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Evaluation of tension-free vaginal tape and transobturator tape surgery performed in one year in terms of mesh erosion

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Ethics Committee Approval
The study was approved by the clinical research ethics committee of the University of Health Sciences Istanbul Gaziosmanpasa Training and Research Hospital (Date: October 5, 2022, number: 126).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Mesh erosion is one of the feared complications in surgeries performed using mesh, and its frequency is increasing as more and more of these surgeries are performed. This study aims to evaluate transobturator tape (TOT) and tension-free vaginal tape (TVT) surgeries performed in the surgical treatment of stress urinary incontinence (SUI) in our clinic in terms of clinical results and mesh erosion.
Methods: This study is a retrospective cohort study. The files of 50 patients who had SUI and underwent TOT and TVT surgery in our clinic between January 2022 and January 2023 were reviewed. Patients diagnosed with pure SUI and for whom surgery was performed were included in our study. The participants were divided into two groups: those who had TOT surgery and those who had TVT surgery. These groups were evaluated and compared in terms of mesh injury, mesh erosion, pelvic pain, dyspareunia symptoms, and urinary retention. The surgical data of patients, incidence of complications, pre- and postoperative incontinence impact questionnaires (IIQ-7) and the scores of the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) were recorded.
Results: The mean follow-up period of the participants was 8.96 (8.47) (range, 6-17 months). TVT surgery was performed on 13 participants and TOT surgery was performed on 37 patients. When the two groups were compared, there was no statistically significant difference in terms of age, body mass index (BMI), parity, menopausal status, duration of incontinence, preoperative IIQ-7 scores, and ICIQ-SF scores (P<0.05). There were no statistically significant differences between surgical durations, length of hospital stay, early surgical complications, postoperative 3rd month IIQ-7, and ICIQ-SF scores (P<0.05). Furthermore, no difference in the rates of mesh erosion and mesh-related complications between the two groups (P<0.05) was observed.
Conclusion: TOT and TVT surgeries seem to be quite safe in terms of complications, as well as being satisfactory in terms of patient satisfaction. Although mesh-related complications can be frightening, the rate of regression is low with appropriate management. Our results show that both operations are safe with an acceptable complication rate when performed by surgeons who have experience with anti-incontinence procedures.

Keywords: trans-obturatar tape, suburetral slings, stress urinary incontinance, tension-free vaginal tape

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Introduction

Stress urinary incontinence (SUI) defined as urinary incontinence while coughing and sneezing in women [1], is a health problem that affects women's quality of life by creating psychological, social, and sexual problems [2]. Hypermobility of the vesicoureteral segment due to pelvic floor insufficiency and failure to transmit intra-abdominal pressure to the bladder neck due to non-retropubic urethra are blamed as the formation mechanism. Its incidence is 22% during the reproductive ages, but it has been reported that it may increase as high as 73% with advanced age and the hypoestrogenemia caused by menopause [3].

SUI surgery aims to prevent involuntary urinary incontinence by supporting the bladder neck and urethra in the retropubic position [4]. Although there are many surgical treatment alternatives, after the clarification of this etiologic mechanism, mid-urethral sling surgery came to the fore. TVT and TOT surgery are the most frequently performed surgeries in urogynecology and urogynecology clinics in the treatment of SUI [5]. In both these surgeries, an attempt is made to support the urethra using mesh, which brings with it the risk of complications in addition to the risks of the surgery [6]. Although many patients undergoing mesh-enhanced vaginal repair recover uneventfully, based on the limited data currently available, there appears to be a small but significant group of patients who experience persistent and life-changing sequelae, including pain and dyspareunia, from the use of vaginal mesh. In the literature, infection, erosion, pelvic pain, dyspareunia, and organ injuries due to mesh erosion requiring resurgery have been described [7]. Concerns exist about the safety and efficacy of transvaginally inserted mesh [8].

In this study, we aimed to evaluate TOT and TVT surgeries in the treatment of SUI in line with the cases performed in our clinic during the last year, in terms of mesh erosion and other mesh complications, and in light of the literature.

Materials and methods

This is a retrospective cohort study. The files of 50 women who were diagnosed as having SUI or mixed-type urinary incontinence and underwent TOT and TVT surgery in our clinic between January 2022 and January 2023 were reviewed retrospectively. Ethical approval was obtained from the ethics committee of Gaziosmanpaşa Training and Research Hospital before starting the study (Date: October 5, 2022, No: 126).

