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ORIGINAL ARTICLE

Short-term outcomes of mini-sling: A minimally invasive technique in the surgical treatment of female stress urinary incontinence

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ABSTRACT

Objective: We aim to present the short-term outcomes of the single-incision mini-sling, an anti-incontinence procedure, as a prospective evaluation by analyzing success rates and complications.

Material and Methods: Between April 2013 and October 2013, in the Department of Obstetrics and Gynecology, Haydarpaşa Numune Training and Research Hospital, thirty patients diagnosed with stress urinary incontinence/mixed urinary incontinence and operated on using the mini-sling technique were included in this prospective cohort study. Following this procedure, this patient group was evaluated in terms of early complications, quality of life, and symptoms. Demographic characteristics, examination findings, frequency of pad use, and perioperative data were recorded. Objective success was evaluated with the cough stress test. Patient Global Impression of Improvement (PGI-I), Urinary Distress Inventory (UDI-6), and Incontinence Impact Questionnaire (IIQ-7) were used to assess subjective success and patient satisfaction.

Results: The mean age of the patients was 49.73±6.90 years, and the mean parity was 3.37±1.61. Patients diagnosed with MUI comprised 46.7% (n=14), while 53.3% (n=16) had SUI. The mean operation time was 15.97±5.55 minutes. No perioperative complications were encountered in any of the patients. The subjective success rate was 90%, and the objective success rate was 80% in the 1st and 3rd postoperative months. Significant improvement was observed in the IIQ-7 and UDI-6 questionnaires compared to the preoperative period. During the early postoperative period, vaginal mesh exposure was detected in 10% (n=3) of the patients, UTI in 6.7% (n=2), and leg pain in 16.7% (n=5). *De novo* urgency was observed in one patient at the postoperative third month, resolving with anticholinergic treatment.

Conclusion: The mini-sling procedure has several advantages, including ease of learning and performance with a single incision and local anesthesia in a much shorter time, reduced hospital stay, and similar success rates to standard midurethral slings. Randomized controlled studies with long-term results are needed to prove these advantages.

Keywords: SIMS, single incision mini-sling, SMUS, standard midurethral slings; stress urinary incontinence.

The research presented in this study originated from the corresponding author's thesis for medical specialization.

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INTRODUCTION

Stress urinary incontinence (SUI), characterized by involuntary urine leakage during physical exertion or activities that increase intra-abdominal pressure, affects millions of individuals worldwide, predominantly women. Surgical intervention for SUI is the preferred treatment modality for patients in whom conservative management fails to provide adequate relief.[1] Midurethral slings with synthetic mesh, tension-free vaginal tape (TVT), and transobturator tape (TOT) are the most common surgical methods. These well-defined procedures are associated with reduced morbidity, shorter hospital stays, and faster return to normal activities and are superior to abdominal surgery.[2]

The blind retropubic application of the first-generation Standard Midurethral Sling (SMUS)-TVT procedure carries some risk of complications, such as bladder injury and life-threatening complications, including bowel perforation and major vessel injury.[3,4] In the second generation, the SMUS-TOT transobturator route is used without the need for blind transition from the retropubic area, thus reducing the risk of vascular and visceral organ injury. This approach was first described by DeLorme in 2001[5] and later confirmed by short-term studies, which found that the success rates were similar to those of the retropubic TVT technique.[6–8]

Despite the high cure rate and low complication risk of the transobturator technique, it is associated with complications such as groin or thigh pain and *de novo* urge incontinence in the postoperative period.[9] To avoid these complications of SMUS, the single-incision mini-sling (SIMS) method, a third-generation MUS procedure, was developed. The aim of the mini-sling method, first defined in 2006, is to avoid major complications that may occur in first- and second-generation sling surgeries, shorten the operation time, and achieve efficacy similar to that of SMUS procedures. It also allows for intraoperative adjustment of the sling.[8]

In this prospective cohort study, we present the short-term outcomes of the mini-sling procedure by analyzing the subjective and objective success rates and complications associated with this method.

