Comparing Laparoscopic Sacrocolpopexy with Vaginal Sacrospinous Ligament Fixation in the Treatment of Vaginal Apical Prolapse; the First Randomized Clinical Trial: A pilot study

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Purpose: To compare two methods of laparoscopic sacrocolpopexy (LSCP) and sacrospinous ligament fixation (SSLF) in terms of efficacy and safety in the treatment of vaginal apical prolapse.

Materials and Methods This prospective, randomized controlled clinical trial was conducted on 32 patients with symptomatic vaginal apical prolapse, referred to the female urology clinic of Kerman University, Iran, during 2018-2019. The patients were re-examined at 12 months after surgery. Objective success was recorded using Pelvic Organ Prolapse Quantification (POP-Q) classification as primary outcome. The subjective success of the methods was determined by the quality-of-life parameters, based on Pelvic Floor Impact Questionnaire (PFIQ-7), Pelvic Floor Distress Inventory (PFDI-20), and Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) scores as secondary outcomes. Moreover, complications were recorded in both groups.

Results: The amount of intraoperative bleeding was significantly higher in the SSLF group, compared to the LSCP group ($P = 0.01$). Persistent pain was observed in two (12%) patients in the LSCP group and five (31%) patients in the SSLF group ($P = 0.2$).
The decrease in the total PFIQ-7 score was in favor of the LSCP group but not statistically significant ($p = 0.06$). The LSCP group showed bigger improvement in vaginal ($p = 0.04$) and bowel ($p = 0.03$) scores. The results of the PISQ-12 and PFDI-20 questionnaires as well as POP-Q examination were not different in two groups.

Conclusion: Although the surgical methods of LSCP and SSLF can be equally effective in the treatment of apical prolapse, LSCP appears to be superior to SSLF regarding less bleeding.

Keywords: pelvic organ prolapse; laparoscopic sacrocolpopexy; vaginal sacrospinous ligament fixation; vault prolapse

INTRODUCTION

Pelvic organ prolapse (POP) is defined as herniation of pelvic organs toward the vaginal wall in women. POP is a significant health concern, affecting almost half of women above the age of 50 years annually, with a lifetime prevalence of 30-50%[1,2,3]. Patients experience symptoms, such as pelvic discomfort, urinary or fecal incontinence, storage and voiding lower urinary tract symptoms, and sexual dysfunction, reducing their quality of life.[4,5] Conservative POP treatments, such as vaginal pessaries, are well-known effective methods. However, patients prefer permanent treatments to maintain their body image and sexual function.

Apical prolapse is defined as the descent of the uterus, cervix, or vaginal vault toward the hymen following hysterectomy[6]. The vaginal apex is supported by the uterosacral-cardinal ligament complex and the levator ani muscle[7], defects in this form of pelvic support occur because of childbirth, hysterectomy, aging, and some congenital anomalies, such as spina bifida.[8,9]
Apical prolapse usually co-occurs with anterior or posterior vaginal compartment prolapse. Since the vaginal apex is the cornerstone of vaginal support, it must be considered in the treatment of various types of prolapse to achieve long-term favorable outcomes in surgery. There are various surgical methods for repairing apical prolapse. These surgeries can be performed using a vaginal or abdominal approach (open, laparoscopic, or robotic), with or without uterine preservation. Studies show that each of these methods has its own advantages and disadvantages.[10,11]
With this background in mind, the present pilot study aimed to compare two minimally invasive vaginal surgeries for repairing apical prolapse, that is, laparoscopic sacrocolpopexy (LSCP) and sacrospinous ligament fixation (SSLF), in terms of effectiveness and complications.