Participans were those who were diagnosed as having SUI and for whom TOT or TVT surgery was performed. TVT surgery was performed in 13 women and TOT surgery was performed in 37 women. Surgery took place after all of the patients were informed in detail about the surgery they would undergo and provided informed consent.

Patients with neurological disease that would impair bladder function, pregnant women, and patients scheduled for surgery due to gynecologic malignancy, urinary system anomalies, and cystocele or rectocele were excluded from the study. Prior to the surgery, detailed anamnesis was taken from all patients and a voiding diary was maintained. A stress test was performed on all patients with urine constricted in the gynecologic examination position and standing, at rest, and under Valsalva. Q-tip testing was performed in the lithotomy position to assess urethral hypermobility. The preoperative stress test of all patients was positive. Bladder neck mobility was considered positive when the amount of angle change in the straining and resting states of the cotton swab was above 30 degrees. Upper urinary tract and post-micturition residue were evaluated through urinary ultrasonography. All patients underwent a simple neurologic examination.

The Turkish-validated versions of the IIQ-7 [9] and ICIQ-SF [10] tests were used to evaluate the symptoms of the patients and standardize them. Complete urinalysis, urine cultures, and post-void residual urine measurements were performed on the patients before the surgery. Those who were found to have an infection in the urine evaluation were treated with appropriate antibiotic therapy. The demographic characteristics of the patients, surgery information, early evaluations in the postoperative period, and surgical complications were recorded.

All surgeries were preferably performed under spinal anesthesia, and in cases where spinal anesthesia was not appropriate or spinal intervention was not accepted by the patient, general anesthesia was administered. Antibiotic prophylaxis was performed using 1 g of cefazolin before the surgery. The surgery was considered successful in patients with a negative post-operative stress test, a residual of less than 100 cc, and full continence. Surgery was considered unsuccessful in patients whose incontinence continued after the operation.

Surgical technique

TVT surgery: At the dorsal lithotomy position, the anterior vaginal wall was incised 1.5-2 cm below the urethra, approximately 2 cm, and the paraurethral areas were separated using sharp and blunt dissection and advanced to the underside of the symphysis pubis. The mesh (Betamix, Transobturatory set, 10 x 450 mm thickness) attached to the TVT needle from the created area was placed under the urethra somewhat laterally, passing it behind the symphysis pubis bone. The same procedure was performed on the other side. The suburethral distance was adjusted by inserting the scissors vertically between the urethra and the mesh. The bladder was evaluated for possible injuries using cystoscopy without any mesh being detected. After making sure that there was no perforation, excess mesh pieces in the suprapubic region were cut.

The vaginal mucosa was then sutured. The procedure was terminated after a tight tampon was placed.

TOT surgery: In the dorsal lithotomy position, the anterior vaginal wall was incised 1-2 cm below the urethra, approximately 2 cm. Paraurethral areas were separated in a sharp and blunt dissection, and the ischiopubic bone was reached with a finger. The skin was incised 1 cm lateral to the ischiopubic ramus on the line running parallel to the clitoris. Using the outside-in technique as described by Delorme [11] in 2001, bevelled needles were inserted through the skin close to the medial part of the obturator foramen, and the vagina was exited through the suburethral space with the help of a finger by passing the obturator membrane. Prolene mesh (Level SVT Helical Set, 10 x 450 mm thick) was attached to the end of the trocar and

pulled back. The same procedure was performed on the other side and the mesh was laid under the urethra. The suburethral distance was adjusted by inserting the scissors between the urethra and the mesh perpendicularly, and the excess mesh pieces were cut. The procedure was terminated after the vaginal mucosa was sutured and a tight pad was placed inside.

After discharge, the patients were seen for follow-ups on the tenth day, third month, and sixth month postoperatively. The symptoms of the patients were evaluated in terms of stress tests, quality of life scores, possible problems related to mesh, and other complications. In the case of mesh complications, the International Continence Society-International Urogynecological Association (ICS-IUGA) complication classification calculator, which is a classification system based on category, time and location, was used [12]. Surgical complications were classified according to the Clavien-Dindo system[13]. In cases diagnosed as vaginal erosion, prophylaxis with first-generation cephalosporin was administered. In cases with bacterial vaginosis, 2 x 500 mg metronidazole p.o. for 7 days was added. In postmenopausal cases, 25 µg/day of estradiol hemihydrate was given intravaginally as a topical estrogen for six weeks. In cases of erosion in the postoperative period or if mesh excision was required for any reason, the eroded mesh part was excised in vaginal erosions without infectious complications. After debriding and debriding the vaginal mucosa edges, suturing was done again.

