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Objective and subjective cure rates of Ophira mini sling: Postoperative 36-month results

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Abstract

This study aimed to evaluate the objective and subjective cure rates of Ophira mini sling for female stress urinary incontinence (SUI) 36 months after surgery. A total of 58 patients who had SUI and were treated with Ophira mini sling between the years 2014 and 2015 were evaluated retrospectively. The objective cure rate was estimated with the negative cough stress test, and the subjective cure rate was estimated with the answer of "no leakage on coughing, sneezing" to question 3 in urinary distress inventory-6 (UDI-6). Incontinence impact questionnaire-7 (IIQ-7) and pelvic distress inventory-20 (PFDI-20) were also evaluated 36 months after surgery. The overall subjective cure rate was 90% (36/40), and the overall objective cure rate was 87.5% (35/40). The UDI-6, IIQ-7, and PFDI-20 scores improved significantly ($P < 0.001$). No major complications were noted. Ophira mini sling could be good option for treating female SUI with high objective and subjective cure rates and no major complications.

Keywords: Mini sling, Ophira, single-incision sling, stress urinary incontinence

Introduction

The complaint of involuntary urinary leakage that the individual has when making effort or physical exertion (e.g., sporting activities, sneezing, coughing) has been defined as stress urinary incontinence (SUI) by the International Continence Society. Millions of adult women in the USA and Europe have urinary incontinence, and SUI is the most common female incontinence type [1,2]. Behavioral, mechanical, pharmacologic, and surgical interventions are made for the treatment. Of these, the most effective is surgical treatment, and standard mid-urethral slings (SMUS) are the most common operations. An incision is made under the urethra, and a sling tape is placed and inserted either into the obturator foramen or behind the pubic bone. SMUS are 1) retropubic sling comprises a tension-free vaginal tape (TVT), 2) an obturator sling comprises a transobturator tape (TOT). TVT was first described in 1995 by Petros and Ulmstein [3]. TVT and TOT have similar objective and subjective cure rates [4,5]. Visceral organ complication rate and bladder perforation rate are more in TVT [5]. The groin-hip pain rate in TOT ranges between 6.8% and 12% [6,7]. New-generation devices need to be developed due to the tape insertion into the retropubic area and obturator

foramen blindly as well as the complication rate of mid-urethral sling. These new-generation slings are called mini slings because a single incision is made in the vaginal mucosa and the skin incision is not needed. They are also called single-incision mini slings (SIMS). Ophira is a kind of mini sling that was developed in 2007. It is fixed with the arms in the obturator internus muscle and has bilateral loose sutures for correcting the tension.

Only a few studies evaluated the midterm results of Ophira mini sling. This study aimed to evaluate the objective and subjective cure rates of Ophira mini sling 3 years after surgery.

Material and Methods

A total of 58 patients who had SUI and were treated with Ophira mini sling between the years 2014 and 2015 at department of gynecology and obstetrics, Inonu University were evaluated retrospectively. Ethics approval was obtained from the Inonu University ethical committee (approval number 2018/15-2). When the patients complained about incontinence, the medical history, systemic and pelvic examination, and urine test were performed. If the urine test results were in the normal range, 72-h voiding diary and cough stress test (CST) were used for diagnosing SUI.

The validity study of the Turkish scales (urinary distress inventory-6 (UDI-6), pelvic distress inventory-20 (PFDI-20) and incontinence impact questionnaire-7 (IIQ-7)) was performed

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before the operations [8,9]. The patients were examined in the first postoperative month and then annually. The UDI-6 score, IIQ-7 score, and PFDI-20 score were measured in every control appointment, and CST was performed as well. Question 3 in UDI-6 was used for assessing subjective success. If the answer to question 3 was “No leakage on coughing, sneezing,” it was assumed that the patient had subjective success. CST was performed postoperatively for assessing objective success.

The study included 40 patients who came for the postoperative control. The patients were kept in lithotomy position with 300-mL bladder filling for evaluating CST. Bladder volume was estimated by ultrasonography.

The exclusion criteria were as follows: (1) female patients who had anti-incontinence surgery previously; (2) female patients who had overactive bladder; (3) female patients who had neurologic disease or coagulation disorders; (4) pregnant women, (5) female patients who could not answer the question; (6) female patients with a postvoid residual (PVR) volume more than 100 mL, and (7) female patients with vulvovaginitis.

The inclusion criteria were as follows: (1) female patients with SUI; (2) female patients who underwent Ophira mini sling procedure; (3) female patients who were CST positive preoperatively; (4) female patients who had/had not pelvic organ prolapse; and (5) female patients who could come for follow-up.

