# Short-term outcomes of patients undergoing laparoscopic sacrocolpopexy without mesh for the treatment of pelvic organ prolapse with apical compartment defect

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**Abstract.** The present study aimed to investigate the clinical efficacy and safety of laparoscopic sacrocolpopexy (LSC) without mesh in the treatment of female pelvic organ prolapse (POP) with an apical compartment defect (a-POP). For this purpose, a total of 24 patients with POP [POP quantification (POP-Q) ≥II] who underwent LSC without mesh between January, 2019 and August, 2020 were analyze retrospectively. The duration of the surgery, intraoperative blood loss, post-operative hospital stay, catheter removal time, post-operative pain and post-operative complications were recorded and evaluated. The changes in the POP-Q scores at 3 months post-surgery were then analyzed. The pelvic floor distress inventory short form 20 (PFDI-20) was used to evaluate the post-operative systemic improvement and subjective satisfaction rate of the patients. All surgeries were successfully completed. The mean duration of the surgery 135.3±31.5 min. The mean loss of blood was 22.9±15.1 ml. No injuries to the great vessels, nerves, rectum, urethra or bladder occurred. The catheter was retained for 2 days and all patients were able to micturate following extubation. The mean observation time following surgery in hospital was 7 days. The average follow-up time was 9.4±4.0 months. According to POP-Q scores, the anatomic cure rate of the LSC without mesh was 100%. The PFDI-20 scores decreased from 90.6±24.6 to 55.8±18.5 (P<0.0001), and the subjective satisfaction rate was 100% (24/24).

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## Introduction

Pelvic organ prolapse (POP) is a common dysfunction of the pelvic floor and >40% of women >40 years of age have POP (1). This condition frequently impairs the quality of life of those affected. For several women, the overall lifetime risk of prolapse surgery is estimated to be 12.6%, and the overall lifetime risk for undergoing surgery to address either stress urinary incontinence or POP is 20.5% in the United States (2,3).

An internationally accepted description of the pathophysiology of POP has been proposed by DeLancey (4): Level 1 refers to the apical part of the vagina, which receives its strength from the cardinal and uterosacral ligaments. POP with an apical compartment defect (a-POP) is a level 1 defect. There are several treatment options for a-POP, including pelvic floor muscle training, pessaries and surgery. Sacrocolpopexy (SC) remains the gold standard for the surgical treatment of a-POP. SC is performed to support DeLancey's level 1 in patients with POP.

Laparoscopic (L)SC is frequently performed, as it is associated with a lower blood loss and a more rapid recovery time, as compared with the open abdominal approach (5). However, mesh-related complications associated with SC, including mesh erosion and mesh exposure (4.2%) are more severe than other complications, including sacral hemorrhage, ileus (2.7%) and occasional discitis (6). It has been reported that LSC performed without mesh may help avoid these mesh-related complications (7). In the present study, classic LSC was modified using ETHIBOND sutures instead of mesh. The present study was a single-center, retrospective study and aimed to determine the peri-operative complications, early post-operative complications and short-term outcomes of patients undergoing LSC without mesh performed by experienced urogynecology specialists.

## Patients and methods

*General information.* All patients were followed-up post-surgery. The present study was approved by the Medical Ethics Committee of Jinhua People's Hospital (approval no. IBR-2018012-R) and written informed consent

was provided by all patients prior to the study initiation. A total of 24 patients with symptomatic a-POP [POP quantification (POP-Q)] (8) stages II-III were admitted to the Department of Gynecology at Jinhua People's Hospital, Jinhua, China, between January, 2019 and August, 2020. The mean age of the patients was 61.6±7.5 years (age range, 48-76 years). All patients were treated with LSC without mesh.

*Inclusion and exclusion criteria*. The inclusion criteria were as follows: Patients who met the diagnostic criteria for symptomatic a-POP (C >1) (9), patients who did not suffer from severe prolapse of the anterior and posterior vaginal wall (Ba <0; Bp <0) and patients aged 45-75 years. The exclusion criteria were as follows: i) Patients who could not tolerate the surgery; ii) patients with severe coagulation disorders; iii) patients with severe heart, liver, kidney or other diseases; and iv) patients with mental disorders or cerebrovascular diseases leading to a decline in the quality of life.

