



The association between mesh-to-urethra distance and lower urinary tract symptoms in stress urinary incontinence patients surgically treated with an intra-operatively trimmed single incision mini-sling

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ABSTRACT

Objectives: We aimed to explore the association between mesh-to-urethra distance (MUD) and lower urinary tract symptoms (LUTS) in stress urinary incontinence (SUI) patients implanted with a single incision mini-sling (SIMS).

Materials and Methods: This study included the patients who visited Urogynecology Outpatient Department of Muğla Sıtkı Koçman University Training and Research Hospital from November 2018 to November 2019 complaining of urinary incontinence and were diagnosed as having SUI. The patients were preoperatively questioned for their demographic characteristics, LUTS and any additional complaints. All patients underwent SIMS surgery with mesh trimmed during the operation. During the follow-ups carried out 48 hours, one month, and four months after the surgery, ultrasound to measure the distance from MUD was performed and patients were re-inquired about LUTS.

Results: When MUD was postoperatively evaluated with regards to SUI, most successful outcomes were achieved when MUD was 2.69 ± 1.25 mm ($p < 0.001$), 2.68 ± 1.30 mm ($p < 0.001$) and 2.42 ± 0.96 mm ($p < 0.001$) at 48 hours, one month, and four months after the surgery, respectively. In terms of urination frequency, SUI surgery was successful when MUD was 2.93 ± 1.36 mm ($p = 0.012$) and 2.85 ± 1.34 mm ($p = 0.001$) at month one and month four, respectively. For nocturia, MUD was statistically significant at postoperative month four and nocturia of patients regressed when MUD was 2.78 ± 1.21 mm ($p = 0.001$).

Conclusion: MUD seems to be a good predictor of treatment success in SUI treatment. There is a linear correlation between LUTS and MUD. To the present date, there is no study on association of LUTS and MUD in patients treated with mini slings.

Keywords: Mini-sling; mesh; stress urinary incontinence; urethra

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INTRODUCTION

Urinary incontinence (UI) has a remarkable negative impact on female quality of life (QoL).^{1,2} There has been a number of therapeutic modalities for UI, the most effective of which is surgical intervention relying on the use of mid-urethral slings at the first place. The single-incision mini slings (SIMS) have attained a widespread use since 2006 owing to its minimal invasive fashion, resulting in fewer complications as retro-pubic or obturator path is not involved in procedure, and short-term post-operative outcomes comparable with conventional methods.³⁻⁵

The distance between the deployed mesh and urethra (MUD) plays a role on the success of surgery.⁶ The mesh can be conveniently displayed through transperineal ultrasound (TPUS) and thus the MUD can be measured.

In this study, our aim is to search for the association of MUD and lower urinary tract symptoms (LUTS) in stress UI (SUI) patients who have undergone SIMS surgery with mesh trimmed during the operation.

MATERIALS AND METHODS

This is a prospective, cross sectional, case-control study which has been approved by Local Clinical Research Ethics Committee (date: 22 Dec 2018 no: 22/VII) of Muğla Sıtkı Koçman University Faculty of Medicine and recruited patients who presented to the hospital's urogynecology outpatient department between November 2018 and November 2019. The patients with any of the following criteria were excluded from the study: A systemic disease (chronic obstructive pulmonary disease, uncontrolled diabetes mellitus, and rheumatoid diseases), history of medication use effecting the urinary tract, urinary tract obstruction, ongoing urinary tract infection, >stage II pelvic organ prolapse (POP) according to POP quantification system, diagnosis of mixed UI, and past pelvic surgery. Among the patients meeting the inclusion criteria, 50 women diagnosed with SUI were included in our study. Verbal and written information was provided to all patients and their informed consents were obtained.

Patient demographics were recorded on admission. Complete urinalysis, urine culture, and blood glucose levels were evaluated.

During the preoperative workup, patients were placed in lithotomy position and thus cough stress test (CST) was applied. In cases with a negative CST result at lithotomy position, the test was repeated while patient was standing. Test was considered positive in the event of urine leakage observed upon coughing or straining. Preoperative query also included LUTS (such as urine leakage, intermittent stream, urinary frequency, urgency,

nocturia, pelvic pain, coital incontinence, hesitancy, dysuria, and presence of additional complaints). Voiding >8 times during waking hours was accepted as urinary frequency and >2 times during night was accepted as nocturia.

