in preoperative and postoperative hemoglobin levels of the participants was 0.18 ± 0.25 mg/dl ($p < 0.05$).

In the early postoperative period, the most common complaint was high thigh pain (24.2%). This pain can be explained by the close proximity of the tape to the gracilis and adductor muscle origins. In the follow-up examinations, this pain was found to have disappeared. Grise et al. (12) have reported a similar finding in their study. Some studies suggest that the outside-to-inside technique, which we used in our study, causes less dyspareunia and pain. The dorsal nerve of the clitoris, protected by the ischiopubic rami, may be injured while perineal and obturator membranes are penetrated in the inside-to-outside technique (13). Dyspareunia rate in our study was 4.5%.

Any operation performed to cure SUI may cause urethral obstruction. Since TOT is "tension-free", post operative obstruction and difficulty in voiding is rare (14). Urethral mobility is maintained in TOT operations allowing the urethra to bend under stress (15). In our study, although the preoperative and postoperative Q-tip test results show statistically significant changes, urethral mobility did not disappear. Costa et al. (6) reported obstruction in 3.8% of their cases. They catheterized the patients to overcome the problem. Deval et al. (16) observed urinary retention (1.5%), and postoperative voiding dysfunction (5.4%) in their study. They loosened the tapes of the patients with urinary retention on the 21st to 24th postoperative days. SUI was not found to recur in these cases. In our study we observed difficulty in voiding in 4.5% and need to strain while voiding in 7.6% of patients. In the early post-op period, we did not catheterize any patient whose post voiding residual volume was less than 100 ml. The catheterization period in most of the patients was around 24 hours whereas three patients needed catheterization for more than 48 hours and only one of them needed catheterization up to six days.

After TOT operations de novo urge is rare, which proves that TOT has minimal obstructive effects (17). In their study, Roumguere et al. (18) reported de novo urgency in 2.5% of patients. Krauth et al. (8) reported this incidence in the 3 month follow up to be 5.2%. In our study, we observed de novo urge in 3% of patients. One of the long term complications of TOT is vaginal erosion. Its possible causes are inadequate suturing of the vaginal incision, infection, rejection of tape material, lateral positioning of the tape, early sexual intercourse, and vaginal perforation (19). Vaginal erosion incidence after incontinence surgery ranges from 0.7% to 13.8% (20, 21). In our study, there were 4 cases of vaginal perforation. 3 of them were found to have vaginal erosion. Lack of experience may explain why all our vaginal perforation cases were encountered in the first 15

Tablo 2. Complications of TOT

Complications		(+) n=66 (%)
Bladder perforation		-
Vaginal perforation		4 (6.1)
Urethra injury		-
Nerve damage		-
Hematoma		-
High thigh pain		16 (24.2)
Urinary infection		1 (1.5)
De novo urge		2 (3)
Vaginal erosion		4 (6.1)
Voiding dysfunction	Strain while voiding	5 (7.6)
	Difficulty in voiding	3 (4.5)
Fewer		1 (1.5)
Dyspareunia		3 (4.5)

Table 3. TOT cure rates

Authors	Case (n)	Duration of follow-up (Month)	Treatment Outcome (%)
Giberti et al. ⁽²²⁾	108	24	80
Cindolo et al. ⁽²²⁾	80	4	92
Roumeguere et al. ⁽²²⁾	120	12	80
Waltregyn et al. ⁽²²⁾	91	36	88
Akın et al. ⁽⁷⁾	24	30	86
Aksakal et al. ⁽²³⁾	28	6	75
Our study	66	14	86

patients operated. We used multifilament tapes in 3 of our perforation cases. We thought the reason behind vaginal erosion to be perforation of the vagina during surgery. Furthermore, it is interesting to note that three of the 4 rejected materials were multifilament. We encountered our 4 vaginal erosions on the 7th, 9th, 9th and 13th postoperative months. While some authors have suggested total resection of the tape, we abided by the literature and resected the tape segment in the erosion zone (13, 20).

In our study we had a “cure” rate of 86% and a recovery rate of 4.5%. Since the operation was considered “successful” if the patient was cured or had recovered, the overall success rate of our study was 90%. This success rate correlates with the current literature (7, 22, 23). (Table 3) Multifilament bands were used in eighteen cases. Due to the insufficient number of patients having had multifilament bands, we were not able to randomize the patients according to the type of filament used during their operations. The short followup period of the study, the lack of randomization of the patients, and the lack of application of urodynamic studies on the patients are the deficiencies of the study.

Conclusion

In conclusion, TOT is an effective and relatively safe operation that is easy to learn. When performed on selected patients by surgeons who have mastered pelvic anatomy and who do not overlook possible complications, it has a high success rate.

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