*Surgical methods*. Modified LSC without mesh was performed by two urogynecology specialists. The instruments used for surgery included the laparoscopic instrument PanOport (Hangzhou Kangji Medical Instrument Co., Ltd.). All patients were administered prophylactic antibiotics (intravenous cefuroxime, 1.5 g; Medochemie Ltd.) 30 min prior to surgery and 2 days after. All patients were administered general anesthesia by the anesthesiologist. The patients were placed in the lithotomy position. The surgical steps were as follows: i) Modified LSC without mesh was performed with four trocars, one for the scope and three side operation trocars; ii) hysterectomy was performed in the usual manner using the laparoscopic approach. The vaginal cuff was closed using 1-0 vicryl lines, with continuous suture. Vesicovaginal fascia and rectovaginal fascia dissections were not performed; iii) an incision was made in the peritoneum between the right-sided uterosacral ligament and ureter to prevent ureter injury or kinking. The right-sided ureter was dissociated from the uterosacral ligament and the presacral region was exposed using a ultrasonic scalpel (FEN11; Johnson & Johnson); iv) the retroperitoneal tunnel was established from the apex of the vagina to the anterior sacral region using a ultrasonic scalpel; v) An ETHIBOND EXCEL Polybutylate-coated braided Polyester Suture [W4843; Johnson and Johnson (Shanghai) Medical devices Co., Ltd.] was used to anchor the vaginal cuff and the anterior longitudinal ligament of the sacral promontory in a tension-free manner. The ETHIBOND suture was placed in a running fashion through the uterosacral ligament; and vi) the peritoneum was closed using 2-0 vicryl lines.

*Outcome measures*. The following information was obtained from inpatient and outpatient medical records: Patient characteristics (age, parity and body mass index), peri-operative data (duration of surgery, estimated blood loss and conversion to laparotomy) and short-term postoperative complications (any surgical complications during hospitalization, and at 1- and 3-month follow-up visits). Primary outcomes included complications, duration of surgery and prolapse recurrence. Complications were defined as ≥1 of the following events occurring during surgery or within the first 6 weeks following surgery: Bowel injury, bladder injury, conversion to laparotomy, ileus, infection, sacral hemorrhage or hospital readmission. These complications were identified from the Clavien-Dindo classification system (10-12). Prolapse recurrence was defined as re-treatment (pessary or surgery) or any post-operative POP-Q point at or beyond the hymen (≥0), occurring at any point in the post-operative follow-up period (12,13). The definition of surgical success was POP-Q point C ≤-6 cm.

The present study also evaluated the change in physical prolapse and its effect on the quality of life of patients. The POP-Q score was used to evaluate POP prior to surgery and at 3 months post-surgery. The pelvic floor distress inventory short form 20 (PFDI-20) was used to evaluate the effects of POP on the quality of life of patients prior to surgery and at 3 months post-surgery (9,14).

*Statistical analysis*. Statistical analysis was performed using SPSS 19 software (IBM Corp.). A paired Student's t-test was used to compare the pre- and post-operative POP-Q and PFDI-20 scores.

## Results

In the present study, 24 patients underwent modified LSC without mesh. All patients attended the clinical follow-up examinations, and POP-Q scores were determined. In addition, all patients completed the questionnaires at the 3-month follow-up. The baseline characteristics of the patients are presented in Table I. The mean age of the patients was 61.6±7.5 years (age range, 48-76 years), and the mean body mass index was 24.5±3.1 kg/m$^2$ (range, 19.5-33.4 kg/m$^2$). All 24 patients were parous, and the mean parity was 2.5±1.4 (range, 1-7). Only 4 patients (16.7%) had a history of diabetes, while 12 patients had a history of hypertension. The mean follow-up period was 9.4±4.0 months (range, 3-19 months).