In order to avoid surgeon-related bias, only the surgeries performed by the same surgeon were included into this study. All surgeries were performed under spinal anesthesia. The patients were placed into lithotomy position. Bladder catheterization was performed using a 18F Foley catheter. A full-thickness incision was performed through the vaginal mucosa at the level of mid-urethral area, that is, 1 cm below the external urethral meatus. Bilateral paraurethral pouches were formed on both sides of urethra making dissections underneath the pubocervical fascia (PCF) toward the retro-pubic space. Monofilament polypropylene mesh was trimmed down to a size of 6 cm of length and 8 mm of width. The mesh was grasped with Péan forceps and inserted through each of the tunnels dissected in paraurethral pouches allowing a rim around the urethra. A space of the thickness of a Metzenbaum scissors was left between the mesh and urethra. PCF was plicated over the mesh. The incision line was closed with separate sutures. Foley catheter was retracted at 8 to 16 hours postoperatively. Patients were discharged to home 24 hours after surgery provided that micturition occurred, on average. The patients were instructed to return for a follow-up check at postoperative 48th hour, month 1, and month 4. During the follow-ups, TPUS was repeated and LUTS were re-questioned. TPUS was performed by the same single investigator while patient bladder was full and once patients were placed into lithotomy position using a GE, Voluson E6 system, vaginal probe. Vaginal probe was taken at vertical position and placed into perineal region. The probe was advanced 2-3 cm along vaginal introitus to pinpoint the location of bladder, urethra, and positional relationship between mesh and urethra. Then, probe was moved to the horizontal axis allowing visualization of pubic bone, bladder neck, urethra, and mesh. In US exam, mesh and pubic bone had a hyperechoic appearance whereas urethra and bladder had hypoechoic appearance. The distance from mesh to urethra was measured from the mesh edge which is closer to urethra in a perpendicular manner to the urethral lumen including the urethral wall (Figure 1, 2).

Statistical Analysis

Statistical analysis was done using SPSS (Statistical Package for Social Sciences) for Windows 17.0. Kolmogorov-Smirnov test was used to verify normal distribution of data. Quantitative (numeric) data were presented as mean \pm standard deviation if they have a normal distribution and as median (minimum-maximum) if they have non-normal distribution. Groups with

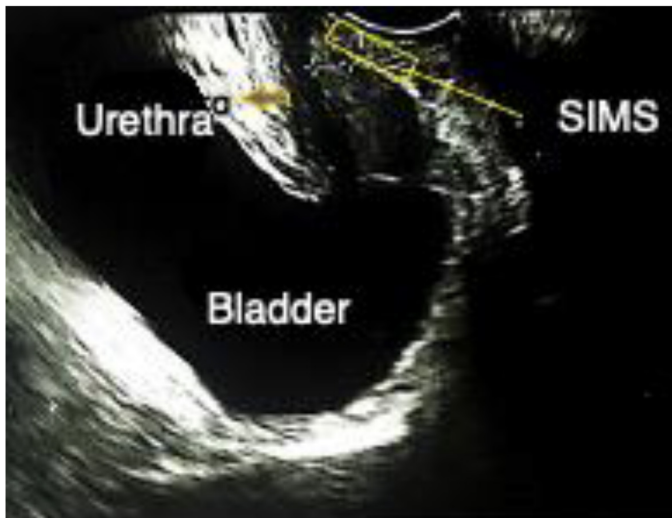


Figure 1. Mesh visualized by TPUS mesh-to-urethra distance: The area between the (+) signs

TPUS: transperineal ultrasound

normally distributed variables were compared using Student’s t-test. The *p*-value was set at <0.05 for statistical significance.

RESULTS

In total, 50 women were included in this study. Demographic features of patients are given in Table 1.

Data from preoperative inquiry about LUTS are shown at Table 2. Table 3 tabulates the correlation between MUD and LUTS of patients as determined at follow-ups conducted 48 hours, one month and 4 months after surgery. In patients with persistent postoperative SUI and hesitancy, MUD measurements were significantly different (*p*<0.001) (Table 3). Accordingly, the longer the MUD, the more frequent SUI was. On the other hand, as MUD got smaller, an increased rate of patients was inflicted with hesitancy. Other LUTS did not have any significant correlation with MUD as determined 48 hours after the surgery.