PATIENTS AND METHODS

This study was a pilot study. This prospective, parallel group randomized controlled trial (RCT) was conducted on women with vaginal apical prolapse, who were referred to the female urology clinic.
The inclusion criteria were as follows: 1 clinic of Ker-

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Table 1. The baseline characteristics of the study population

Variables	LSCP group (n=16)	SSLF group (n=16)	*P*-value
Mean (range) age, years	63.1 (33.7–86.3)	65.4 (38.2–88.1)	$P > 0.05$
Mean (SD) BMI, kg/m^2	25.03±3.55	23.50±2.23	0.155
Obstetric history			
Median (range) parity	2 (0–7)	2 (1-5)	NA
C-section	9 (56)	7 (43)	0.724
Hysterectomy	9 (56)	10 (62)	0.919
History of anti-incontinence surgery	1 (6)	0 (0)	0.407
History of Cystocele repair	5 (31)	4 (25)	0.994
History of other abdominal surgery	2 (12)	2 (12)	0.700
Urinary incontinence	7 (43)	9 (56)	0.480
Stress urinary incontinence	5 (31)	7 (43)	0.608
Overactive bladder	2 (12)	2 (12)	
Dyspareunia	7 (43)	8 (50)	0.987
Menopause	12 (75)	13 (81)	0.924

Data are presented as n (%) or mean (range) or mean ± SD

man University of Medical Sciences, Kerman, Iran.) age range of 18-75 years; 2) vaginal apical prolapse stage II or higher; 3) symptomatic prolapse; 4) no response to conservative treatments; and 5) request for the surgical treatment of prolapse.

The exclusion criteria were as follows: 1) contraindications to major surgery or anesthesia; 2) any urogenital or pelvic malignancy; 3) active urogenital or pelvic infection; 4) pregnancy or lactation, and 5) history of allergy to synthetic meshes.

After obtaining informed consent, patients were randomly divided into two groups, using the block randomization with a 1:1 ratio provided by the statistician. The size of each block was four. The patient and the surgeon were not blinded regarding the allocation; however, the caregiver who managed the follow-up examination, as well as the statistician, was blinded. The patients' demographic information, including age, parity, body mass index (BMI), hormonal and menopausal status, and history of urinary and genital surgery, were recorded. A urologist completed the short forms of the Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) for the patients. The pelvic examination was recorded, according to the Pelvic Organ Prolapse Quantification (POP-Q) system, as the standard pelvic examination system of the International Continence Society (ICS).

Urine analysis and culture and measurement of postvoid residual urine, were performed for the patients. Urodynamic evaluation was performed, if patient had complained of incontinence. All surgeries were performed in a single center (Shahid Bahonar Hospital, Kerman University of Medical Sciences). LSCP was performed by an endourologist (second author), and SSLF was performed by a female urologist (first author).

LSCP technique

Three laparoscopic ports were used including one 10-mm umbilical port for vision and two 5-mm ports laterally in each side between the umbilicus and the anterior superior iliac spine. The anterior peritoneum was dissected away from the vaginal apex, exposing the full thickness of the vaginal wall; dissection continued down to the rectovaginal space. The peritoneum overlying the sacral promontory was incised longitudinally down to the vaginal apex. Next, the presacral adipose tissue was carefully dissected away. A Y-shaped PVDF (DynaMesh-PRS) mesh was introduced through the 10-mm port. The anterior leaf of the mesh was sutured to the vaginal apex, using a permanent 2-0 Nylon suture; the posterior leaf was also sutured in a similar fashion through the proximal part of the rectovaginal fascia (in patients with uterine prolapse, bilateral windows were made in the broad ligament at the level of the cervicouterine junction lateral to the uterine artery in the avascular area, and the left and right pieces of anterior mesh arms are passed through the left and right broad ligament and attached to the cervix and upper vagina with nonabsorbable suture; then, a posterior mesh arm is fixated to the posterior vagina and cervix with nonabsorbable suture). The other side of the mesh was then brought to the sacral promontory area. After adjusting the length of the mesh, it was fixed to the anterior longitudinal ligament, using the laparoscopic anchor system to fix the mesh at the sacral promontory. Finally, the peritoneum was re-approximated to cover the mesh.

SSLF technique

The surgery was performed with the patient in the lithotomy position. A midline vaginal incision was made anteriorly in the vaginal epithelium, which is separated from the pubocervical fascia, to expose the paravesical space. After identifying the sciatic spine, the sacrospinous ligament was palpated via blunt dissection. Afterward, the suture was fixed approximately 2 cm medial to the spine, using a Capio suture capturing device and delayed absorbable suture (vicryl 0). In addition, bilateral SSLF was performed by placing one suture on each ligament. Each suture was passed through the vaginal epithelium at the level of the vault and left for later tying (in patients with uterine prolapse, the anterior cervix is exposed, and a free needle is used to pass the two sutures through the anterior cervix). The suture was tied before completely closing the vaginal wall so that the vaginal apex or cervix could be attached to the sacrospinous ligament. Finally, the remainder of the vaginal incision was closed.