The peri-operative data are presented in Table II. Hysterectomy was performed in all cases, 16 patients underwent bilateral salpingo-oophorectomy and 8 patients underwent bilateral salpingectomy. The mean duration of the surgery was 135.3±31.5 min, the mean loss of blood was 22.9±15.1 ml, the average length of hospital stay was 7±1.0 days and the mean drainage tube removal time was 1.9±0.28 days.

The complications associated with surgery are presented in Table III. *De novo* stress urinary incontinence (SUI) occurred in 4 patients (16.7%) post-surgery; however, the symptoms were moderate, and no patient underwent urethral sling surgery. A total of 2 patients suffered from mild pelvic pain following surgery, which was relieved following magnetic therapy. Common peri-operative complications that did not occur in the present study were vaginal injuries, bowel injuries, bladder injuries, ileus, sacral hemorrhage and discitis (6).

In addition, comparisons were made between the pre- and post-operative objective and subjective outcome measures for patients at the 3-month follow-up (Table IV). A significant improvement was observed in the apical compartments (point C). There were no apical failures (point C), and no patients presented anterior or posterior POP-Q points (Ba or Bp) >0. In addition, the PFDI-20 scores significantly improved following surgery. All 24 patients met both the objective and subjective success criteria.

Table I. Patient baseline characteristics.

| Patient characteristics (n=24) | Mean ± SD (range) or n (%) |
|---|---|
| Age, year(s), mean (range) | 61.6±7.5 (48-76) |
| BMI, kg/m$^2$, mean (range) | 24.5±3.1 (19.5-33.4) |
| Parity, mean (range) | 2.5±1.4 (1-7) |
| History of POP surgery | 0 |
| Presence of diabetes | 4 (16.7%) |
| Presence of hypertension | 12 (50%) |
| Follow-up time (months) | 9.4±4.0 (3-19) |

BMI, body mass index; POP, pelvic organ prolapse.

Table II. Characteristics of the surgery.

| Characteristics | Mean ± SD (range) or n (%) |
|---|---|
| Duration of surgery (min) | 135.3±31.5 (67-185) |
| Hysterectomy | 24 |
| Bilateral salpingo-oophorectomy | 16 |
| Bilateral salpingectomy | 8 |
| Estimated blood loss (ml) | 22.9±15.1 (5-50) |
| Length of stay, day(s) | 7.0±1.0 (5-9) |
| Drainage tube removal time, day(s) | 1.9±0.28 (1-2) |

Table III. Surgical complications.

| Variable | n (%) |
|---|---|
| Conversion to open surgery | 0 |
| Bowel injury | 0 |
| Bladder injury | 0 |
| Vaginal injury | 0 |
| Pain | 2 (8.3%) |
| Ileus | 0 |
| Sacral hemorrhage | 0 |
| Discitis | 0 |
| *De novo* stress urinary incontinence | 4 (16.7%) |
| Hospital readmission | 0 |
| Prolapse recurrence | 0 |

Table IV. Changes in the POP-Q/PFDI-20 scores.

| Variable | Pre-operative | Post-operative | P-value |
|---|---|---|---|
| Point B a, cm | -0.4±0.7 | -1.6±0.5 | <0.0001 |
| Point B p, cm | -1.3±0.5 | -1.7±0.5 | 0.001 |
| Point C, cm | 2.5±1.3 | -7.5±0.7 | <0.0001 |
| a-POP-Q stage 0 | 0 | 24 | |
| a-POP-Q stage I | 0 | 0 | |
| a-POP-Q stage II | 2 | 0 | |
| a-POP-Q stage III | 22 | 0 | |
| a-POP-Q stage IV | 0 | 0 | |
| PFDI-20 | 90.6±24.6 | 55.8±18.5 | <0.0001 |

a-POP-Q, female pelvic organ prolapse with an apical compartment defect quantitative; PFDI-20, pelvic floor distress inventory short form 20.

