**Functional Urology** 

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# What are the Predictive Factors of the Cure and Complication Rates for Midurethral Slings in the Treatment of Stress Urinary Incontinence in Women: A Multicenter and Multivariate Analysis Study

Kadınlarda Stres Tip İdrar Kaçırma Tedavisinde Midüretral Slinglerin Başarı ve Komplikasyon Oranlarını Etkileyen Faktörler Nelerdir: Çok Merkezli ve Multivaryan Analiz Çalışması

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## What's known on the subject? and What does the study add?

To our knowledge, this was the biggest multicenter study about midurethral slings in our country. We hope the results will be a guide for the surgeons.

# Abstract

Objective: Predictive factors that could affect the cure and complication rates of midurethral slings (MUS) in the treatment of stress urinary incontinence (SUI) were investigated.

Materials and Methods: A total of 594 women (outside-in transobturator in 285, inside-out transobturator in 91, and retropubic in 218) with SUI and who had undergone MUS were evaluated. The median age was 53.9 (27-82) years. Univariate analyses were done using chi-square test, Student's t-test and the Mann-Whitney U test. Multivariate analyses were done using logistic regression analysis to determine predictive factors affecting cure and complication rates.

Results: The mean follow-up time was 48 months. The subjective cure rate was 84% and complication rate was 11.2%. On univariate and multivariate analyses, the cure rate was found to be increased in younger patients [odds ratio (OR): 0.97, 95% confidence interval (CI): 0.95-0.99, p=0.038] and in patients with pure SUI (OR: 2.17, 95% CI: 1.31-3.60, p=0.002). The type of surgery was the only statistically significant parameter affecting the complication rate, which was significantly higher in retropubic MUS procedure (OR: 6.28, 95% CI: 3.51-11.22, p<0.001).

**Conclusion:** MUS is an effective and safe surgical procedure in the treatment of SUI. In this study, age and type of incontinence were the only significant predictive factors affecting the cure rate. Our study suggests that retropubic approach could be considered a risk factor for complication after MUS.

Keywords: Stress urinary incontinence, midurethral sling, transobturator, retropubic, complication

#### Öz

Amaç: Kadınlarda stres tip idrar kaçırma (STİK) tedavisinde midüretral sling (MUS) uygulanmasının sonuç ve komplikasyon oranlarını etkileyen prediktif faktörleri araştırdık.

Gereç ve Yöntem: Ürodinamik STİK tespit edilip MUS uygulanan 594 kadın hasta (285 transobturator dıştan içe, 91 transobturator içten dışa, 218 retropubik) araştırıldı. Ortalama yaş 53,9 (27-82) idi. Univaryan analizde ki-kare, Student-t ve Mann-Whitney U testleri kullanıldı. Multivaryan

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# Öz

analizde lojistik regresyon testi kullanılarak kür ve komplikasyon oranlarını predikte eden faktörler araştırıldı.

**Bulgular:** Ortalama 48 ay takip süresinde subjektif kür oranı %84 olurken komplikasyon oranı %11,2 oldu. Univaryan ve multivaryan analizde kür oranının genç hastalarda [p=0,038, göreceli olasılıklar oranı (OR): 0,97, %95 güven aralığı (GA): 0,95-0,99] ve saf STİK olan hastalarda (p=0,002, OR: 2,17, %95 GA: 1,31-3,60) arttığı tespit edildi. Uygulanan cerrahi tipinin komplikasyon oranlarına etki eden tek prediktif faktör olduğu tespit edildi ki bu retropubik MUS'de anlamlı olarak daha yüksekti (OR: 6,28, %95 GA: 3,51-11,22, p<0,001).