Outcome measures

All information regarding the duration of surgery, length of hospitalization, decrease in the hemoglobin level, need for blood transfusion, and intra- and postoperative complications were recorded.

The patients were examined in the first, sixth, and

Table 2. Comparison of different perioperative clinical characteristics of the study population

LSCP (N=16)	SSLF (N=16)		*P*-value
bleeding			
< 200 Cc	12 (75)	4 (25)	0.013
200-400Cc	2 (12)	7 (44)	
> 400Cc	2 (12)	5 (31)	
Hemoglobin decrease	1.19 ± 0.48	3 ± 0.67	< 0.0001
Blood Transfusion	0	2 (12)	0.14
Duration of surgery	3.56±0.51	3.31± 0.48	0.16
Duration of Hospitalization	3.31±0.48	3.56±0.51	0.164

Data are presented as count (percent) or mean ± standard deviation

Table 3. Comparing the results of the POP-Q examination stage in two groups before and after the intervention.

	LSCP (n=16)	SSLF (n=16)	*P*-value
preoperative POP-Q			0.5
Stage II	3 (19)	4 (25)	
Stage III	8 (50)	7 (44)	
Stage IV	5 (31)	5 (31)	
postoperative POP-Q			> 0.999
stage < I	15 (94)	15 (94)	
stage > I	1 (6)	1 (6)	

Data are presented as n (%)

twelfth months after surgery, when the patients completed the questionnaires again, and pelvic examination was carried out. The primary outcome was Objective success that was defined as apical prolapse less than or equal to stage I on the vaginal examination, and secondary outcome was subjective success that was defined as the improvement of PFDI-20, PFIQ-7, and PISQ-12 scores.

Compliance with Ethical Standards

This study was supported by a grant from the Kerman Universit of Medical Sciences. The authors had no financial relationships or any conflict of interest. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethics Committee of the university approved the clinical study (IR.KMU.REC.1397.094). Informed consent was obtained from all participants involved in the study. The RCT registration code is IRCT20180106038231N1

Statistical analysis and sample size

As this was a pilot study, all patients that had met the inclusion criteria and completed the consent form in a specific period of time (December 2018 until December 2019) were included in the study. 16 patients were included in each group. The best procedure for comparing pre and post scores is the Analysis of covariance (ANCOVA). Since the ANCOVA underlying assumptions