MATERIAL AND METHODS

Between April 2013 and October 2013, in the Department of Obstetrics and Gynecology at Haydarpaşa Numune Training and Research Hospital, thirty patients who were diagnosed with SUI/mixed urinary incontinence (MUI) and underwent surgery with the mini-sling technique were included in this prospective cohort study. This study was approved by the Haydarpaşa Numune Training and Research Hospital Ethics Committee and was conducted in accordance with the Declaration of Helsinki. Each participant was informed verbally and in writing about the study, and informed consent was obtained.

Patients who had predominant SUI symptoms, failed conservative treatment, or refused such treatment were included in the study. Women who had previously undergone urogynecologic or neurosurgical surgery, had predominant symptoms of overactive bladder, were under the age of 30, had a preoperative residual urine volume of ≥100 ml, or had not completed fertility planning were excluded.

Following the procedure, this patient group was evaluated in terms of early complications, quality of life, and the effect of the surgery on symptom severity. Demographic characteristics, vaginal examination findings, frequency of pad use, stress test results, Q-tip test results, intraoperative and postoperative complications, and procedure duration were recorded for all patients who underwent the mini-sling operation.

The Urinary Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) were administered to each participant preoperatively and in the early postoperative period at the first and third months. Subjective success and patient satisfaction were assessed using the Patient Global Impression of Improvement (PGI-I) scale at 1 and 3 months postoperatively. Responses of “much better” and “very much better” in this questionnaire were considered indicators of subjective success.

The stress test was used to evaluate objective success before and after the procedure. The test was considered positive when urine leakage was observed from the external urethral meatus during coughing in the lithotomy position or while standing. Patients with a negative stress test were considered to have achieved objective success.

Bladder neck mobility was assessed using the Q-tip test. While 200 ml of urine was present in the bladder, the angle change between the straining and resting positions of a cotton swab inserted into the internal urethral meatus was recorded. A measured angle >35° was accepted as an indicator of decreased anatomical support of the bladder neck and increased mobility.[10] Therefore, the Q-tip test was also used to evaluate the success of the operation.

During gynecological examinations, the presence of cystocele, uterine descent, and additional gynecopathologies were investigated. All participants underwent ultrasonography (Mindray DC-7) preoperatively and postoperatively to determine residual urine volume following micturition. Complete urine analysis and urine culture were assessed before and after surgery in each case to evaluate the presence of urinary tract infection. Changes in the frequency of pad use were questioned to assess the severity of urinary incontinence, and patients’ responses were recorded as “always,” “sometimes,” or “never.”

Surgery

For prophylaxis, 2 g cefazolin was administered to all patients before surgery. Four patients received general anesthesia, 10 received spinal anesthesia, and 16 received local anesthesia under intravenous sedation. The mini-sling procedure used the Ophira® Mini Sling System (Promedon) kit, which contains a 100% polypropylene mesh with multiple attachment points and an application guide for implanting the mesh into the obturator internus muscle. A ring-shaped polypropylene suture was centrally positioned within the mesh for tension adjustment to address postoperative urinary retention.

The patients were placed in the lithotomy position with slightly flexed legs, and the bladder was emptied using a Foley catheter. A 1–3 cm vertical midline incision was made 1 cm below the urethral meatus, extending through the vaginal wall. The vagina was dissected from the urethra at the 2 and 10 o’clock positions bilaterally using surgical scissors. The sling material was guided through the opening channel to the marked points, and the obturator internus

muscle was implanted without mesh penetration. Mesh tension was adjusted using Metzenbaum scissors while the patient coughed. Once adequate tension was achieved, the guide was removed, and the incision was sutured. Patients without micturition difficulties and with a post-void residual urine volume <100 ml were discharged.

The IIQ-7 and UDI-6 questionnaires, Q-tip test, and stress test were administered to patients who were subsequently evaluated at the conclusion of the first and third months. The presence of lower urinary tract symptoms, abnormal vaginal discharge, and dyspareunia was also assessed. The outcomes obtained in the early postoperative period were compared with those obtained in the preoperative period.