Statistical analysis

Normality control of continuous variables was evaluated using the Shapiro-Wilk test. Non-parametric analyses were used for variables that were not parametric or conforming to the normal distribution. The independent sample t-test and Mann-Whitney U test were used for continuous variable comparisons between TVT and TOT groups. The Wilcoxon test was used for preop and post-op comparisons within the groups. To determine whether the changes according to time differed according to the groups, repeated measures of analysis of variance (ANOVA) (time x group interaction) were analyzed. Fisher's exact test was used in the analysis of categorical data. The analysis of the data was performed using the IBM SPSS 21 package program. A *P*-value of ≤0.05 was considered statistically significant.

Results

The mean age of the patients was 59.38 years in the TVT group and 61 years in the TOT group. When both groups were compared, no statistical difference was found between the groups in terms of age (*P*=0.527). Other demographic characteristics are shown in Table 1.

In the preoperative evaluation of the patients, their symptoms and durations were questioned, and their evaluations were made using the q test and cough test. The preoperative evaluation results of the patients are shown in Table 2.

In this study, mesh-related complications were observed in eight women from a group of 50 participants. Three were in the TVT group, and the remaining five were in the TOT group. In one patient, during the cystoscopy performed during the TVT surgery, it was noticed that the bladder mucosa was perforated when the mesh was passed through, and TOT surgery was performed on the patient by removing the mesh. In the postoperative six-month follow-up, only one patient had inguinal pain after TVT surgery; no inguinal pain was observed in the group that underwent TOT surgery. Vaginal mesh erosion-exposure (greater than 2 cm) that required excision was observed in one patient after TVT surgery and one patient after TOT surgery. The mesh of both patients was excised under general anesthesia and the mucosa was repaired. After the TOT surgery, approximately 0.5 cm of mesh erosion was observed in another patient; the mesh was treated with local estrogen therapy for six weeks without excision, and it was completely epithelialized over the mesh. Dyspareunia developed in three patients who underwent TOT surgery, but only one required mesh excision. Although excision was recommended for one patient, it was not performed, because the patient rejected the procedure. Mesh excision was determined for six of eight patients who developed complications, but five of them were treated by excision of the mesh. One patient with erosion did not accept excision and the mucosal repair was renewed with local anesthesia. Considering the regression with treatment in post-op symptoms, only one patient who underwent TOT reported intense pain in the mesh area, and the pain did not regress despite the removal of the mesh. The symptoms of the other seven patients disappeared with appropriate management. The classification of patients with complications according to the ICS-IUAG classification is shown in detail in Table 3. When looking at the Clavien-Dindo stages, only one patient was found to be stage 3, one patient was stage 2, and the remaining six patients were stage 1.

Table 1: Demographic characteristics of the patients

		TVT			TOT			
		Mean (SD)	**Median [IQR]**	**Min-Max**	**Mean (SD)**	**Median [IQR]**	**Min-Max**	***P-value***
Age (years)		59.38 (7.22)	58 [53.5-65]	49-72	61 (8.07)	61 [55-66.5]	46-78	0.527[a]
BMI (kg/m^2)		30.24 (6.22)	27.4 [25.8-34.76]	21.9-44.1	27.83 (5.82)	27.56 [23.34-30.93]	17.72-42.31	0.214[a]
Parity (n)		2.38 (0.96)	2 [2-3]	1-4	2.46 (1.02)	2 [2-3]	1-5	0.799 [b]
Vaginal birth (n)		1.62 (1.33)	2 [0-2.5]	0-4	1.89 (1.26)	2 [1-3]	0-5	0.539 [b]
		n	**%**		**n**	**%**		***P-value***
Mena-pause	No	11	84.6		33	89.2		0.643
	Yes	2	15.4		4	10.8		
Hrt usage	No	12	92.3		34	91.9		1.000
	Yes	1	7.7		3	8.1		
Smoke	No	11	84.6		33	89.2		0.643
	Yes	2	15.4		4	10.8		
Vaginal birth	No	4	30.8		6	16.2		0.420
	Yes	9	69.2		31	83.8		
Cesarean	No	10	76.9		30	81.1		0.707
	Yes	3	23.1		7	18.9		
Previous surgery	No	10	76.9		32	86.5		0.413
	Yes	3	23.1		5	13.5		