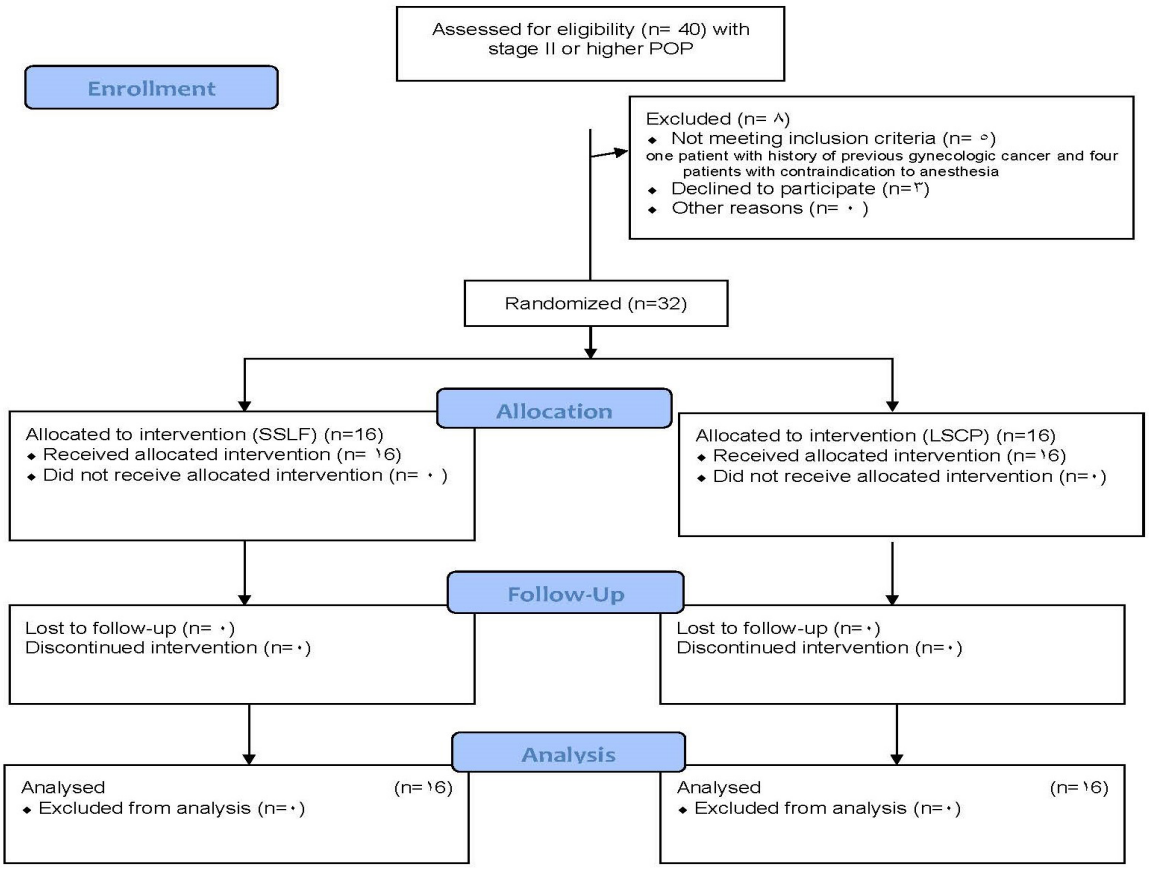

Figure 1. CONSORT 2010 Flow Diagram of the study on patients with pelvic organ prolapse

Table 4. The mean PFIQ-7 details scores before and after the surgery compared between two treatment groups.

Subscales	Preoperative Mean ± SD	postoperative Mean ± SD	*P*	Total Mean ± SD	*P*
Bladder					
LSCP	11.28 ± 1.96	0.29 ± 0.45	< 0.001	-97.17 ± 4.85	0.35
SSLF	12.29 ± 1.69	0.61 ± 0.50	0.002	-95.38 ± 4.15	
Bowel					
LSCP	11.08 ± 1.64	0.23 ± 0.44	< 0.001	-97.97 ± 4.09	0.031
SSLF	11.66 ± 1.70	0.64 ± 0.47	0.002	-94.21 ± 4.45	
Vagina					
LSCP	12.96 ± 2.36	0.29 ± 0.45	< 0.001	-97.74 ± 4.03	0.041
SSLF	12.35 ± 1.47	0.65 ± 0.44	0.002	-94.60 ± 4.06	
Total PFIQ-7					
LSCP	35.31 ± 5.44	0.77 ± 1.34	< 0.001	-96.64 ± 3.97	0.064
SSLF	36.14 ± 4.06	1.93 ± 1.46	0.002	-95.75 ± 3.96	

P : *P*-value

were not met, (the beta coefficient for the covariate was not equal among groups) the difference between post and pre scores was calculated. Then this difference was divided to the pre scores, for baseline adjustment. The final score was compared using the independent-samples *T*-test or Mann–Whitney *U* test. The normality test was checked by Shapiro–Wilk test in each group. For more precision, the Q-Q plot was also investigated for normality assumption, and almost all points were around the line with 45 degrees, which confirmed normality.

If normality and homogeneity of variances were established in both groups, the comparison between scores was performed with independent samples t-test. Otherwise, Mann–Whitney U test was used. The Chi-square test was used for the association between categorical variables. Fisher's exact test was used if at least 25 percent of cells had an expected count of less than 5. The analysis approach was intention to treat. Data analysis was performed using SPSS version 20 software. A P-value of < 0.05 was considered statistically significant.

RESULTS

Thirty-two patients, with the mean age of 64.2 years and the median parity of two, participated in this study (**Table1**).

