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ARAŞTIRMA / RESEARCH

Outcome of sacrospinous ligament fixation with conventional instruments in the treatment of Stage 3-4 vaginal vault prolapse

Evre 3-4 vajinal cuff prolapsusu tedavisinde konvansiyonel enstrümanlar kullanılarak sakrospinöz ligament fiksasyon sonuçları

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Abstract

Purpose: The objective of this study was to investigate the effectiveness of the sacrospinous ligament fixation (SSLF) at 12 months following the operation.

Materials and Methods: This retrospective study included patients diagnosed with vaginal vault prolapse and underwent SSLF between January 2014 and May 2017. The subjective evaluation was performed according to the Patient Global Impression of Improvement (PGI-I). The objective success rate at the end of 12 months was evaluated, and the Pelvic Organ Prolapse-Quantification System (POP-Q) Stage 0 or 1 was considered as a successful outcome. The effectiveness of the operation and the complication rates were evaluated during one-year follow-up.

Results: A total of 26 patients were included in the study. Twelve patients (46.2%) underwent unilateral SSLF and 14 patients (53.8%) bilateral SSLF operation. At 12 months, the objective and subjective success rates were 100% and 100%, respectively. There was a significant difference between the unilateral and bilateral SSLF groups in terms of the operation time and intraoperative bleeding. After one-year follow-up, only three patients (11.3%) complained about mild gluteal pain.

Conclusion: The suspension of the vagina to the unilateral or bilateral sacrospinous ligament was an effective and safe surgical method in patients with post-hysterectomy vaginal vault prolapse.

Keywords: Sacrospinous ligament, vaginal prolapse, hysterectomy.

Öz

Amaç: Çalışmamızda sakrospinöz ligament fiksasyonunun (SSLF) ameliyat sonrası 12 aylık dönemdeki etkinliği araştırıldı.

Gereç ve Yöntem: Çalışmaya Ocak 2014 ve Mayıs 2017 tarihleri arasında vajinal cuff prolapsusu tanısı almış ve SSLF uygulanmış hastalar dahil edildi. Sübjektif değerlendirme Hasta Global Düzelme İzlenimi (PGI-I) skorlama sistemi kullanılarak gerçekleştirildi. 12. ayda objektif başarı oranı değerlendirildi ve Pelvik Organ Prolapsusu-Kantifikasyon Sistemi (POP-Q) Evre 0 veya 1 sonuçları objektif başarı kriteri olarak kabul edildi. Operasyonun bir yıllık dönemdeki etkinliği ve komplikasyon oranları değerlendirildi.

Bulgular: Toplam 26 hasta çalışmaya dahil edildi. On iki hastaya (%46.2) unilateral SSLF uygulanırken, 14 hastaya (%53.8) bilateral SSLF yapıldı. Objektif ve sübjektif başarı oranı 12. ayda sırasıyla %100 ve %100 idi. Bilateral ve unilateral SSLF uygulanmış gruplar arasında ameliyat süresi ve intraoperatif kanama miktarı yönünden anlamlı bir fark izlendi. Bir yıllık takibin sonunda yalnızca üç hastada hafif şiddette gluteal ağrı gözlendi.

Sonuç: Unilateral veya bilateral sakrospinöz ligament süspansiyonunun histerektomi sonrası vajinal cuff prolapsusu olan kadınlarda etkili ve güvenli bir cerrahi yöntem olduğunu göstermektedir.

Anahtar kelimeler: Sakrospinöz ligament, vajinal prolapsus, histerektomi.

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INTRODUCTION

Pelvic organ prolapse (POP) is the herniation of the pelvic organs and/or the uterus through the vagina as a result of the dislocation of the organs downwards. Usually bladder, uterus and post-hysterectomy vaginal cuff, ileum and colon are involved in POP[1]. Hysterectomy is one of the most common surgical procedures in a woman's lifetime. Approximately 10% of all women undergoing previous hysterectomy due to the prolapse symptoms visit a gynecologist for the surgical correction of a vaginal vault prolapse[2]. Until date, several procedures have been defined for the surgical treatment of POP using vaginal and open/closed abdominal approaches. The most common surgical methods include sacrospinous ligament fixation (SSLF) and sacrocolpopexy owing to their high success rates reported in the literature[3]. In the last decades, many studies have shown that SSLF is an effective surgical procedure to correct uterine prolapse and post-hysterectomy vaginal vault prolapse[4-7]. This minimally invasive method is preferred thanks to its low failure and complication rates[8].

