

CLINICAL ARTICLE

Sacrocolpopexy after sub-total hysterectomy vs. sacral hysteropexy for advanced urogenital prolapse: A propensity-matched study

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Abstract

Objective: To compare objective and subjective outcomes of laparoscopic sacral colpopexy with supracervical hysterectomy (L-SCP) and robotic sacral hysteropexy (R-SHP).

Methods: This is a multicenter retrospective propensity score matched study. In the period between January 2014 and December 2018, we enrolled 161 patients with apical prolapse stage 2 or above, alone or with multicompartiment descensus.

Results: After propensity-match analysis, there were 44 women for each group. Patients of the two groups had similar preoperative characteristics. No difference was found in terms of estimated blood loss, hospital stay, operative time, and intraoperative or postoperative complications. Subjective success rate, 12 months after surgery, was statistically better in the L-SCP group ($P=0.034$): 81.8% and 97.8% women had Patient Global Impression of Improvement scores less than 3, in R-SHP and L-SCP, respectively. The objective cure rate was high in both groups without any significant differences in recurrence rate ($P=0.266$).

Conclusion: Both procedures are safe and effective in pelvic organ prolapse treatment. Patients who no longer desire uterine preservation could be encouraged to consider L-SCP. R-SHP is an alternative in women who are strongly motivated to preserve their uterus in the absence of abnormal uterine findings.

KEYWORDS

Hysteropexy, mini-invasive surgery, pelvic organ prolapse, robotic surgery, Sacropexy, urogynecology

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1 | INTRODUCTION

Defective anatomical pelvic support causes pelvic organ prolapse (POP) that can affect the anterior, middle (apical vaginal wall), and posterior compartments.¹ Currently, the reference standard surgical procedure for apical prolapse correction is considered laparoscopic sacral colpopexy;² it is often associated with concurrent total or subtotal hysterectomy. Subtotal hysterectomy is preferred to decrease vaginal mesh erosion.³ Traditionally, regardless of the surgical technique used, hysterectomy has often been associated with surgical pelvic support correction because the uterus is supposed to play a passive role in the development of prolapse and relapse.⁴ However, it is estimated that about one-third of hysterectomies are performed on a healthy uterus only for POP repair.⁵ For this reason, there is growing interest in uterine-sparing and hysteropexy procedures in the case of healthy uterus. Literature has not clarified whether concurrent hysterectomy during the surgical procedure for POP improves postoperative outcomes and decreases the risk of recurrence.

The aim of this study was to compare the long-term anatomical and subjective outcomes of two different approaches through a propensity-matched analysis: laparoscopic sacral colpopexy with supracervical hysterectomy (L-SCP) versus robotic sacral hysteropexy (R-SHP).

2 | MATERIALS AND METHODS

This is a multicenter study conducted at the Urological Referral Center of the University of Padua and at the Female Pelvic Medicine and Reconstructive Surgery Center of the Fondazione Policlinico Universitario Agostino Gemelli IRCCS of Rome, including patients with apical prolapse Pelvic Organ Prolapse Quantification (POP-Q) System stage of 2 or greater¹ alone or in association with anterior and/or posterior descensus who underwent R-SHP at the Padua center (cases) and L-SCP at the Rome center (controls).

The primary objective of the study was to analyze the subjective outcomes in the two groups. Secondary outcomes included the analysis of long-term anatomical recurrence rates and perioperative data.

The research was authorized by Ethical Committee of Fondazione Policlinico Universitario Agostino Gemelli IRCCS—Università Cattolica del Sacro Cuore (Protocol ID: 3880, Prot. N. 0029006/20). Patients were selected from the two hospitals' databases among patients submitted to the described surgical procedures between January 2014 and December 2019.

Inclusion criteria were: patients with POP-Q stage of 2 or above for the apical compartment. The exclusion criteria were age older than 80 years, previous total hysterectomy, uterine cervical dysplasia or endometrial hyperplasia, uterine fibromatosis, personal or familial history of hereditary syndrome with high risk of endometrial or ovarian cancer, anesthesiologic contraindications for minimally invasive approach, and previous major open transabdominal surgery.

In the final analysis, patients who did not complete the follow-up examinations were not included. All the procedures were performed by expert urogynecologic surgeons (FDM, AE, GC, GP). Patients were counseled about the two surgical procedures and the surgical selection was based on women's preference.

In both groups, additional procedures were performed when indicated, included bilateral salpingectomy or salpingo-oophorectomy, and placement of a mid-urethral sling (MUS). All patients of the L-SCP group were submitted to concomitant bilateral salpingectomy; bilateral salpingo-oophorectomy was proposed to all postmenopausal women. In patients with concomitant symptomatic stress urinary incontinence (SUI), we recommended the option of postponing MUS placement and performing a delayed (two-step) continence procedure if incontinence persisted. The informed decision was balanced on the risks and benefits of combined prolapse surgery with a concurrent anti-incontinence procedure.