Perioperative data

Table 2 depicts the perioperative data. The duration of surgery was 3.56±0.51 hours in the LSCP group and 3.31± 0.48 hours in the SSLF group ($P = 0.16$). The mean reduction of hemoglobin level was 1.19 ± 0.48 g/dl in the LSCP group and 3 ± 0.67 g/dl in the SSLF group ($P < 0.0001$). Two patients in the SSLF group required blood transfusions (12%) in the postoperative period, whereas no such case was reported in the LSCP group. ($P = 0.14$) Moreover, the length of hospitalization was not different in two groups (**Table 2**).

No intraoperative complications, such as bladder and rectal injuries, were observed in any of the patients. For one patient, the laparoscopic approach was converted to open surgery due to severe adhesions. Hematoma, mesh erosion, pelvic abscess, fistula, embolism, and death were not observed in any of the patients in the two groups.

Outcome

Primary outcome: All but one patient in each group showed stage less than I in postoperative POPQ examination (**Table 3**).

Failure of surgery was identified 6 months after surgery. In one case, which was after LSCP, the patient had a relative recovery and did not need reoperation. In another case, failure after vaginal surgery, the patient preferred to use a pessary.

Secondary outcome: Both groups showed improvement in PFIQ-7 scores (**Table 4**). Comparing two groups, the LSCP group showed a bigger improvement in vaginal ($p = 0.04$) and bowel ($p = 0.03$) scores. The difference in the total PFIQ-7 score was in favor of the LSCP group but not statistically significant ($p = 0.06$) (**Table 4 and Figure 2**).

The results of the PISQ-12 and PFDI-20 questionnaires was not different in two groups.

Table 5. The mean PFDI-20 details scores before and after surgery compared between two treatment groups.

	preoperative Mean ± SD	postoperative Mean ± SD	*P*	Total Mean ± SD	*P*
POPDI-6					
LSCP	18.25 ± 1.85	1.36 ± 1.19	< 0.001	-92.97 ± 6.15	0.95
SSLF	17.78 ± 2.04	1.21 ± 1.23	0.002	-93.21 ± 6.90	
CRAD-8					
LSCP	16.15 ± 1.67	3.07 ± 1.06	< 0.001	-81.06 ± 6.28	0. 95
SSLF	16.15 ± 2.15	3.01 ± 1.05	0.002	-81.62 ± 5.06	
UDI-6					
LSCP	13.45 ± 1.89	1.20 ± 0.48	< 0.001	-98.86 ± 0.32	> 0.999
SSLF	13.84 ± 1.56	1.32 ± 0.51	< 0.001	-98.46 ± 0.38	
Total PFDI-20					
LSCP	47.79 ± 3.28	4.41 ± 1.46	< 0.001	-90.82 ± 2.98	0.751
SSLF	47.73 ± 3.11	4.16 ± 1.53	0.002	-91.27 ± 3.13	

P : *P*-value

Table 6. The mean PISQ-12 scores before and after surgery compared between two treatment groups.

	Preoperative Mean rank ± SD	Postoperative Mean rank ± SD	*P*	Total Mean rank ± SD	*P*
LSCP	1.42 ± 1.02	0.62 ± 0.52	0.001	-0.62 ± 0.52	0.65
SSLF	1.31 ± 1.09	0.56 ± 0.55	0.021	-0.56 ± 0.55	

(**Tables 5,6 and Figure 2**)

DISCUSSION

Surgeries used to repair apical prolapse focus on correcting the vaginal anatomy to restore the normal function of the bladder and intestines. Various surgeries have been reported so far for the treatment of apical prolapse[11], with abdominal and vaginal approaches. The abdominal surgeries can be either open, laparoscopic, or robotic. SSLF is a vaginal surgery, while LSCP is an abdominal method; each of these methods has its advantages and disadvantages. The present study aimed to evaluate the effectiveness and complications of these two surgical methods.