[a]: Independent Sample t-test, [b]: Mann-Whitney U test, P2: Fisher's Exact test

Table 2: Preoperative evaluations of the patients

		TVT			TOT			
		Mean (SD)	**Median [IQR]**	**Min-Max**	**Mean (SD)**	**Median [IQR]**	**Min-Max**	***P1*-value**
Duration of incontinence (years)		3.92 (1.75)	4 [2.5-5]	1-7	2.19 (1.47)	2 [1-3]	1-6	0.22
		n	**%**		**n**	**%**		***P2*-value**
Q test	No	4	30.8		12	32.4		1.000
	Yes	9	69.2		25	67.6		
Cough test	No	1	7.7		2	5.4		1.000
	Yes	12	92.3		35	94.6		
Nocturia	No	11	84.6		31	83.8		1.000
	Yes	2	15.4		6	16.2		
Pelvic organ prolapse	No	11	84.6		32	86.5		1.000
	Yes	2	15.4		5	13.5		

P1: Mann-Whitney U test, *P2*: Fisher's Exact test

Table 3: Early and late complication information of the patients

		TVT			TOT			
		Mean (SD)	**Median [IQR]**	**Min-Max**	**Mean (SD)**	**Median [IQR]**	**Min-Max**	***P1*-value**
Urinary catheter stay (hours)		26.46 (4.77)	24 [24-28]	24-36	26.38 (6.14)	24 [24-24]	24-48	0.632
Hospital stay (hours)		1.23 (0.44)	1 [1-1.5]	1-2	1.11 (0.31)	1 [1-1]	1-2	0.278
		n	**%**		**n**	**%**		***P2*-value**
Intraoperative bladder injury	No	12	92.3		37	100.0		0.260
	Yes	1	7.7		0	0.0		
Hematoma	No	13	100.0		37	100.0		-
Pelvic pain	No	12	92.3		37	100.0		0.260
	Yes	1	7.7		0	0.0		
Mesh erosion	No	12	92.3		35	94.6		1.000
	Yes	1	7.7		2	5,4		
Pain in the mesh area	No	13	100.0		35	94.6		1.000
	Yes	0	0.0		2	5.4		
Dyspareunia	No	13	100.0		34	91.9		0.558
	Yes	0	0.0		3	8.1		
Mesh removal patient	No	11	84.6		33	89.2		0.643
	Yes	2	15.4		4	10.8		
Denova urge incotinance	No	11	84.6		35	94.6		0.275
	Yes	2	15.4		2	5.4		
Improvement in postoperative symptoms after treatment	No	3	%35		5	%65		0.357
	Yes	3	%100		4	%80		

P1: Mann Whitney U test, *P2*: Fisher Exact test

Table 4: Preoperative and postoperative survey results of the patients

	TVT			TOT				
	Mean (SD)	**Median [IQR]**	**Min-Max**	**Mean (SD)**	**Median [IQR]**	**Min-Max**	***P*$_{group}$-value**	***P*$_{all}$-value**
ICIQ-SF Score Preop	12.92 (1.44)	13 [11.5-14]	11-15	12.9 (1.31)	13 [12-14]	11-15	0.964	0.941
ICIQ-SF Postop	1.85 (1.41)	2 [1-3]	0-5	1.92 (1.62)	2 [1-3]	0-5	0.982	
***P*$_{time}$-value**	0.001			<0.001				
IIQ-7 Preop	15.54 (1.27)	15 [14.5-16.5]	14-18	15.46 (1.14)	15 [14.5-16]	14-18	0.891	0.612
IIQ-7 Postop	0.77 (0.93)	1 [0-1]	0-3	0.95 (0.97)	1 [0-1]	0-3	0.553	
***P*$_{time}$-value**	0.001			<0.001				

P_{group}: Mann Whitney U test, P_{time}: Wilcoxon test, P_{all}: Repeated Measures ANOVA (timexgroup interaction)

Pre/postoperative IIQ-7 and ICIQ-SF questionnaires results are given in Table 4. In both tests, statistically significant improvement was found in postoperative data compared to preoperative scores. These results showed that there was a positive change in the quality of life of the patients with both surgeries, independent of complications. The variation of ICIQ-SF scores and IIQ-7 scores over time did not differ between the groups (P>0.05).