Surgical technique

Cefazolin (1 g) was administered for prophylaxis preoperatively. Surgeries were performed under general or epidural/spinal anesthesia. The patients remained in lithotomy position. An 18F Foley catheter was replaced with the bladder. Pelvic reconstructive surgery was performed, and the Ophira mini sling was inserted into the dissected mid-urethral tissue, which extended to the pubic rami. The vaginal wall was closed using 2/0 polyglactin sutures. The operation time was recorded for prolapse surgery and mini sling separately. The Foley catheter was removed within postoperative 24 hours, and the patient was discharged if the PVR volume was less than 100 mL.

Statistical analysis

Data were presented as means $\pm$ standard deviations, medians, or percentages. Student t test and the paired t test were used to compare pre- and postoperative continuous data. A P value less than 0.01 was considered to reflect statistical significance. All data were analyzed using IBM SPSS Statistics version 22, 2013 (IBM Corp, NY, USA).

Results

A total of 40 patients evaluated retrospectively. In the postoperative 36th month, the overall subjective cure rate was 90% (36/40) and the overall objective cure rate was 87.5% (35/40).

The mean age of patients was 63 ± 11.2 years, and the mean body mass index was 27 kg/m². The demographic data of patients are presented in Table 1. The mean operation time for mini sling was 11 ± 2.1 min. No major intraoperative and postoperative complications were recorded. The mean value for hospital stay was 2.1 ± 0.6 days. The postoperative urge incontinence was evaluated

in two patients (5%), and it resolved with anticholinergic drugs.

Postoperative urethral obstruction was diagnosed if the PVR volume was more than 100 mL. However, no urethral obstruction occurred.

Table 1. Demographics and preoperative characteristics of patients

	Mean $\pm$ SD/ n
Age (year)	63 ± 11.2
Body mass index (kg/m ²)	27 ± 3.6
Gravidity	6.2 ± 2.6
Parity	5.2 ± 2.4
Comorbidities	
Hypertension	12
Diabetes mellitus	8
Coronary artery disease	5
Asthma	4
Rheumatoid arthritis	1
Menopause	15

The operation data are shown in Table 2. No major bleeding was noted. The mean hemoglobin level was 12.5 ± 0.17 g/dL preoperatively and 11.4 ± 0.2 g/dL at 2 h after the surgery. No complication related to mesh was reported.

Table 2. Operation data of patients

	Mean $\pm$ SD/ % of 40
Operation time	11 ± 2.1 min
Operations	
Vaginal hysterectomy	37.5%
Abdominal hysterectomy	12.5%
Anterior colporrhaphy	45%
Posterior colporrhaphy	50%
LeFort	5%
Abdominal hysterectomy	10%
Hemoglobin levels	
Preoperatively	12.5 ± 0.17 g/dL
2 h postoperatively	11.4 ± 0.2 g/dL
Complications	
Mesh erosion	0
Repeat incontinence surgery	0
PVR volume ≥ 100 mL	
De novo urge incontinence	0
	5%
Hospital stay time	2.1 ± 0.6

Questions 1 and 2 of the UDI-6 questionnaire were related to irritation symptoms, 3 and 4 were related to SUI, and 5 and 6 were related to obstructive symptoms. The IIQ-7 included four domains: questions 1 and 2 are related with physical activity, questions 3 and 4 are related with travel, question 5 is related with social relationships, and questions 6 and 7 are emotional health questions. All the parameters of UDI-6, IIQ-7, and PFDI-20 showed significant improvement in the third postoperative year (Table 3) ($P < 0.001$).

Table 3. Changes in UDI-6, IIQ-7, and PFDI-20 scores

	Preoperatively	Postoperatively	P
UDI 1-2	47.5 ± 17.2	25.9 ± 19.2	<0.001
UDI 3-4	35.9 ± 3.5	5.9 ± 2.1	<0.001
UDI 5-6	23.1 ± 3.9	4.3 ± 2.1	<0.001
UDE total	35.8 ± 2.3	12 ± 1.6	<0.001
IIQ1-2	2.3 ± 0.2	0	<0.001
IIQ-3-4	2 ± 0.3	0.1 ± 0.08	<0.001
IIQ-5	0.9 ± 0.01	0.07 ± 0.04	<0.001
IIQ 6-7	1.5 ± 0.3	0.1 ± 0.08	<0.001
IIQ total	6.5 ± 1	0.1 ± 0.1	<0.001
PFDI-20	18.8 ± 1.3	3.1 ± 0.4	<0.001

Discussion

Several surgical methods have been developed for treating SUI after exploring pathophysiology. Other than retropubic colposuspension operations, midurethral slings (TVT and TOT) have been frequently used for treating SUI with high objective and subjective cure rates. Although SMUS is a minimally invasive method, SIMS has been developed to avoid complications of blunt transition from the retropubic area and obturator foramen.