SSLF is a surgical method, commonly used since 1982.[12] With technological advances in today's world, it has become easier to implement this method. The advantages of this method include the short duration of surgery, lack of need for general anesthesia, simultaneous repair of defects in other vaginal compartments, and low morbidity after surgery. On the other hand, the disadvantages of this method include its ineffectiveness in orthopedic deformities, impossibility of simultaneous surgery of intraabdominal pathologies, and disorientation of vaginal alignment after surgery. SSLF is usually performed via the posterior approach. In a systematic review, the success rate of this method was reported to be 84.6%, the recurrence rate of apical prolapse was

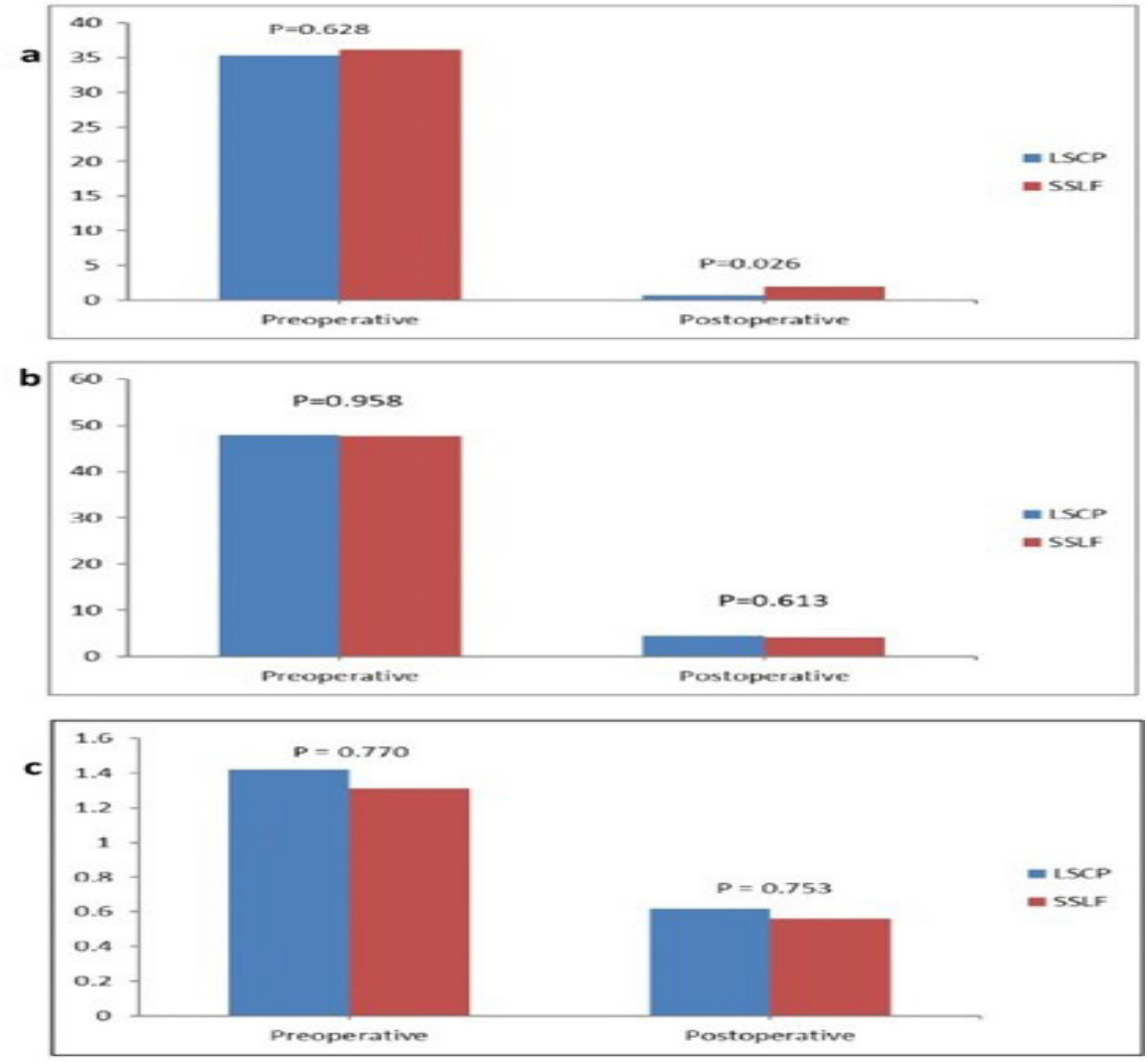

Figure 2. (a) The mean PFIQ-7 total scores before and after the surgery compared between two treatment groups, **(b)**The mean PFDI-20 total scores before and after surgery compared between two treatment groups, **(c)** The mean PISQ-12 scores before and after surgery compared between two treatment groups

5.3%, and the recurrence rate of anterior compartment prolapse was 18.3%.[13] Various studies have shown the convenience and effectiveness of the anterior approach for SSLF.[14,15,16] The anterior approach was selected for SSLF in the present study.

