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Long-term outcomes and quality of life effects of single incision mini sling procedure in stress urinary incontinence patients

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ABSTRACT

Objective: We aimed to evaluate the long-term outcomes and quality of life of patients who underwent single incision minisling (SIMS) procedure.
Study design: 62 patients who were diagnosed with stress urinary incontinence (SUI) and received treatment with SIMS procedure (Ophira, Promedon, Argentina) were included in the study. Mean age was 50.73 ± 9.28 years and mean follow-up duration after surgery was 30.68 ± 7.52 months. Preoperative urological and gynecological features of the patients were recorded. Gynecological examination, pelvic ultrasonography, stress test, Q-tip test, cystometry were performed and incontinence and quality of life questionnaires (ICIQ-SF, IIQ-7, UDI-6, VAS-QOL, FSFI) were completed by all patients before and after the operation.
Results: Stress urinary incontinence was observed in all patients during pre-op evaluations. 62 patients aged between 35–85 (mean age 50.73 ± 9.28) years were included and follow up duration ranged between 12–44 (average 30.68 ± 7.52) months. In regard to patient evaluations, 27 patients (43.5%) felt that the surgery was very effective, 25 (40.3%) felt surgery was effective and 10 (16.1%) did not report any difference after surgery. In the long-term postoperative follow up; 2 (3.2%) patients had dyspareunia and 7 (11.3%) patients had vaginal tape erosions which were diagnosed 2–40 months postoperatively. According to Q-tip test results, proximal urethral mobility was significantly decreased after surgery. All questionnaire scores were also significantly improved at post-operative evaluations. ($P < 0.001$)
Conclusions: Our study confirmed that the Ophira mini sling technique provided high subjective cure rate and improved symptoms and quality of life in patients with SUI. These results suggest that the single incision mini sling procedure is an advisable alternative to other surgical procedures due to its low complication rates and ease of learning and applying the procedure. This procedure also demonstrated excellent tolerability, minimal pain, low morbidity and increased quality of life scores, in ICIQ-SF, IIQ-7, UDI-6, VAS-QOL, FSFI.

Introduction

Urinary incontinence is a major health problem with an annual incidence of 2–10% and prevalence of 10–40% depending on the definition, patient sex and type of incontinence. However, it is known to be an under-reported condition even though it is manageable in the majority of patients. Besides its medical and financial burden, the condition also causes extreme distress to patients [1,2]. Stress urinary incontinence (SUI) is a form of urinary incontinence caused by physical pressure to the bladder which is much more common among females [3].

As SUI is such a widespread problem, various options for therapy exist. First line treatment is conservative therapy in the majority of patients; electrical simulation and pelvic muscle training with or without pharmacotherapy are used in this approach [4]. Women who do not benefit sufficiently from initial therapy should be evaluated for surgical options. Surgical treatment modalities, such as tension-free vaginal tape and transobturator tape, have shown significant success [5,6]. However, these surgeries pose a risk for major complications such as vascular injuries and chronic pain [7]. Furthermore, the long-term objective cure rate of these interventions are questionable. The single-incision midurethral sling procedure was developed to reduce complications via shortening of insertion trajectories during surgery [7]; other advantages of the surgery include the

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use of shorter polypropylene tape, the ability to perform the surgery through a single incision, and the fact that the procedure can be performed under local anesthesia [8,9].

The single incision mini-sling (SIMS) procedure is a relatively new treatment option. Reports have been available about the procedure and its success rates since the last ten years; however, available data is insufficient and further studies are required to determine the success and complications of the procedure, especially in the long-term. We aimed to evaluate long-term outcomes and quality of life in SUI patients who underwent the SIMS procedure.

Materials-methods

Study group

Sixty-two patients who underwent single incision mini-sling (SIMS) operation for SUI in Izmir Tepecik Training and Research Hospital, Obstetrics and Gynecology Clinic in two years period were included the study. A detailed medical history was taken preoperatively and postoperatively in all cases and physical examination was performed.

Patients who were planning to conceive (n = 3), those with a history of severe systemic disease (n = 8) or vaginal hysterectomy (n = 5), and patients with urge incontinence and mixed urinary incontinence (n = 12) and patients who were lost during follow up period were excluded from the study.

Ethical approval

Ethical approval was obtained from the local ethics committee of İzmir Tepecik Training and Research Hospital. Verbal and written approval for inclusion into the study was obtained from each participant.

Measurements

Demographic characteristics were recorded and questionnaires to measure incontinence and quality of life were implemented on all patients. Validated Turkish translations of the following questionnaires were used for the evaluation of patient complaints: International Consultation on Incontinence Questionnaire- Short Form (ICIQ-SF) [10], Incontinence Impact Questionnaire (IIQ-7) [11], Visual Analogue Scales and Assessment of Quality of Life (VAS QOL), Urinary Distress Inventory (UDI-6) [11], and Female Sexual Function Index (FSFI) [12,13]. Patients' cystometry, stress tests (Marshall, Bonney, Q type test), number of pads used per day, ultrasonography and operation results were also recorded. All pelvic examinations were performed and recorded according to the POP-Q system.