## Discussion

The results of the present study suggested that LSC without mesh is an effective treatment option for a-POP, as it avoids mesh-related complications and improves the quality of life of those affected. To the best of our knowledge, the present study is the first to report the short-term outcomes of 24 patients with a-POP who underwent LSC without mesh. Notably, all patients were did not suffer from severe prolapse of the anterior and posterior vaginal wall (Ba <0; Bp <0).

The safety of the mesh remains controversial, since the US Food and drug administration's (FDA) ban on selling and distributing surgical mesh intended for the transvaginal repair of anterior compartment prolapse (15). Severe complications associated with LSC mesh include erosion, mesh exposure, sacral hemorrhage, ileus and discitis (6). In the present study, a 3-month follow-up period demonstrated that peri-operative complications were less common, in comparison with complications reported in a previous study (15.2-17.0%) (16). Notably, mesh-related complications were not observed in the present study. However, suture erosion and exposure should be considered. During surgery, it is essential that the suture does not fully penetrate the vaginal mucosa (6). Suture erosion and exposure were not observed in the present study, and the incidence of mesh and suture complications was 0.7-9.2% in other studies (6,16).

In the present study, *de novo* SUI following surgery occurred in 4 patients (16.7%), while the current reported incidence of *de novo* SUI ranges from 7.5-23.0% (17). From this group, no patients underwent urethral sling surgery as their symptoms were not severe enough. The most frequent peri-operative complications reported in previous studies (10-12) were not observed in the present study, including vaginal injuries, bowel injuries, bladder injuries, ileus, sacral hemorrhage and discitis (6). This surgery had lower blood loss (22.9±15.1 vs. 51.0±40.2 ml) and a shorter duration of surgery (135.3±31.5 vs. 146.54±25.90 min) as compared with robotic-assisted LSC. The short-term peri-operative complications included two cases (8.3%) of slight pelvic pain, which is higher than that reported in a previous study (0%) (18). However, both cases were relieved following magnetic therapy. In the present study, the mean improvements in PFDI-20 scores were similar to those reported in the study by Culligan *et al* (14).

The average duration of hospital stay was 7 days. In future studies, the authors, aim to decrease the length of hospital stay following the performance of day surgery. Taken together, these results suggested that LSC without mesh is an effective and safe treatment option for patients with a-POP, without severe prolapse of anterior and posterior vaginal wall, particularly when ovarian cysts need to be solved at the same time. For patients with POP

at stages III and IV, who often suffer from severe prolapse of the anterior and posterior vaginal wall, transvaginal surgery would perhaps be the optimal treatment option instead.

The present study is not without limitations. Firstly, it was a retrospective study and not a randomized control trial. Furthermore, the sample size was very small as only 24 patients were assessed. Furthermore, a short follow-up period of only 3 months was implemented. Thus, further prospective studies are required to focus on overcoming these limitations.

In conclusion, the present study demonstrates that LSC without mesh is an effective and safe treatment option for patients with a-POP, with satisfactory subjective and objective outcomes at the 3-months follow-up. Notably, this technique avoids surgical mesh-related complications.

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**Availability of data and materials**

All data generated or analyzed during this study are included in this published article.

**Authors' contributions**

PX was involved in the design of the study, in data collection, the writing of the manuscript and in surgical procedures. SL was involved in data collection and in the writing of the manuscript. EH was involved in the follow-up of the patient (assessment of the questionnaire and gynecological examination). HX, JL and BY performed surgical procedures. LM was involved in the follow-up of the patient (assessment of the questionnaire and gynecological examination). YS provided theoretical guidance and also assisted in data collection and in the reviewing of the manuscript. PX and BY confirm the authenticity of all the raw data. All authors have read and approved the final manuscript.

**Ethics approval and consent to participate**

The present study was approved by the Medical Ethics Committee of Jinhua People's Hospital (with the approval no. IBR-2018012-R) and written informed consent was provided by all patients prior to the study initiation.

**Patient consent for publication**

Not applicable.

**Competing interests**

The authors declare that they have no competing interests.

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