**Sonuç:** Kadınlarda STİK cerrahi tedavisinde MUS başarıyla uygulanabilmektedir. Yapılan çalışmada yaş ve idrar kaçırma tipinin kür oranlarına etki eden prediktif faktörler olduğu bulunurken, uygulanan cerrahi tipinin komplikasyon oranlarını etkileyen tek prediktif faktör olduğu tespit edildi. **Anahtar Kelimeler:** Stres tip idrar kaçırma, orta üretra gevşek sling, transobturator, retropubik, komplikasyon

#### Introduction

Stress urinary incontinence (SUI) is a common condition in women, with a prevalence of 35.5% in urology and obstetrics and gynecology outpatient clinics in Turkey (1), similar with that in the other European countries with the rate of 35% (2).

The main goal of the surgical treatment of SUI is to restore continence with minimal morbidity. Midurethral slings (MUS) are defined and performed continuously for the treatment of female SUI. Tension-free vaginal tape (TVT), which is a minimally invasive technique, was described in 1995 by Ulmsten and Petros (3) and has been used for the treatment of SUI in women. Despite the high success rates ranging from 84% to 95% that were notified for TVT, (4,5,6,7), there are concerns regarding its operative safety. Most perioperative complications of the TVT procedure have been related to penetration into the retropubic space (8,9). Transobturator tape (TOT), which was described by Delorme et al. (10) in 2001, was adopted because of perioperative and postoperative complications of TVT.

The aim of this study was to evaluate the predictive factors that could affect the effectiveness and complication rates of MUS, which has been performed for the surgical treatment of SUI in 5 medical centers in Turkey since 1999.

### **Materials and Methods**

In this study, we included a total of 594 women (outside to in transobturator in 285, inside to out transobturator in 91, retropubic in 218) from 5 medical centers in Turkey, who were diagnosed with urodynamic SUI and underwent a MUS operation between October 1999 and August 2011 (Table 1). The study was approved by the istanbul University Cerrahpaşa Faculty of Medicine Local Ethics Committee (approval number: 32821). Consent form was filled out by all participants.

The median age was 53.9 (27–82) years. A postoperative follow-up period of less than 6 months was the exclusion criterion in this study.

Patients presenting with stress or mixed (stress + urgency) type urinary incontinence were evaluated with medical history,

physical examination, urinalysis, urine culture, 3-day bladder diary and multichannel urodynamic studies. Provocative stress test was performed in all patients and urethral mobility and pelvic organ prolapse (POP) were evaluated. The urodynamic study consisted of uroflowmetry, measurement of post-void residual urine, 1-h pad test, cystometry and measurement of valsalva leak point pressure. Most of the urodynamic investigations in this study were performed according to the standards of International Continence Society (ICS) "Good Urodynamic Practice" after it was published (11) and the ICS terminology was used for all definitions (12). The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was used as a patient reported outcome measure after the validation of the Turkish version in 2004 (13). In total, 246 of 594 women had completed ICIQ-SF.

All patients underwent retropubic or transobturator placement of midurethral slings as previously defined (1,6) either using ready to use slings or homemade meshes by experienced surgeons or residents. All patients received intravenous antibiotic at the beginning of the operation. The operations were performed under local or general anesthesia. Cystoscopy was performed in all TVT patients, however, it was done in TOT patients if there was a hematuria or any difficulties during the passage of the trocars. The catheter was removed in the evening of the operation day in TVT group and immediately after the operation in TOT group.

Two outcome measures were evaluated; subjective cure rate and complication rate. Subjective cure was defined as the statement of the women of not experiencing any loss of urine upon

Table 1. The number of patients recruited by each of the five centers

Institution	n	%
İstanbul University Cerrahpaşa Faculty of Medicine	307	51.7
İzmir Ege University	91	15.3
İstanbul Marmara University	81	13.6
Kocaeli University	67	11.3
Ankara Gazi University	48	8.1
Total	594	100

physical activity, coughing or sneezing. Any amount of leakage was considered as surgical failure. Reported complications were bleeding, bladder perforation, other organ injury, retention, voiding dysfunction, de novo urgency, urinary infection, pain, and skin complications.