The SUI diagnosis was made subjectively via stress testing performed while the bladder was partially filled with the patient in the lithotomy position. Bladder neck mobility was examined with the Q-tip test which was performed by insertion of a Q-tip into the internal urethral meatus and observation of angle change with the Valsalva maneuver compared to resting. If the change was in excess of 30°, bladder neck mobility was determined to be positive [14].

Simple cystometry tests were performed after urinary tract infection was excluded with urinalysis and urinary culture. Cystometry was postponed until after the treatment in those with active infections. Briefly, after normal voiding, patients were seated on the gynecology table and put into the dorsal lithotomy position. Under aseptic technique, a 14 F catheter was introduced into the urethra and residual volume was measured. The piston of a 50 ml syringe was removed and the syringe was connected to the catheter. The bladder was filled with 300–500 ml's of warm saline and the liquid column was elevated 15 cm's above the pubis (in the absence of straining, any increase in liquid level would suggest detrusor contraction). While filling was continued, the patient was asked to note when they felt liquid presence, when they had first desire to void, when they felt a normal desire to void, and when maximum urgency to void was felt (maximum cystometric capacity).

All repeat evaluations (questionnaires, stress tests and cystometry) were performed at post-op 12 months and in the last examination of the cases. Mean follow-up duration of all patients was 30.68 ± 7.52 months.

Procedure

All 62 patients with stress incontinence were operated with the Ophira mini sling system (Promedon-Argentina). The surgeries were performed under the guidance of the same operator with the help of different surgical residents. Fifty-one (82.25%) of the procedures were performed under local anesthesia with intravenous sedation, while 11 (17.75%) were performed under spinal anesthesia because of patients insisted demand. We opted for a first generation cephalosporin (1-dose) for infection prophylaxis. Intraoperative complications were recorded in the operative records of each patient. Cystoscopy was not routinely used. In patients with a suspicion for urinary retention, residual volume was evaluated with ultrasonography. Postoperative complications were evaluated during follow up studies which were performed on post-op first month, sixth month, and once a year after the first year. Patients who were followed for over 1 year were included in the evaluation of long-term complications and quality of life parameters.

The single incision mini sling (SIMS) procedure was performed as follows: after vulvovaginal antisepsis, the bladder was emptied with a Foley catheter and the catheter was removed. 10 ml's (5 ampules) of lidocaine and epinephrine solution was injected into the area from the midurethra to the obturator internus muscle, towards the vaginal fornices. Local anesthesia was supplemented with 1 ml of intravenous midazolam for sedation. A 1-cm vertical vaginal incision was performed 1 cm inferior to the external urethral meatus. Followed by minimal vaginal dissection towards the obturator muscle from the inferior of the ascending ramus of the ischiopubic bone, while preserving the endopelvic fascia. The arms of the mesh were fixed to both sides of the obturator internus muscle with the aid of a trocar. After procuring 1–2 mm's of space between the mesh and the urethra, the vaginal wall was closed and sutured. Post-op catheterization was not performed in any patient except the cases under spinal anesthesia. Patients' perioperative and postoperative complications, type of mesh material used (polypropylene monofilament mesh), and findings such as fever, analgesic requirement, and duration of hospital stay were recorded. Voiding difficulties and residual volume were evaluated. Patients were discharged if residual volume was lesser than 100 ml's.

Complications which developed within the first 15 days were identified as early postoperative complications, while problems continuing after 15 days and those which developed after 15 days were identified as late complications. Postoperative follow up duration was 12–44 months for all of the study group. The efficacy of the mini-sling procedure was evaluated as follows: those with negative stress-test and residual volume below 100 ml's and those with complete continence were defined as 'cured', while those who still had leakage but reported lower frequency of incontinence were defined as 'partial recovery'. These two groups were accepted to have had 'successful' interventions, while those who reported a lack of change and continued to have incontinence were accepted to have had 'unsuccessful' interventions.

Statistical analysis

The SPSS version 20 computer software was used to analyze all data. The normality of distribution of continuous variables were checked with the Shapiro-Wilk test. The Wilcoxon Signed Rank test was used to compare the pre- and post-op results because variables did not show normal distribution. As such, the comparison of two unrelated categorical variables were performed with the Pearson Chi-square test. Categorical variables were given as frequency (n) and percentage (%). Numerical variables were given as mean, median, standard deviation, minimum–maximum value and sample size. Results were evaluated with a 95% confidence interval and P values below 0.05 were accepted to be significant.

Results

In total, 62 patients aged between 35–85 (mean age: 50.73 ± 9.28 years) were included in the study. Patients' post-op follow up duration ranged between 12–44 months (average: 30.68 ± 7.52 months).

When the pre-op and post-op results of patients were compared, mean angle change in the Q-tip test was reduced to 21.03 ± 19.46° from a pre-op mean of 37.33 ± 4.55°. Residual volume and the volume at which patients felt first desire to void were similar. Average number of pads used per day was also significantly reduced at post-op (Table 1).

In regard to patient's last evaluations, 10 (16.1%) did not report any difference after surgery, 25 (40.3%) felt surgery was effective, while the remaining 27 (43.5%) felt that the surgery was very effective. Subjective cure rates were accepted as 83.8%.