The SSLF technique for the treatment of the vaginal vault prolapse was first developed by Richter[9]. However, we owe its popularity to Nichols[10], who reported positive comments on the results of SSLF. The subjective and objective success rates of SSLF were found to be 84 to 99% and 67 to 93%, respectively[10]. Thanks to these high success rates, the SSLF technique is commonly used for the repair of the vaginal apex prolapse in patients who have a history of a previous transvaginal intervention. A variety of postoperative complications such as infection, hemorrhage, neuropathy, and musculoskeletal pain have been reported[1,11].

In this study, we present our results of SSLF with one-year follow-up results in patients with vaginal vault prolapse, which was performed by a single surgeon using conventional surgical instruments.

MATERIALS AND METHODS

In this retrospective study, a total of 26 patients who underwent SSLF by a single surgeon in three different centers between January 2014 and May 2017 were analyzed. The POP was evaluated using the Pelvic Organ Prolapse-Quantification System (POP-Q)[12,13]. We only included the patients who underwent benign hysterectomy and complained about the vaginal vault prolapse (POP-Q Stage 3-4). A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki. No Ethics Committee approval was required due to the retrospective nature of the study.

Table 1. Demographic and clinical characteristics of patients.

Characteristics	Values n (%), median(range)
Age	61 (49-76)
Parity	3 (1-5)
BMI	24.1 (19.8-32.3)
Symptom Mass sagging into vagina Sagging+Incontinence Sagging+Feeling of pelvic pressure	 21 (80.8 %) 4 (15.4 %) 1 (3.8 %)
Concomitant morbidities Cystocele Rectocele Cystorectocele Stress urinary incontinence Enterocele	 4 (15.4 %) 1 (3.8 %) 1 (3.8 %) 4 (15.4 %) 16 (61.5 %)
Operation SSLF SSLF+TVT SSLF+Enterocele	 6 (23.1 %) 4 (15.4 %) 16 (615 %)
Operation time (min)	35.5 (20 - 40)
Length of hospital stay (day)	2 (2 - 4)
Amount of bleeding (mL)	50 (30 - 100)
Intraoperative complication	0 (0 %)
Postoperative complication Gluteal pain (mo 3)	 3 (11.5 %)
Recurrence	0 (0 %)
Subjective/objective response rate	100% /100%

SSLF: Sacrospinous Ligament Fixation TVT: Trans Vaginal Tape

All patients underwent gynecological examination, transvaginal and abdominal sonography before the operation. The clinical and demographical data of the patients were retrieved from the hospital database. Data including age, birth history, body mass index (BMI), and pre- and postoperative complications were recorded. All patients were scheduled for follow-up in the gynecological outpatient clinics at three, six, and 12 months. The final evaluation was based on the last visit at 12 months. The subjective

evaluation was performed according to the Patient Global Impression of Improvement (PGI-I)[14]. A low score on the PGI-I indicates an overall improvement in a woman's perception of her condition after treatment (PGI-I score of 1 or 2 = very much better and much better, respectively). The objective success rate was also evaluated, and the POP-Q Stage 1 was considered as a successful outcome. The POP-Q Stage ≥2 was considered failure at the end of 12-month gynecological examination visit.

Table 2. Results of bilateral and unilateral SSLF at the end of 12-month follow-up.

Characteristics	Unilateral SSLF (n=12), median	Bilateral SSLF (n=14), median	P value
Age (year)	65.5(49 - 76)	57 (49 - 73)	0.110
BMI (kg/m²)	24.3 (21.1 – 30.2)	24.6 (19.8– 32.3)	0.681
Parity	3 (2-5)	3 (1 - 4)	0.693
Operation time (min)	22 (20-40)	38 (31-41)	**<0.001**
Length of hospital stay (day)	2 (2-3)	3(2-3)	0.098
Amount of bleeding (mL)	40 (30 - 80)	60 (40- 100)	**0.005**

Mann-Whitney U test was used.; **SSLF**: Sacrospinous Ligament Fixation; **BMI**: Body Mass Index

Table 3. PGI-I scores after SSLF.