Discussion

SUI surgery is a frequently performed treatment in urogynecology clinics because of the increasing quality of life expectation of women, the awareness that this is not a destiny based on the effects of training and social media, and the effective treatment options with high success rates. In addition to potential general surgical problems, each surgery carries its own risks of complications. Besides general surgical complications in TOT and TVT surgeries, there are some concerns about the use of mesh. In July 2011, the United States Food and Drug Administration (FDA) issued a safety statement titled "Update on Serious Complications Associated with Transvaginal Surgical Mesh Placement for Pelvic Organ Prolapse." As a warning, the purpose of this paper was to invite healthcare providers and patients to be more selective because important complications with the placement of this mesh were not uncommon, and it was not clear if these repairs were more effective than meshless repairs. Many countries, considering this warning, concluded that it was necessary to reconsider the use of mesh and decided not to use it as much due to serious complications [14]. When we look at the literature, there are many case reports about mesh-related complications and articles on their management. Contrary to Richter et al. [15], who argued that post-operative groin and leg pain, which can be permanent, was more common in TOT surgery than in TVT, in our study, there was one patient with groin and leg pain in the TVT group, but no leg pain was observed in the TOT group. This result needs to be confirmed by studies with a larger number of participants. In all surgeries using mesh, the most feared complication is mesh-related erosion. These can be small or present as the opening of a fairly large area. The general tendency is to provide an environment for the repair of the mucosal area on the mesh with sexual abstinence and local estrogen treatment of small erosion areas [16,17]. In larger erosion areas where the mesh is infected, and in small erosion areas that do not regress despite local treatment, the mesh should be removed locally or totally [18]. In our study, mesh erosion developed in a total of four women, one from the TVT group and three from the TOT group; because one of them was very small, it was followed up with local estrogen therapy

and sexual abstinence, and spontaneous closure was ensured requiring no excision. In one case, due to the accompanying severe inguinal pain, excision was performed even though the mesh erosion area was small. In all four patients, the symptoms completely regressed after excision and treatment were provided.

In a case presented by O'kane et al. [19], intravesical mesh erosion occurred in a patient after TVT was detected during routine follow-up in which the patient had no symptoms. Although excision was suggested, it was rejected by the patient, and prophylactic weekly 1 g antibiotic prophylaxis was started to prevent stone formation and possible infective processes in the bladder; routine follow-up was performed using cystoscopy. The authors did not indicate a negative process related to the patient in their article in which they reported a follow-up of about three years. This case highlights the importance of subsequent follow-up in preventing complications. Patients should be informed in detail about the potential complications of this surgery, which include a foreign material being inserted into the body, and they should be motivated to adhere to their routine follow-ups.

In our study, eight (16%) patients who developed complications were treated with an appropriate approach and full recovery was achieved in seven (88.8%) patients. In one patient (2%), persistent inguinal pain developed despite the excision of the mesh. In the literature, the incidence of erosion due to mesh has been reported as a rare complication ranging from 0.2% to 22% [20,21]. Considering our results, the complication rate is at an acceptable level and is compatible with the literature.

Limitations

There are some limitations to our study. The menopausal status of the patients, whether they used HRT, the duration of treatment, the presence of vaginal mucosal atrophy, and wound healing can be affected in the presence of additional diseases such as diabetes. It is known that this reduces surgical success, and we could not exclude these factors. Because our study was retrospective, we could only reach a limited patient group, and some records were incomplete or insufficient. There is a need for studies with more stringent exclusion criteria related to additional diseases and conditions, and thıs may be the focus of other studıes. Another important limitation is that causality cannot be determined because cross-sectional data are analyzed. Health status and reproductive variables were self-reported. This national study evaluates only non-institutionalized adults and this may limit the generalizability of these results to other groups.

Conclusion

When the results of our study are evaluated together with the literature, neither TOT nor TVT surgery seems to have an advantage over the other in terms of mesh-related complications. TOT and TVT surgeries seem to be quite safe in terms of complications, as well as acceptable in terms of patient satisfaction. Although mesh-related complications can be frightening, the rate of regression is high with appropriate management.This means that in SUI treatment the surgeon can choose either of the two methods, based on his/her experience and the patient’s compatibility.

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