Finally, all questionnaire results were found to be significantly improved at post-op (Table 2).

In regard to late complications, 2 patients (3.2%) had persistent de novo urge, 2 (3.2%) had dyspareunia, 10 (16.1%) suffered urinary tract infection, 7 (11.3%) had mesh erosions. The remaining 41 (66.1%) patients did not develop any late complications. The following early complications did not encountered in any of the patients such as; bleeding, post-op urinary retention, voiding difficulty, post-op leg pain, mesh infection and fever.

Table 1
The distribution of long term objective measures.

	PRE-OP (n = 62) Mean ± SD	POST-OP (n = 62) Mean ± SD	*p* value
Angle change during Q-tip test	37.33 ± 4.55	21.03 ± 19.46	0.001
Residual volume (ml)	20.83 ± 20.55	14.63 ± 15.20	0.091
Volume at first desire to void (ml)	163.58 ± 82.19	186.78 ± 93.31	0.078
No of pads per day	2.60 ± 1.69	0.98 ± 1.19	0.001

Table 2
The distribution of long term self-reported questionnaire scores.

	PRE-OP (n = 62) Mean ± SD	POST-OP (n = 62) Mean ± SD	*p* value
ICIQ-SF	14.63 ± 3.15	6.31 ± 6.39	0.001
IIQ-7	13.31 ± 4.50	3.23 ± 5.02	0.001
UDI-6	12.73 ± 2.94	5.60 ± 4.41	0.001
VAS-QOL	4.21 ± 0.85	1.44 ± 1.00	0.001
FSFI	18.49 ± 7.12	21.89 ± 6.12	0.001

Discussion

The frequency of SUI and better understanding of its pathophysiology have led to the development of various surgical methods for treatment. The most recent developments in surgery are generally comprised of methods which utilize synthetic slings [15,16]. However, many sling procedures have been associated with high rates of neurological and vascular injuries due to requirement for excessive surgical exploration and dissection of critical areas [17].

In the current study, which utilized the single incision mini sling (Ophira, Promedon) system in the treatment of SUI, subjective success rate was found to be 83.9% with an average follow up duration of 30 months (min-max: 12–44). In other studies which utilized the Ophira SIMS procedure, success rates varied between 68.1% and 85.3% (18–20). Prior to the Ophira procedure, the Arc-to-Arc mini sling surgery (which is also performed through a single incision under local anesthesia) was considered as a successful option with up to 60% objective cure at 6 years follow up [21].In a randomized controlled trial which compared the outcomes of the Contasure-Needleless technique, the Ophira procedure, and the synthetic midurethral sling (SMUS) procedure reported that the Ophira procedure resulted in significantly lower objective cure rate compared to SMUS, even though patient reported outcomes were similar [18].

In terms of urinary function questionnaires, there are only a few studies which have evaluated and compared the pre-op and post-op results of patients who underwent the Ophira procedure. One study reported significant improvement in ICIQ-SF and UDI-6 scores of their patients [19], while the other reported improvements in the ICIQ-SF, UDI-6 and IIQ-7 scores of participants [22]. In the current study, 4 major urinary function questionnaires (ICIQ-SF, IIQ-7, UDI-6 and VAS-QoL) and 1 sexual function (FSFI) questionnaire was completed by all patients before and after surgery in their last examinations. The post-op results of all questionnaires were significantly improved after the surgery.

Regarding complications, several studies have reported that major complications may occur during the sling procedures, including bleeding into the retropubic space and the obturator muscle and also damage to the bowel and vasculature. The risk for such complications are associated with the extent of dissection, the number of blind needle passages and also requirement for additional incisions [19]. In the current study, major complications did not develop in any of the patients. A total of 24 minor complications were observed (2 persistent de novo urge, 2dyspareunia, 10 urinary tract infection, 7 mesh erosions), while the remaining 41 patients did not develop any complications. In a large study comprised of 149Ophira recipients, minor mesh exposure occurred in 3, urinary retention occurred in 4, urinary tract infection occurred in 8, and de novo urge persisted in 7 patients with an average follow up duration of 9 months. In another Ophira study, 10 (6.1%) of patients had de novo urge incontinence, 2 (1.2%) had bladder outlet obstruction, 15 (9.9%) had dyspareunia. Interestingly, 14 of the patients who had dyspareunia were found to have developed mesh erosion [22]. A smaller study by Palma et al. reported no complications; however, the number of patients in this study was only 18, and 2 patients were lost to follow up [23]. While pain complication was not reported in these studies, a study by Yildiz and colleagues found that pain had developed in 3 of their 173 patients. However, pain was not severe and was managed with anti-inflammatory medications [20].

The number of patients in the current study is lower than some of the major studies on this topic. The absence of a control group which received another type of surgery is also a limitation. However, there are only a handful of studies on this procedure and further studies should have done for long-term effectiveness.

Conclusions

The single incision mini sling procedure was found to provide a high subjective cure rate and did not cause any major complications with a long-term follow up duration 30 months.

Conflicts of interest and source of funding

All authors declare that there is no potential conflict of interest and no financial support.

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