#### Statistical Analysis

Statistical analysis was done to assign the factors that had a significant impact on the effectiveness and complication rates of MUS. Statistical analyses were done with SPSS version 15.0. Univariate analyses were done using chi-square test, Student's t-test and the Mann-Whitney U test. Multivariate analyses were done using logistic regression analysis.

#### Results

The median follow-up period was 48 months. Patient characteristics are shown in Table 2. Preoperative evaluation findings and operative characteristics are shown in Table 3 and Table 4, respectively. Subjective cure rate was 84% and overall complication rate was 11.2%.

In univariate analysis, age, having stress incontinence (rather than mixed or urge incontinence), presence of detrussor overactivity in preoperative urodynamic investigation, use of a ready to use mesh, and concurrent POP repair were the factors that had a significant influence on the improvement of subjective cure rate (Table 5). However, number of delivery and pregnancies, comorbidity [diabetes mellitus (DM), neurologic disease], preoperative ICIQ-SF score, abdominal leak point pressure (ALPP)

**Table 2. Patient characteristics** 

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Mean age (years)	53.9 (±10.7)
Body mass index	28.6 (20-70)
Type of incontinence	
Mixed type	298 (50.2%)
Stress type	282 (47.5%)
Urge type	13 (2.2%)
Number of pregnancies	4.2 (±2.4)
NSD	2.9 (±1.6)
Sectio	0.07 (±0.3)
Previous pelvic surgery	
No	441 (74.2%)
Hysterectomy	43 (7.2%)
MUS	21 (3.5%)
POP	21 (3.5%)
Other	33 (5.7%)
No data	35 (5.9%)

 ${\it NSD:}\ Normal\ spontaneous\ delivery,\ MUS:\ Midurethral\ sling,\ POP:\ Pelvic\ organ\ prolapse$ 

and experience of surgeon did not affect the subjective outcome. In multivariate analysis, increased age was a factor that negatively affected subjective cure rate and only to have a "stress type of incontinence" proved to improve cure rate (Table 6).

Univariate analysis of factors that could affect complication rate is shown in Table 7. Complication rate in the retropubic MUS patients were significantly higher compared to that in transobturator (either "inside-out" or "outside-in") MUS patients (50/168 vs. 17/359, respectively) (p<0.001). The type of mesh used also seemed to affect complication rate in univariate analysis. The complication rate was higher in patients who were operated with homemade meshes compared to those operated with ready to use meshes (17/71 vs. 50/456, respectively) (p=0.01). In multivariate analysis, only the type of surgery proved to affect complication rate (Table 8). Table 9 shows the complications with respect to types of MUS.

**Table 3. Preoperative findings** 

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Qmax in uroflowmetry	27.1 (±8.3)
PVR	10.5 ( <u>+</u> 23)
VLPP	65.4 ( <u>+</u> 33.2)
DOA in cystometry	11.5% (68/594)
ICIQ-SF score	16.3 (±3.6)

PVR: Post-void residual, VLPP: Vesical leak point pressure, DOA: Detrussor overactivity, ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form

**Table 4. Operative characteristics** 

Mean operative tin	ne (min)	36.4	±24.1
Mean hospital stay	(hours)	39.5	±22.3
Type of anesthesia			
General		359	60.4%
Spinal		199	33.5%
Local		5	0.8%
Experience of surge	eon		
Experienced		476	80.1%
Asistant		118	19.9%
Route of MUS inse	rtion		
TOT outside in		285	48.0%
Retropubic		218	36.7%
TOT inside out		91	15.3%
Source of mesh			
Ready to use		506	85.2%
Home made		88	14.8%
Co existance POP s	urgery		
Yes		65	10.9%
No		529	89.1%