Open abdominal sacrocolpopexy (ASC) has been employed since 1962 and modified over the years. 16This surgery was performed with a laparoscopic approach in 1994. The advantages of laparoscopy include less intraoperative bleeding, faster postoperative recovery, and high effectiveness.[10] Conversely, the disadvantages of the abdominal method include the risk of lumbosacral osteomyelitis and mesh erosion to the vagina, bladder, rectum, and colon.[17] More, in the abdominal approach, if vaginal vault prolapse is repaired alone and defects of other compartments are not corrected, cystocele and rectocele are likely to occur in one-third of patients after surgery, leading to dissatisfaction and need for reoperation.[18]

In a review study by Lee et al. the success rate of laparoscopic and robotic approaches was reported to be 91%, with a conversion rate of 3%.[19] There are many studies comparing the two methods of open ASC with SSLF. In this regard, Benson et al., in a prospective RCT, reported that ASC is superior to bilateral SSLF in repairing apical prolapse.[20] Moreover, Maher et al., in a prospective RCT, indicated that the two methods of open and vaginal abdominal surgeries were highly effective in the treatment of apical prolapse. However, the patients in the abdominal surgery group underwent longer surgeries and took longer to return to daily activities.[21] A systematic review revealed that the effectiveness of abdominal and vaginal surgeries was not significantly different in terms of the improvement of prolapse symptoms. However, the recurrence rate of vault prolapse, dyspareunia, and de novo stress urinary incontinence were lower in the ASC group, while the durations of surgery and recovery were longer, and the costs were higher.[22]

Today, use of LSCP is common throughout the world, and various studies have compared it with the open method. Coolen et al conducted a study to compare these two methods.[23] According to their results, the objective success rates in the laparoscopic and open methods were 83.8% and 89.2%, respectively, and the subjective success rates were 71% and 74%, respectively. Moreover, in a study by Freeman et al., the recovery rates of the open and laparoscopic groups were 90% and 80%, respectively.[24] In addition, the amount of intraoperative bleeding, length of hospitalization, and postoperative pain were lower in the laparoscopic group.

The number of vaginal surgeries with synthetic meshes for vaginal apical prolapse has reduced in recent years due to the warnings of the United States Food and Drug Administration (FDA) about the use of mesh in vaginal and laparoscopic surgeries.[25] One of the advantages of the present study is that two surgical methods of LSCP (with meshes) and SSLF (without meshes) were compared, which has been less discussed in the literature. In this regard, a retrospective study by Marcickiewicz examined 111 patients with apical prolapse after hysterectomy, undergoing LSCP (n = 60) or SSLF (n=51).[26] The surgery duration in the SSLF group was significantly shorter than the LSCP group (62 vs. 129 minutes). Three patients in the laparoscopic group underwent open surgery (one due to bleeding, one due to colon injury, and one due to severe adhesions). The mean length of hospital stay was almost equal in the two groups (4 vs. 3.7 days). The subjective success in the LSCP and SSLF groups was 78% and 82%, respectively. The recurrence of vault prolapse was not observed in any of the groups, whereas cystocele was observed in 25% and 27% of patients in the LSCP and SSLF groups, respectively. More, 6% and 8% of patients in the LSCP and SSLF groups were symptomatic, respectively.[26] According to our results, the two surgical methods were similar in terms of efficacy. However, complications were significantly fewer in the LSCP group, compared to the SSLF group.

A major limitation of this study was that it was conducted in one surgical center, and the number of participants was limited; therefore, further multicenter studies with a larger sample size are recommended in the future. More, longer follow-ups are required to confirm the results. Finally, LSCP and SSLF were not compared in terms of cost-effectiveness.

CONCLUSIONS

Treatment of vaginal apical prolapse is a controversial clinical issue, and the best surgical method is still subject to controversy. According to the results, LSCP and SSLF are both effective methods for the treatment of apical prolapse; however, the laparoscopic approach seems to cause less complications. Due to technological advances in laparoscopy, it seems that this method can replace conventional methods.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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