During the evaluations carried out 48 hours after the surgery, the patients no longer complaining of SUI had a mean MUD of 2.69±1.25 mm in comparison to 4.26±1.28 mm in those with ongoing SUI (*p*=<0.001). In addition, MUD had a significant

Table 1. Demographic features of patients		
	Mean	Minimum-maximum
Age (years)	54.08±11.96	30-80
Gravidity (n)	2.92±1.29	1-6
Parity (n)	2.24±0.77	1-4
BMI (kg/m ²)	28.42±5.05	16-46.7
BMI: body mass index		

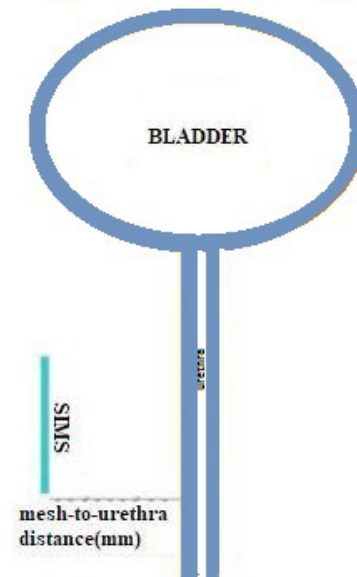


Figure 2. Mesh localization, measurement of the mesh-to-urethra distance

correlation with hesitancy. Patients with hesitancy had a mean MUD of 1.55±0.07 mm, whereas those without hesitancy had a mean MUD of 3.16±1.42 mm (*p*<0.001).

When patients were examined one month after the surgery, MUD was significantly correlated with SUI and frequency. Such that, MUD, on average, was 4.39±0.76 mm in patients with persistent SUI while measured as 2.68±1.30 mm in patients with regressed SUI (*p*<0.001). Patients with ongoing urinary frequency had a mean MUD of 4.11±1.15 mm, whereas those with decreased frequency had a mean MUD of 2.93±1.36 mm

Table 2. Preoperative symptoms of patients			
Lower urinary tract symptoms	(n=50)		
		n	%
Intermittent stream	No	37	74.0
	Yes	13	26.0
Frequency	No	8	16.0
	Yes	42	84.0
Urgency	No	11	22.0
	Yes	39	78.0
Nocturia	No	4	8.0
	Yes	46	92.0
Pelvic pain	No	21	42.0
	Yes	29	58.0
Coital incontinence	No	39	78.0
	Yes	11	22.0
Hesitancy	No	43	86.0
	Yes	7	14.0
Dysuria	No	46	92.0
	Yes	4	8.0

Table 3. The correlation between MUD and LUTS of patients as determined at 48-hour, 1-month and 4-month follow-ups after surgeries

	48 hours			1 month			4 months		
	n	Mean ± SD (mm)	p	n	Mean ± SD (mm)	p	n	Mean ± SD (mm)	p
SUI	No (n=37)	2.69±1.25	<0.001	No (n=35)	2.68±1.30	<0.001	No (n=32)	2.42±0.96	<0.001
	Yes (n=13)	4.26±1.28		Yes (n=15)	4.39±0.76		Yes (n=18)	4.58±0.95	
Intermittent stream	No (n=48)	3.12±1.43	0.547	No (n=47)	3.16±1.43	0.475	No (n=48)	3.17±1.43	0.548
	Yes (n=2)	2.50±1.41		Yes (n=3)	3.76±0.51		Yes (n=2)	3.80±0.84	
Frequency	No (n=39)	2.95±1.38	0.179	No (n=39)	2.93±1.36	0.012	No (n=39)	2.85±1.34	0.001
	Yes (n=11)	3.61±1.53		Yes (n=11)	4.11±1.15		Yes (n=11)	4.43±0.90	
Urgency	No (n=46)	3.09±1.43	0.890	No (n=46)	3.17±1.42	0.740	No (n=47)	3.15±1.43	0.340
	Yes (n=4)	3.20±1.52		Yes (n=4)	3.42±1.23		Yes (n=3)	3.96±1.07	
Nocturia	No (n=34)	2.85±1.44	0.073	No (n=35)	3.03±1.43	0.211	No (n=35)	2.78 ± 1.21	0.001
	Yes (n=16)	3.63±1.28		Yes (n=15)	3.58±1.29		Yes (n=15)	4.18±1.40	
Pelvic pain	No (n=23)	3.13±1.57	0.890	No (n=39)	3.12±1.50	0.483	No (n=42)	3.11±1.40	0.321
	Yes (n=27)	3.07±1.32		Yes (n=11)	3.46±0.95		Yes (n=8)	3.66±1.50	
Coital incontinence	No (n=50)	3.10±1.42	-	No (n=49)	3.17±1.40	0.476	No (n=48)	3.17±1.43	0.582
	Yes (n=0)	-		Yes (n=1)	4.20±0.00		Yes (n=2)	3.75±0.91	
Hesitancy	No (n=48)	3.16±1.42	<0.001	No (n=49)	3.23±1.38	0.174	No (n=50)	3.20±1.41	-
	Yes (n=2)	1.55±0.07		Yes (n=1)	1.30±0.00		Yes (n=0)	-	
Dysuria	No (n=50)	3.10±1.42	-	No (n=50)	3.19±1.40	-	No (n=50)	3.20±1.41	-
	Yes (n=0)	-		Yes (n=0)	-		Yes (n=0)	-	