MUS: Midurethral sling, TOT: Transobturator tape, POP: Pelvic organ prolapse

Table 5. Univariate analysis of factors that could effect surgical outcome

Variable	Cured	Not cured	р	
Age, mean (±SD)	53.7 (±10.5)	56.2 (±11.3)	0.04**	
Number of NSD, mean (±SD)	2.8 (±1.5)	3.3 (±1.7)	0.11**	
Number of pregnancies, mean (±SD)	4.1 (±2.3)	4.3 (±2.4)	0.06**	
Comorbidity (DM, neurologic disease)				
Yes	32	8	0.47*	
No	436	81		
Type of incontinence				
Mixed	218	59	0.003*	
Stress	239	29		
Urge	15	2		
Preoperative ICIQ-SF score, mean (±SD)	16.3 (±3.6)	16.2 (±4.0)	0.72**	
DOA in urodynamics				
Yes	44	19	0.01*	
No	429	71		
ALPP, mean (±SD)	64.6 (±35.3)	63.1 (±29.1)	0.44**	
Type of surgery				
TOT outside in	228	55	0.57*	
TOT inside out	82	9		
Retropubic	163	26		
Type mesh used				
Ready to use	433	72	0.001*	
Home made	40	18		
Concurrent POP repair				
Yes	45	15	0.04*	
No	428	75		
Experience of surgeon				
Experienced	377	68	0.37*	
Not experienced	96	22		

<sup>\*</sup>Chi-square

SD: Standard deviation, NSD: Normal spontaneous delivery, DM: Diabetes mellitus, ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form, DOA: Detrussor overactivity, ALPP: Abdominal leak point pressure, TOT: Transobturator tape, POP: Pelvic organ prolapse

Table 6. Multivariate analysis of factors that could effect surgical outcome

	В	SE	Wald	df	р	Exp (B)
Age	-0.02	0.01	4.29	1	0.038	0.97
Type of incontinence, stress	0.77	0.25	9.1	1	0.002	2.1
Type of mesh (home made vs. ready to use)	0.62	0.34	4.34	1	0.067	1.87
Concurrent POP repair	-0.52	0.44	1.35	1	0.244	0.59
DOA in urodynamics	-0.57	0.33	2.90	1	0.088	0.56

POP: Pelvic organ prolapse, DOA: Detrussor overactivity, B: Coefficient, SE: Standard error, df: Degree of freedom, Exp (B): Confidence interval of odds ratio

<sup>&</sup>quot;Student's t-test

Table 7. Univariate analysis of factors that could effect complication rate

Variable	Complication	No complication	p	Total	
Age, mean (±SD)	52.6 (±9.0)	54.0 (±10.9)	0.28**		
Number of NSD, mean (±SD)	2.97 (±1.6)	2.95 (±1.5)	0.91**		
Number of pregnancies, mean (±SD)	4.6 (±2.6)	4.1 (±2.4)	0.16**		
Comorbidity (DM, neurologic disease)					
Yes	5	41	0.9*	46	
No	62	478		540	
Preoperative ICIQ-SF score, mean (±SD)	15.3 (±4.7)	16.3 (±3.5)	0.65***		
DOA in urodynamics					
Yes	10	58	0.34*	68	
No	57	468		526	
ALPP, mean (±SD)	59.3 (±30.7)	65.9 (±34.9)	0.15**		
Type of surgery					
TOT outside in	11	274	0.000*	285	
TOT inside out	6	85		91	
Retropubic	50	168		218	
Type mesh used					
Ready to use	50	456	0.01*	506	
Home made	17	71		88	
Postoperative ICIQ-SF score, mean (±SD)	5.0 (±6.2)	3.1 (±5.6)	0.25***		
Concurrent POP repair					
Yes	5	60	0.33	65	
No	62	467		529	
Experience of surgeon					
Experienced	60	416	0.40*	476	
Not experienced	7	111		118	

<sup>\*</sup>Chi-square

Table 8. Multivariate analysis of factors that could effect complication rates

	В	SE	Wald	df	р	Exp (B)
Type of surgery (Transobturator vs. retropubic )	-0.888	0.182	23.7	1	0.000	0.411
Type of mesh (home made vs. ready to use)	-0.611	0.414	2.174	1	0.140	0.543

B: Coefficient, SE: Standard error, df: Degree of freedom, Exp (B): Confidence interval of odds ratio

#### Discussion

In the present study, the age of the patients and the type of incontinence were found to be independent factors affecting the cure rates of MUS in the treatment of SUI in women. There are studies assessing the risk factors affecting cure and complication rates after MUS (14,15,16). The factors that have been demonstrated to affect success following MUS procedure were the type of incontinence, previous continence surgery, age, body mass index, usage of anticholinergic medications

preoperatively, concurrent prolapse surgery and the type of surgery (14,15,16).