PGI-Scores	No (%)
1 (Very much better)	19 (73.1%)
2 (Much better)	7 (26.9 %)
3 (A little better)	0
4 (No change)	0
5 (A little worse)	0
6 (Much worse)	0
7 (Very much worse)	0

PGI-I: Patient Global Impression of Improvement; SSLF: Sacrospinous Ligament Fixation.

Surgical technique

The patients were placed in the lithotomy position. The sacrospinous ligament was accessed through an incision following the posterior vaginal wall up to the vaginal vault. Blunt dissection was used to open the right and/or left pararectal space and locate the ischial spine. A window was created through the rectal pillar, large enough to insert two fingers. Just lateral to the rectum and above the puborectalis muscle, the right and/or left sacrospinous ligament-coccygeus muscle complex was localized. Following the positioning of three Breisky specula, prolene 1-0 sutures were made under direct vision. These two permanent non-absorbable sutures were tied to the sacrospinous ligament in 0.5 cm interval. Following the placement of the suture about 2 cm lateral to the ischial spine, the unilateral or bilateral SSLF was completed.

Statistical analysis

All data were analyzed using the SPSS for Windows version 22 (IBM Corp., Armonk, NY, USA). Continuous variables were presented in median (range) and categorical variables in number and percentage. For the analysis of qualitative data, the chi-square test was used. For the analysis of quantitative data, the Mann-Whitney U and paired-samples t-test were used. A p value of less than 0.05 was considered statistically significant.

RESULTS

The median age of the patients was 61 (range, 49 to 76) years. The median values of BMI and number of births were 26.7 (21.1 to 34.2) kg/m² and 3 (1 to 4), respectively. Concomitant to the cuff prolapse, four patients (15.4%) had cystocele, one patient (3.8%) rectocele, one patient (3.8%) cystorectocele, four patients (15.4%) stress urinary incontinence, and 16 patients (61.5%) enterocele. Twelve patients (46.2%) underwent unilateral SSLF and 14 patients (53.8%) bilateral SSLF operation. In addition, simultaneously four patients (15.4 %) underwent transvaginal tape (TVT) and 16 patients (61.5 %) enterocele repair.

Table 4. Value of POP-Q before and after (at 1 year) operation.

	Aa	Ba	Ap	Bp	TVL
Preop	2.7± 0.28	2.8±0.3 1	2.7±0.3 6	2.7±0.3 1	6,2±1.2 3
Postop 1st year	2.9± 0.18	2.9±0.2 1	2.9±0.2 2	2.5±0.2 4	8,3±0.8 1
P value	0.001	<0.001	<0.001	<0.001	<0.001

Paired-Samples t-test was used;nPOP-Q: Pelvic Organ Prolapse-Quantification System.

The median operation duration was 35.5 (20 to 40) min, the median amount of bleeding was 50 (30 to100) mL, and the median hospitalization time was two (2 to 4) days. No intra- and postoperative complication was observed. During the 12-month follow-up period, only three patients (11.5%) complained about mild gluteal pain. No recurrence was observed during follow-up. The vaginal

examination showed that the posterior total vaginal length (TVL) was over 7 cm in all patients. The subjective and objective success rates were 100% and 100%, respectively. Demographic and clinical characteristics of the patients are shown in Table 1. There was no statistically significant difference in the age, BMI, number of births, and length of hospitalization between the groups (Table 2). In all of the patients with recovery, the improvement of SSFL was rated using the PGI-I as "very much better" or "much better. The PGI-I results are presented in Table 3. At one year postoperatively, the POP-Q evaluation was performed and compared with the preoperative POP-Q findings. Postoperative Aa, Ba, Ap, Bp, and TVL were significantly lower than the preoperative values ($p<0.001$) (Table 4). The comparison of the patients who underwent unilateral and bilateral SSLF showed that there was a significant difference in the operation time and intraoperative amount of bleeding between the groups.