Statistical Methods

Statistical analysis was performed using SPSS 17.0. Normally distributed data are presented as mean±SD. Categorical outcomes were summarized using frequency distributions. For quantitative data, the Wilcoxon signed-rank test was used. For categorical data, p-values were calculated using the Chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 30 patients with ages ranging from 37 to 63 years, with a mean age of 49.73±6.90 years, were included in the study. The mean parity of the patients was 3.37±1.61 (min=1, max=7). Body mass index ranged from 22 to 45, with an average of 30.6±5.4 kg/m². While 40% (n=12) of the patients were menopausal, 36.7% (n=11) were in the perimenopausal period, and 23.3% (n=7) were in the reproductive period. None of the menopausal patients received hormone replacement therapy. Two patients (6.7%) had previously undergone hysterectomy for benign reasons. The rate of patients without pelvic organ prolapse was 53.3% (n=16), while 26.7% (n=8) had Stage I and 20% (n=6) had Stage II cystocele. The proportion of patients with systemic diseases was 90% (n=27).

While the proportion of patients with MUI was 46.7% (n=14), that of patients with SUI was 53.3% (n=16). Anticholinergic treatment was initiated preoperatively in all patients with MUI, and none of the patients benefited from medical treatment.

In the same session as the mini-sling application, 23.3% (n=7) of the patients underwent an additional operation or intervention. Colporrhaphy posterior (CP), perinoplasty, colporrhaphy anterior (CA), laparoscopic tubal ligation, hysteroscopic endometrial ablation, and cystoscopy were performed in addition to the mini-sling procedure. The mini-sling and additional operation times were recorded separately. The duration of the mini-sling operation ranged from 8 to 30 minutes, with a mean duration of 15.97±5.55 minutes. General anesthesia was performed in 13.3% (n=4) of patients, spinal anesthesia in 33.3% (n=10), and local anesthesia supported by intravenous sedation in 53.4% (n=16). There were no complications due to anesthesia.

No patient experienced perioperative bladder injury, hematoma, hemorrhage, nerve injury, or urethral injury. The Foley catheter was removed at the 24th hour postoperatively in patients who received general or spinal anesthesia and at the 6th hour postoperatively in those who received local anesthesia. High residual volume was defined as exceeding 100 ml following Foley catheter removal. No cases exceeded this value. Therefore, no evidence of urinary retention was observed in any patient, which correlated with the clinical findings. The postoperative hospitalization period varied between 8 and 48 hours, with a mean duration of 21.63±11.5 hours.

Subjective and objective success rates at the first and third months were 90% (n=27) and 80% (n=24), respectively.

The mean preoperative Q-tip test results were 54.5±16.6°, and the mean postoperative measurements were 20.33±12.73°. Compared to the preoperative values, the decrease in postoperative Q-tip test results by 34.17±14.74 units was statistically significant (p<0.01). There was no significant difference in the first and third postoperative month Q-tip test results (Table 1, 2).

Table 1: Comparison between preoperative and postoperative 1st month results of Q Tip Test, UDI-6 and IIQ-7 Questionnaire, postvoid residual

	Preoperative		Postoperative 1st month		p
	Mean	SD	Mean	SD	
Q Tip Test	55.5	16.986	20.33	12.7	<0.05
UDI-6 (1.-2.)	3.60	1.714	1.40	1.4	<0.05
UDI-6 (3.-4.)	4.00	1.114	0.69	1.105	<0.05
UDI-6 (5.-6.)	1.20	1.472	0.73	0.944	<0.05
IIQ-7	13.37	6.392	1.1	3.1	<0.05
PVR (mL)	7.17	14.145	14.5	25.8	NS

PVR: Postvoid residual; UDI-6: Urinary Distress Inventory, IIQ-7: Incontinence Impact Questionnaire; SD: Standart deviation; NS: Not significant.

Table 2: Comparison between postoperative 1st and 3rd month results of Q Tip Test, UDI-6 and IIQ-7 Questionnaire, postvoid residual

	Postoperative 1st month		Postoperative 3rd month		p
	Mean	SD	Mean	SD	
Q Tip Test	20.33	12.7	17.8	15.1	NS
UDI-6 (1-2)	1.40	1.40	1.1	1.1	NS
UDI-6 (3-4)	0.69	1.1	0.9	1.3	NS
UDI-6 (5-6)	0.73	0.9	0.4	0.5	<0.05
IIQ-7	1.1	3.1	1.1	2.8	NS
PVR (mL)	14.5	25.8	10.2	13.8	NS

PVR: Postvoid residual; UDI-6: Urinary Distress Inventory; IIQ-7: Incontinence Impact Questionnaire; SD: Standart deviation; NS: Not significant.