MUD: mesh-to-urethra distance; LUTS: lower urinary tract symptoms; SD: standard deviation

($p=0.012$). According to our results, the greater MUD gets, the more the complaints of SUI and frequency are. Depending on the patient responses to our inquiries about LUTS one month after the surgery, there was no statistically significant association among the results.

When inquiries and evaluations were repeated four months after the surgery, comparing the results of SUI, nocturia, and frequency complaints these found to be in a statistically significant association with MUD. Such that, MUD, on average, was 4.58 ± 0.95 mm in patients with persistent SUI while measured as 2.42 ± 0.96 mm in patients with regressed SUI ($p<0.001$). Patients with alleviated urinary frequency had a mean MUD of 2.85 ± 1.34 mm, whereas those with ongoing complaint had a mean MUD of 4.43 ± 0.90 mm ($p=0.001$). Similarly, patients with attenuated nocturia had a mean MUD of 2.78 ± 1.21 mm vs 4.18 ± 1.40 mm in those with ongoing nocturia ($p=0.001$). Our assessment of MUD with regards to status of SUI, nocturia and frequency complaints demonstrates that as smallest MUD gets, the lowest complaint prevalence and thus the highest surgery success rate can be achieved. We did not find any statistically significant association between MUD and any other LUTS.

DISCUSSION

The main goal of UI surgeries is to maintain continence, to significantly improve QoL, and to ensure the surgery results in minimal morbidity.^{7,8}

In a study, patients underwent SIMS and transobturator tape (TOT) surgery and six weeks later CST was negative in 91% of patients in both groups.⁹ In the same study, CST was repeated one year after with a negative result in 85% of TOT and in 89% of SIMS receivers. Similarly, in a randomized controlled trial comparing patients implanted with transvaginal tape (TVT) or SIMS, rates of recovery were comparable in both groups (55.8% in SIMS, 66.6% in TVT). In our cohort, 48 hours, one month and four months postoperative CST tests were negative in 74.1%, 70%, and 64% of patients, respectively.

When preoperative evaluations for LUTS were compared to the respective postoperative evaluations, all symptoms regressed upon sling surgery. Our patient cohort was composed of SUI patients, 18 (36%) of whom stated incontinence was ongoing four months after the surgery. Costa et al.¹⁰ investigated a cohort of SUI patients associated with urethral hypermobility whereby 56.3% relieved of urgency and 48.3% relieved of urge

incontinence after TOT insertion. In line with the available literature, symptom of urgency in our cohort declined from a preoperative high level of 78% to postoperative level of 6%.

Among the factors playing a role on the success of sling surgery, the relationship between the inserted synthetic mesh material and the urethra is of paramount importance. Therefore, recent studies have been employing US examination with an attempt to quantify the MUD and the distance from mesh to symphysis pubis (MSD) as well as to elaborate angulation of mesh and the relationship of mesh with mid-urethra.¹¹

Chantarasorn et al.¹² have analyzed TOT-inserted patients and concluded success rates were lower in patients with a broader MSD, likewise, the same patient group had persistent or worsened urge UI while patients who suffered voiding dysfunction had narrower distance. The authors have pointed out the mean MSD was 12.29 ± 2.51 mm in patients with ongoing SUI vs 10.81 ± 2.44 mm in patients with alleviated SUI ($p=0.032$). The same study also reported patients with post-operative persistent or deteriorated urge UI had a mean MSD of 11.9 ± 2.47 mm compared to a 10.46 ± 2.37 mm in improved patients ($p=0.006$). Further, they measured an average distance of 9.91 ± 1.66 mm in patients who developed voiding dysfunction ($p=0.014$).