DISCUSSION

In this study, we evaluated the clinical outcome, complications, and patients' satisfaction after SSLF. The SSLF is an effective, safe, and minimally invasive technique used for the management of the POP. In our study, the SSLF was carried out in 26 patients with vaginal vault prolapse by a single surgeon using conventional instruments. No recurrence of prolapse was observed during one-year follow-up. Only three of the patients (11.5%) experienced mild gluteal pain during the control examination at three months. However, we observed no other complication during the 12-month follow-up period. Subjective and objective evaluation also showed a significant improvement in the PGF-I and POP-Q scores at one year following surgery.

In a recent SSLF study including 55 Asian women with POP-Q Stage 3-4 using conventional surgical instruments, the objective success rate, recurrence rate, and satisfaction rate were found to be 98%, 2%, and 94%, respectively at 24 months[15]. In the aforementioned study, the mean blood loss was 100 mL and the mean operation time was 60 min. In addition, two patients developed a pelvic hematoma (5cm and 7 cm in size), and one patient experienced gluteal pain, which was completely relieved with physiotherapy after three months[15]. In another study, the objective success rates of SSLF at one and seven years were reported as 96% and 94%, respectively[6].

In our study, the overall follow-up period was 12 months and the objective success rate was 100%. Our results are consistent with the aforementioned study. Regarding the complication rates, similar to the aforementioned study, only three patients complained about gluteal pain at three months, which disappeared after 12 months. In addition, in our study, the median operation duration was 35.5 min and the median amount of bleeding was 50 mL. The relatively shorter operation time and the smaller amount of bleeding in our study can be attributed to the fact that our patients had isolated vaginal vault relapses and the surgical intervention was indicated for this condition alone.

Sentürk et al.[16] reported that SSLF was successful with local anesthesia in 11 elderly patients who had a high risk for general anesthesia. The authors observed no complication, despite the use of local anesthesia, and only two patients had relapse after two years. In a prospective, observational study, 20 patients who had relapse after unilateral SSLF underwent bilateral SSLF and followed for 12 months[7]. In this study, the success rate was 90% and no intra- or postoperative complication was observed. In the aforementioned study, the authors concluded that bilateral SSLF was a safe and effective intervention in patients with relapse after unilateral SSLF with improved quality of life and sexual functions. One of the important limitations of our study was that we were unable to perform an objective evaluation of the quality of life and sexual functions. During the gynecological examinations, however, we found that our patients had a sufficient vaginal length (>7 cm) and we observed no anatomical or functional problem, which might cause sexual dysfunction. In addition, none of our patients provided any negative feedback about the sexual functions.

In a meta-analysis including 34 studies, the reported objective success rate was 94% in 1,062 patients who underwent SSLF and followed[17]. In this meta-analysis, 109 patients (18%) had recurrent prolapse, and 81 of them had cystocele, 32 had cuff prolapse, and 24 rectocele. Seven patients in the cystocele group, 20 in the cuff prolapse group, and four in the rectocele group were re-operated[17]. Although the reported rate of cystocele was high in this meta-analysis, the rate of the symptomatic cystocele was not reported. The authors, consequently, suggested that the vaginal retroversion due to SSLF weakened the anterior vaginal wall, which is a predisposing

factor for the cystocele. In our study, we did not observe any prolapse recurrence during one-year follow-up. Nevertheless, recurrence should be closely monitored in the long-term.

In a large meta-analysis involving 3,893 patients who underwent SSLF due to POP between 1995 and 2011, the cure rate was 84.6% (69 to 00)[11]. Regarding the recurrence rates, vaginal apex recurrence was found in 5.3% (0 to 14), anterior prolapse in 18.3% (0 to 42), and posterior prolapse rate in 2.4% (0-6). In this meta-analysis, the complications were also reported: neurovascular injury in 7.4% (0 to 36), urinary retention in 13.4% (0 to 75), urinary tract infection 8.8% (4 to 21), and cuff infection in 1.1% (0 to 2)[11].