SIMS include tissue fixation system (TFS), Mini-Arc, AJUST, single-incision sling (SIS), Contasure-Needleless, and Ophira. Ophira (Promedon; Cordoba, Argentina) is made of type 1 polypropylene mesh; it is a kind of SIS. A fishbone-like TFS is present at the end of each arm. It can be fixed to the obturator internus muscle. At the same time, the advantage of Ophira is the possibility of correction after placing fixation. SMUS has no correction advantages (Figure 1).



Figure 1. Ophira mini sling system

In 2013, a TVT- Secur from SIMS was distracted from the market by the manufacturer (Ethicon) due to low second- and third-year objective and subject cure rates. In 2018, a review comparing

SIMS and SMUS other than TVT, based on the results of 29 RCTs, showed no significant difference between SMUS and SIMS with regard to short-, mid-, and long-term subjective cure rates. Although the midterm objective cure rates of SMUS and SIMS were not different, the long-term objective cure rates were higher in SMUS. SIMS was found to be associated with shorter operation time, less blood loss, less pain and less postoperative voiding dysfunction [10]. When AJUST, Mini-Arc, SIS, Ophira, TFS, and Contasure-Needleless were compared with SUMS, the lowest objective cure rates were observed in Ophira [odds ratio (OD), 0.50; 95% confidence interval (CI), 0.30–0.83] and highest objective cure rates were observed in TFS (OD, 1.67; 95% CI, 0.52–5.30) [10].

Palma et al [11] applied Ophira mini sling to 124 patients and reported the second- year subjective and objective cure rates as 91.6% and 85.3%, respectively. In Farzenah et al.'s [12] study including 72 patients (12–20 months), the objective cure rate was 88.6%. Smith and colleagues [13] applied Ophira mini sling to 30 patients; 93.3% reported subjective cure and 90% of the patients had a negative CST. In Yıldız et al.'s study evaluating the safety and efficacy of Ophira mini sling, the third-year objective cure, subjective cure, and failure rates were 83.8%, 6.4%, and 9.8%, respectively. The present study showed that the overall subjective cure rate was 90% (36/40), and the overall objective cure rate was 87.5% (35/40) in the postoperative 36th month.

In the present study, the mean operation time was 11 ± 2.1 min. This value has been reported in the range of 7.9–20 min in the literature [12,14-16].

In TOT, a blind transition through the obturator foremen led to complications of vascular nerve and bladder injury. Groin pain, groin neuropathy, and abscess formation may occur after TOT operation, decreasing patients' quality of life [17-19]. The complication rate is low during mini sling insertion due to the lack of transmission through the pubic ramus. Jurakova et al [16] did not experience any major intraoperative or postoperative complications in 95 patients treated with Ophira. No major complications related to SIMS have been reported in the literature. In the present study also, no major intraoperative or postoperative complication was reported. The propylene-induced complications (mesh erosion, dyspareunia) were not observed.

The IIQ-7 and UDI-6 scores were found to be significantly improved in Yıldız et al.'s (third year) and Palma et al.'s (second year) studies [13,20]. In the present study, a significant improvement was observed in both questionnaire scores ($P < 0.001$).

Post-Ophira de novo urge incontinence incidence ratio was 2.9% and 12.2% in Sharifiaghdas et al.'s [12], and Pascom et al.'s [20] studies, respectively. This rate was 6.4% in Guncer et al.'s study. It was 5% in the present study.

The limitation of this study was that all patients undergoing Ophira also underwent pelvic organ prolapse reconstruction at the same time. Despite additional operations, intraoperative hemorrhage was minimal and a decrease in the mean postoperative hemoglobin level was approximately 1.1 g/dL. The incidence of urinary incontinence increased with pelvic organ prolapse. When anti-incontinence surgery is combined with pelvic organ

prolapse surgery, Ophira mini sling may be a good option due to the short operation time and less intraoperative and postoperative complications. Studies on the short- and long-term outcomes of Ophira mini sling are limited. Besides, no study has evaluated the long-term (10th year) outcomes yet.

Conclusion

In conclusion, the objective and subjective cure rates in the postoperative 36th month were higher in patients who underwent pelvic organ reconstruction and were treated with Ophira mini sling. For the treatment of SUI, Ophira mini sling can be a good option since there were no major complications while it provided short operation time and minimal intraoperative hemorrhage risk. Increasing the number of studies showing midterm results related to Ophira and conducting studies evaluating the long-term results may increase the feasibility of the operation.

Financial Disclosure

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Ethical approval

Ethics approval was obtained from the Inonu University ethical committee (approval number 2018/15-2).

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