In another study utilizing TPUS, Kociszewski et al.⁶ have recruited 72 women with SUI who had underwent TVT surgery and post-operatively evaluated MUD as well as the kinking of the mesh during rest or during Valsalva maneuver. They sought for the correlation of US results and surgery success and have figured out the most successful outcomes were attained when MUD was 3.8 mm. The authors have also specified the distance less than 3 mm was associated to postoperative complications and, on the other hand, if greater than 5 mm, their patients have not benefited from the surgery ($p=0.00038$).⁶ An evaluation in patients treated with TOT identified a mean distance of 24 mm from mesh to internal urethral meatus in whom treatment success was achieved.¹³

In this study, we sought to explore the association of MUD and LUTS in patients who were treated with SIMS. During the first follow-up visit, conducted 48 hours after the surgery, we have identified mean MUD was 4.26 ± 1.28 mm in those with persistent SUI vs. 2.69 ± 1.25 mm in those who gained benefit from sling surgery ($p<0.001$). In the same follow-up, patients with hesitancy were found to have a mean MUD of 1.55 ± 0.07 mm ($p<0.001$). There is no other study in the literature evaluating the relationship between MUD and SUI in 48th hour postoperative.

In the second follow-up carried out one month after the surgery, we have found out MUD was statistically significantly positive correlation to SUI and frequency. In our assessment of the

association between SUI and MUD, mean MUD in patients with ongoing SUI was 4.39 ± 0.76 mm compared to a mean MUD of 2.68 ± 1.30 mm in those who no longer had SUI ($p<0.001$). In patients with and without urination frequency, MUD was 4.11 ± 1.15 mm and 2.93 ± 1.36 mm on average, respectively ($p=0.012$).

When our patients returned for the follow-ups on month 4, we have identified a statistically significant association of MUD and each of SUI, frequency, and nocturia. Such that, mean MUD in the group still experiencing SUI was 4.58 ± 0.95 mm, whereas this distance was 2.42 ± 0.96 mm in the group no longer experiencing any SUI ($p<0.001$). MUD was 4.18 ± 1.40 mm in patients with nocturia compared to 2.78 ± 1.21 mm in patients without nocturia ($p=0.001$). Likewise, patients with and without frequency complaint had a mean MUD of 4.43 ± 0.90 mm, respectively ($p=0.012$).

Zhu et al.¹⁴ have demonstrated chronic pelvic pain is a risk factor for UI. Consistently, 58% of our patients were complaining of pelvic pain at preoperative period which declined to 16% in postoperative period.

Abdel-Fattah et al.¹⁵ have stated a higher frequency of *de novo* urge UI in the patients treated with SIMS. The irritation due to the contact of the mesh material to the urethra as a consequence of its position is blamed for the *de novo* urge UI. In our study, on contrary to the literature, no *de novo* urge UI has developed.

In our literature search, we did not encounter any studies to compare MUD and relate it with LUTS in patients who underwent TMS surgery.

Study Limitations

Limitations of our study are small sample size and restricted time frame of follow-up, which was 4 months.

CONCLUSION

Based on US examination of MUD, LUTS and cut-off values have a linear correlation. In particular, in patients who were treated with SIMS, elimination of the complaints of SUI, frequency and nocturia were observed when MUD was 2.42 ± 0.96 mm, 2.85 ± 1.34 mm and 2.78 ± 1.21 mm, respectively. No correlation was identified between other components of LUTS and MUD. To the best of our knowledge, there has been no previous study on association of LUTS and MUD after implantation of mini slings. Therefore, larger studies with a greater number of patients to be conducted in multiple centers and by different surgeons are needed.

Acknowledgement: This study was originally conducted as a graduation thesis in obstetrics and gynaecology (E.K.P.)

ETHICS

Ethics Committee Approval: This is a prospective, cross sectional, case-control study which has been approved by Local Clinical Research Ethics Committee (date: 22 Dec 2018 no: 22/ VII) of Muğla Sıtkı Koçman University Faculty of Medicine and recruited patients who presented to the hospital's urogynecology outpatient department between November 2018 and November 2019.

Informed Consent: Verbal and written information was provided to all patients and their informed consents were obtained.

Peer-review: Internally and externally peer-reviewed.

Contributions

Surgical and Medical Practices: E.K.P., A.A.S.; Concept: E.K.P., E.A., A.A.S.; Design: E.K.P., E.A., A.A.S.; Data Collection or Processing: E.K.P., E.A., A.A.S.; Analysis or Interpretation: E.K.P., E.A., A.A.S.; Literature Search: E.K.P., A.A.S.; Writing: E.K.P., E.A., A.A.S.

DISCLOSURES

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

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