When preoperative and postoperative pad use frequency was evaluated, 80% (n=24) of the patients required continuous pad use preoperatively, whereas postoperatively, no patient needed to use a pad continuously. According to postoperative evaluations at the first and third months, 76.7% (n=23) of the cases did not use any pads, while 23.3% (n=7) used them occasionally. This reduction in pad use was statistically significant ($p<0.01$).

To assess the negative effects of urinary incontinence on daily life and mental well-being, all patients completed the IIQ-7 questionnaire preoperatively and postoperatively. A statistically significant improvement was observed in the postoperative first-month scores compared to preoperative scores. The mean decrease of 12.20±6.91 points in IIQ-7 scores in the postoperative period compared to the preoperative period was statistically significant ($p<0.01$). Similarly, there was a statistically significant reduction in the total UDI-6 scores postoperatively compared to preoperative scores ($p<0.01$), with a mean decrease of 5.93±2.72 points. Specifically, for questions 3 and 4 of the UDI-6 test, which evaluate the stress component of urinary incontinence, a mean reduction of 3.30±0.95 units was observed in the postoperative period compared to preoperative scores, a difference that was highly significant ($p<0.05$).

When comparing the postoperative first-month and third-month results, no significant differences were observed in the scores of questions 1 and 2, as well as questions 3 and 4 of the UDI-6 questionnaire, or in the IIQ-7 questionnaire scores. However, a significant reduction was noted in the scores of questions 5 and 6 of the UDI-6 questionnaire, which assess pelvic organ prolapse symptoms, at the third postoperative month. This reduction was attributed to the completion of the postoperative recovery period. Comparisons of preoperative and postoperative clinical parameters and questionnaire scores are summarized in Tables 1 and 2.

In the first postoperative month, no patients experienced hematoma, abscess formation, *de novo* urgency, or urinary retention. However, five patients (16.7%) reported groin pain, which resolved by the third postoperative month. Lower urinary tract infections were detected in two patients (6.7%), both of whom responded to appropriate antibiotic therapy. One patient (3.3%) developed *de novo* urgency incontinence at the third month and benefited from anticholinergic treatment.

Vaginal mesh or tape exposure was observed in one patient in the first postoperative month and in two additional patients in the third month, resulting in a total of three cases (10%). These patients were treated with local estrogen therapy and antibiotic administration. One patient with vaginal exposure experienced dyspareunia, necessitating the removal of the exposed portion of the tape. In the remaining two patients who received local estrogen therapy, the exposed area regressed. Despite the presence of mesh exposure, these patients reported “very much better” and “much better improved” responses on the PGI-I scale. However, both patients had positive stress test results postoperatively.

DISCUSSION

The surgical treatment of stress urinary incontinence has evolved significantly over the past few decades. Among the surgical options, midurethral slings using synthetic mesh have gained widespread popularity due to their effectiveness and relatively low complication rates. This study contributes to the extant literature on the surgical management of SUI by providing evidence regarding the safety and efficacy of the single-incision mini-sling (SIMS) procedure. Our findings demonstrated a high subjective success rate with minimal complications. In this study, early follow-up data collected at 1 and 3 months revealed subjective and objective success rates of 90% and 80%, respectively.

A study from Türkiye presented long-term results of minisling and TOT, and the authors showed mini-slings to be superior to TOT at the end of a 5-year follow-up. In their study, the difference in decreased cure rates between 5 and 3 years was 7% (90% to 83%) for an adjustable mini-sling vs. 9% (84% to 75%) for the transobturator tape.[11] In another study on minislings, Palma et al.[12] reported the results of 149 women with SUI; the Ophira minisling system was administered under local (73%), general (18%), and regional (9%) anesthesia in their series. The mean procedure duration was 12.6 minutes, and the mean follow-up period was 9 months. Minor complications were observed, including urinary retention, mesh erosion, UTI, and *de novo* urgency.