There are several studies that demonstrated the relationship between the age of the patient and success of MUS. Chen et al. (17) reported that the success rate of transobturator MUS was greater in women aged 60 years old or younger, compared with those older than 60 years [odds ratio (OR): 11.7; 95% confidence interval (CI): 1.8–76]. Patient age was found the only statistically significant parameter affecting the cure rate in another study

<sup>\*\*</sup>Student's t-test

<sup>\*\*\*</sup>Mann-Whitney U

SD: Standard deviation, NSD: Normal spontaneous delivery, DM: Diabetes mellitus, ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form, DOA: Detrussor overactivity, ALPP: Abdominal leak point pressure, TOT: Transobturator tape, POP: Pelvic organ prolapse

Table 9. The complications with respect to types of midurethral sling

	Transobturator		Retropubic	Retropubic	
	n	%	n	0/0	
Overall complications	17/359	4.7	50/168	29.7	0.001*
Immediate complications	1	0.3	3	1.8	
Hemorrhage	-	-	1	0.6	
<ul> <li>Bladder perforation</li> </ul>	1	0.3	2	1.2	
Short term complications	16	4.4	47	27.9	
<ul> <li>Voiding dysfunction</li> </ul>	8	2.2	31	18.4	
<ul> <li>Infections</li> </ul>	1	0.3	3	1.8	
• Pain	2	0.5	8	4.7	
<ul> <li>Skin infection and erosion</li> </ul>	5	1.4	5	3.0	

\*Chi-square test

and the cure rate was significantly lower in TVT patients over 55 years of age (18). However, there are also several studies that have demonstrated satisfactory outcomes after TVT in elderly patients (19,20). Nonetheless, elderly is known to be a greater risk for morbidity in any surgery. In this study, the subjective cure rate was lower in elderly patients (OR: 0.97, 95% CI: 0.95-0.99, p=0.038).

Mixed urinary incontinence was found to be a significant independent predictor for failure in our study. Holmgren et al. (21) reported that the long-term (8 years) cure rate after TVT in women with mixed urinary incontinence was lower than in women with pure SUI (21). However, others have found that the presence of urge symptoms did not reduce the success rates (22,23). Existing literature showed the difference between the mixed and pure SUI, however, those studies mostly included patients who were treated with retropubic MUS (21,23). Our study included both retropubic and transobturator groups and demonstrated that to have a pure SUI improved the success rate 2.17 times (OR: 2.17, 95% CI: 1.31-3.60, p=0.002) greater than mixed incontinence. Postoperative urge incontinence remains one of the most significant reasons for patient dissatisfaction and patients with mixed urinary incontinence should be informed preoperatively about the lower cure rates.

Although the type of mesh, concurrent prolapse repair and detrussor overactivity were significant in univariant analysis, they were not affecting the outcome of the surgery significantly in multivariate analysis. Some other studies indicated these variables as independent risk factors for surgical outcome (14,15,16). In a recent study, it was reported that concomitant prolapse surgery decreased the likelihood of surgical failure after MUS (14), and that concurrent prolapse surgery, taking anticholinergic medications preoperatively and increased age were independent risk factors affecting successful outcome after MUS (16).