In our study, we did not observe any recurrence or complication during the relatively short 12-month follow-up period. In the aforementioned meta-analysis, the recurrence and complication rates occurred in the long term. In these studies, there were no systematic information about the symptomatic cases and the need for a second surgical intervention. In particular, information about the operation standards was lacking. The conflicting results can be explained by several factors such as different levels of surgical experience, suture materials used, surgical equipment, and bilateral *versus* unilateral techniques. In addition, in our study, all patients were operated by a single surgeon, two non-absorbable sutures were assured to the sacrospinous ligament both in unilateral and bilateral SSLF, the sacrospinous ligament was directly visualized, and the sutures were made with a conventional surgical needle holder. Therefore, the recurrence and complication rates were relatively lower in our study. Only three patients (11.5%) experienced mild gluteal pain at three months, which resolved at six- and 12-month control visits.

Miyazaki[18] reported 74 patients who underwent SSLF with a Miya hook. Although the author did not discuss the results of prolapse treatment, he showed that it was a safe technique. The author also found no complication such as neurovascular injury or bladder-rectum injury. The mean blood loss was 75 mL and none of the patients needed blood transfusion.

Currently, there are several instruments designed for passing the suture through the ligament in SSLF. The main ones include Deschamps needle[19], Miya hook[18], Shutt suture punch system[20], autosuture endostitch[21], Laurus needle deployment system[22], and Aksakal automatic suturing system[23]. Previous studies have shown that these instruments are reliable which contribute to the minimally invasive surgical interventions[18,19,23,24]. In present study, ligament sutures were tied with conventional surgical instruments and no complication occurred. Also, similar success rates were obtained. In addition, we observed no intra- or postoperative complication during follow-up. However, although rare, serious complications may occur in SSLF operations including neurovascular injuries, bladder and rectum injuries, and serious abscess[11,17]. In addition to these serious complications, gluteal pain can be also seen. This complication is usually relieved within six weeks after surgery[25,26]. Of note, in a randomized, double-blind, placebo-controlled study, postoperative gluteal pain was unable to be relieved with intraoperative local anesthesia application with a reduced need analgesics[27].

While some symptoms related to POP result from vaginal prolapse, some others may be already existing or be related to the bladder, lower gastrointestinal system, and pelvic floor dysfunction as a result of prolapse. Ellerman et al.[28] evaluated 237 patients with POP and reported that 63% of the patients were admitted with a palpable vaginal mass, 73% with urinary incontinence, 62% with micturition, and 31% with defecation problems. In our study, all patients applied with a palpable mass sagging into the vagina and four patients with concomitant urinary incontinence and one patient with a pressure feeling in the pelvis[28].

The literature review revealed no difference between bilateral and unilateral SSLF regarding the success, recurrence, and complication rates[1,11]. In two prospective, randomized studies, patients who had an apical prolapse and underwent bilateral or unilateral SSLF were compared with abdominal sacral colpopexy. Although Benson et al.[29] recorded better results with abdominal sacral colpopexy, Maher et al.[30] found comparable success rates in both groups.

It has been also shown that unilateral SSLF prophylactic to vaginal hysterectomy may reduce the recurrence rates in patients with stage3-4 POP [31]. In our study, although there was a significant difference between the unilateral and bilateral SSLF in terms of the operation time and amount of bleeding, these complications did not cause any additional morbidity.

Nonetheless, there are some limitations to this study. The retrospective design, small sample size, and relatively short follow-up period are the main limitations. In addition, the lack of an objective query of the quality of life is another limitation. Furthermore, we applied enterocele repair procedures to 16 patients. The additional procedure applied could have affected our results. Nevertheless, we believe that 26 patients with an isolated vault prolapse can be considered as an adequate sample size and that this study would provide an important contribution to a growing body of knowledge in the literature.

In conclusion, our study results suggest that SSLF, which is performed with conventional surgical instruments after hysterectomy in patients with vaginal vault prolapse, is an effective and safe intervention, and the morbidity and efficacy rates of unilateral and bilateral approaches are similar. However, further large-scale, prospective studies are needed to confirm these findings.

Yazar Katkıları: Çalışma konsepti/Tasarımı: HŞ; Veri toplama: EAŞ, İY, MEŞ; Veri analizi ve yorumlama: HŞ, İY, EAŞ; Yazı taslağı: HŞ, EAŞ; İçeriğin eleştirel incelenmesi: AA; Son onay ve sorumluluk: HŞ, İY, EAŞ, MEŞ, AA; Teknik ve malzeme desteği: -; Süpervizyon: AA, HŞ; Fon sağlama (mevcut ise): yok.
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