Djehdian et al.[13] used the same minisling system (Ophira) and compared the efficacy and safety of the minisling with transobturator tape in women with SUI. Following a 6-month follow-up period, four patients in the minisling group were reported to develop mesh erosions; three of these cases required mesh resection. On the other hand, mesh erosion was observed in one case who underwent TOT. Consistent with these data, we observed mesh exposure in three patients, which was considered to be higher in frequency compared to conventional methods.

During the follow-up period, based on the safety outcome in terms of adverse events, we observed mesh exposure in three patients and *de novo* urgency in one patient. In a recently published RCT comparing standard midurethral slings and minislings, mesh exposure was higher in the minisling group, whereas the rate of partial or total removal of the mesh for any reason was low and similar in both groups.[14] All patients with mesh exposure in our study were first given local estrogen therapy, and the mesh of one symptomatic patient was excised. The exposed mesh area of the other two regressed, and one patient with *de novo* urgency benefited from anticholinergic therapy.

The mesh adjustment mechanism may have some importance for success rates and complications; however, the majority of mini-sling systems are claimed to have the disadvantage of the absence of a mesh adjusting mechanism, which may lead to difficulty in urination or failure of incontinence surgery. In our study, we used an adjustable minisling system, and in the early postoperative follow-up, none of the patients developed voiding difficulties or urinary retention, thus eliminating the need to use retention sutures.

A review that assessed the cost-effectiveness of different management approaches for SUI indicated that the transobturator approach may be more cost-effective than the retropubic approach. Furthermore, fewer adverse events were reported following the transobturator approach, with the exception of groin pain.[15] Given this information, a pertinent question arises regarding whether the minisling approach demonstrates comparable cost-effectiveness to the TOT approach. Previous data showed that one of the minisling materials, TVT-Secur, is inferior to standard mid-urethral slings for the treatment of women with stress incontinence and has already been withdrawn from clinical use, while authors also pointed out that the evidence on

comparisons between other single-incision slings with retropubic or transobturator slings is limited. On the other hand, a brief economic commentary identified two studies that reported no difference in clinical outcomes between single-incision slings and transobturator mid-urethral slings. In the same brief report, single-incision slings were claimed to be more cost-effective than transobturator mid-urethral slings based on a one-year follow-up. The authors concluded that fixation mechanisms might have a significant impact on outcomes.[16]

White et al.[17] demonstrated in their prospective, nonrandomized, parallel cohort study that the safety and efficacy of SIMS are noninferior to TOT at 36 months. Both objective and subjective treatment success met the prespecified noninferiority margin. Adverse event and reoperation rates were low and comparable between groups. Consistent with previous studies, patients in this multicenter, prospective study exhibited objective success rates of 88.7% for SIMS and 95.9% for TOT at 12 months, with sustained outcomes over 36 months. The researchers concluded that SIMS retains the benefits of TOT while minimizing neurological sequelae and mesh volume, thereby addressing concerns associated with transvaginal mesh. Furthermore, they posit that the minimally invasive nature of SIMS, which is feasible under local anesthesia in an outpatient setting, enhances its efficacy and reduces costs in the surgical management of female SUI.

The limitations of the study include the relatively small sample size and short postoperative follow-up period. Further research involving long-term outcomes and randomized controlled trials is necessary to demonstrate noninferiority to retropubic and transobturator slings and to establish reliability.

A notable strength of this study is its single-center and prospective design, with all procedures performed by the same surgeon, thereby eliminating variability in surgical techniques and protocols.

CONCLUSION

This study evaluated the initial outcomes, safety, and efficacy of a specific minisling material using validated questionnaires and clinical parameters. The mini-sling system demonstrated acceptable efficacy rates during the three-month follow-up period. Given the low incidence of complications and the relative ease of acquisition of the technique, despite limited data in the literature, the mini-sling appears to be a potentially advantageous and non-inferior method compared to standard mid-urethral slings.

Statement

Author Contributions: Concept – NA, RGİ; Design – NA, RGİ; Supervision – NA, GK, EÖ; Resources – NA, RGİ; Materials – RGİ; Data collection &/or processing – RGİ, ECT; Analysis and/or interpretation – RGİ, EÖ; Literature search – RGİ, EÖ; Writing – RGİ; Critical review – EÖ, NA.

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