In the present study, number of delivery and pregnancies,

comorbidity (DM, neurologic disease), ALPP, and preoperative ICIQ-SF score did not affect the surgical outcome. However, it was observed that women with an ALPP of 60 cm H<sub>2</sub>O or less had 12 times greater risk for continued SUI than women with a ALPP of more than 60 cm H<sub>2</sub>O (24). In this study, we found no relationship between ALPP and treatment outcome. Pregnancy, delivery and other conditions, such as comorbidities, have been evaluated in the literature and identified as risk factors for SUI (25), however, they were not found as independent risk factors for outcome in our study. In addition, preoperative ICIQ-SF score that revealed the degree of incontinence and quality of life of the women did not affect the surgical outcome, although 246 of 594 women had completed ICIQ-SF score sheet in this study.

The complication rate in the retropubic MUS patients was significantly higher compared to that in transobturator (either "inside out" or "outside in") MUS patients. The type of the surgery predicts the complication rate of MUS. In addition, our study demonstrated that among the predictive factors that could affect the complication rates associated with MUS. Only the type of surgery proved to affect complication rate.

The complication rates are higher with retropubic routes than with transobturator tapes (26), although there are some studies against this conclusion (27,28,29). For instance, a randomized comparative trial suggested that patients in transobturator group had more complications than the retropubic group (27). However, in another study, it was demonstrated that TOT was equally effective as TVT with fewer complication, and the authors suggested that TOT would be the procedure of choice (30). In our opinion, the study design is important when comparing the complications rate between two groups. Minor complications included in the study (e.g.\_groin pain) and follow-up time could affect the complication rates of MUS. Similarly, Latthe et al. (31) reported that the rate of major complications, such as bladder injuries and haematomas, was higher in TVT than in TOT. However, groin/thigh pain and vaginal injuries were lower in TVT than

in TOT (31). Additionally, operator experience may be another important factor for the complication rates. However, experience of surgeon did not affect the outcome and complication rate of the surgery in our study. Hence, most of the surgeries were performed by experienced surgeons with residents observing by experienced surgeons during the procedure in our study. In the existing literature, there are several major complications after retropubic MUS, such as nerve, bowel or major vascular injuries, pelvic hematoma, necrotizing fasciitis, ischiorectal abscess, and even death (26). Notwithstanding, the majority of complications were not reported in small randomized controlled trials. In the present study, reported complications were bleeding, bladder perforation, other organ injury, retention, voiding dysfunction, de novo urgency, urinary infection, pain, and skin complications (Table 9). The risk of complication in retropubic MUS was 6.28 (95% CI: 3.51-11.22, p<0.001) times higher than in transobturator MUS in a 48-month follow-up period.

#### Study Limitations

Some limitations should be pointed out with regard to our study design. The retrospective nature was the first bias of our study. Besides, this study was not a randomized trial. However, it was a multicenter study including sites throughout the country. The operations were performed by different surgeons and this point could be thought as another bias. However, the cure rate was not affected by the experience of the surgeon.

# Conclusion

We conclude that age of the patient and type of incontinence were significant predictive factors affecting the cure rate for MUS in women with SUI. Risk factors for treatment failure are similar for TVT and TOT. However, retropubic approach should be considered a high risk factor for complication after MUS.

# **Ethics**

Ethics Committee Approval: The study was approved by the İstanbul University Cerrahpaşa Faculty of Medicine Local Ethics Committee (approval number: 32821).

**Informed Consent:** Consent form was filled out by all participants.

Peer-review: Externally peer-reviewed.

## **Authorship Contributions**

Surgical and Medical Practices: O.D., B.Ç., C.Özyurt, T.T., C.Ö., İ.Ş., Concept: S.Ç., O.D., C.Özyurt, C.Ö., B.Ç., Design: S.Ç., O.D., T.T., B.Ç., Data Collection or Processing: S.Ç., N.M., C.Ö., S.Çiftçi, L.İ., İ.Ş., Analysis or Interpretation: S.Ç., O.D., N.M., A.Ş., Literature Search: C.Özyurt, İ.Ş., N.M., T.T., Writing: S.Ç., N.M., T.T., O.D.

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