All patients signed the written consent to undergo the described procedure and to permit data use. All procedures performed in studies involving human participants were under the ethical standards of the institutional and national research committee and in compliance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

A urogynecologist from each team evaluated the patients preoperatively, obtaining a careful medical history and performing standardized urogynecologic examinations, urodynamic tests, cervical smear test, and pelvic ultrasound evaluation. Prolapse was classified in accordance with the POP-Q System.¹

Operative time was defined as the interval between the skin incision and its closure. Intraoperative and postoperative complications were defined as adverse events occurring during surgery or within the first 4 postoperative weeks according to Dindo' classification.⁶ Follow-up visits were performed at 1, 6, and 12 months after the surgery and then yearly, until 60 months after the surgery, by a urogynecologist of each group. Anatomical surgical failure was described as POP stage of 2 or greater in any compartment.

At the 12-month follow up, patients completed validated questionnaires: Patient Global Impression of Improvement (PGI-I),⁷ to measure patients' satisfaction rate after surgery (value <3 represents improved postoperative condition compared with how it was before the surgery), and International Consultation on Incontinence Questionnaire—Short form (ICQ-SF)⁸ (about urinary dysfunction, a score ≥ 6 is a pathologic value); sexually active women also completed the Female Sexual Distress Scale (FSDS)⁹ (about sexual function, a score of ≥ 11 is a pathologic value).

The two surgical teams performed all procedures using a standard technique in accordance with previously published experiences.¹⁰⁻¹³

In the hysteropexy group, we bilaterally fenestrated the right broad ligament at the level of the cervico-uterine junction in an avascular space lateral to the uterine artery to pass the cephalad part of the anterior mesh, whereas in the supracervical hysterectomy group, a standard subtotal hysterectomy was performed and the specimen was placed into an endobag and retrieved through the umbilicus with extracorporeal morcellation using a cold knife.

Briefly, in both groups, two adequately shaped polypropylene type 1 meshes, fixed with non-absorbable sutures, were used to correct the POP. The anterior mesh was fixed to the longitudinal vertebral ligament at L5–S1 level with 1–0 non-absorbable suture on a non-cutting needle.

Because of the non-randomized nature of the study design and the possible allocation biases arising from the retrospective comparison between the two groups, a propensity-matched analysis was carried out to decrease biases arising from different covariates. It was developed through a multivariable logistic regression model. We included in the model age, body mass index (calculated as weight in kilograms divided by the square of height in meters), the preoperative stage of apical prolapse. Patients submitted to R-SHP surgery were matched 1:1 with patients undergoing L-SCP using a caliper width of 0.1 or less standard deviations of the logit odds of the estimated propensity score. Univariate analysis was carried out to verify any difference between the groups. The χ^2 analysis or Fisher exact test were used, when appropriate, for categorical variables and the Student *t*-test and Mann–Whitney *U*-test, when appropriate, for continuous variables. Differences between the groups were considered statistically significant at a *P*-value less than 0.05 (95% confidence interval). The NCSS statistical software program, version 11.0 (NCSS Statistical Software, Kaysville, UT, USA), was used.

3 | RESULTS

Between January 2014 and December 2019, 161 patients were enrolled. Forty-eight patients were excluded: 25 because of age greater than 80 years, 14 for previous longitudinal major abdominal surgery, and four because they had not completed all the indicated follow up. A total of 118 patients were eligible for the propensity analysis (49 in the R-SHP group and 69 in the L-SCP group). After propensity-match analysis, there were 44 women for each group

(Figure 1). Patients' characteristics and perioperative data are summarized in Tables 1 and 2.

Only one intraoperative complication was recorded: a minor bladder injury that was repaired intraoperatively, in an R-SHP group. All procedures were completed endoscopically, with no need for conversion to laparotomy. Among patients with SUI, 2/7 (28.6%) in the R-SHP group and 6/21 (28.6%) in the L-SCP group underwent a concomitant incontinence procedure with trans-obturator tape.

There was no statistical difference between the two groups in terms of postoperative complications (9.1% in R-SHP versus 2.3% in L-SCP, *P*=0.167). Specifically, in the R-SHP group, four grade I complications (three cases of postoperative fever treated with paracetamol and one urinary retention, which resolved spontaneously) were recorded. Conversely, in the L-SCP cohort, we observed one grade II complication (one urinary infection treated with antibiotics). No mesh erosion occurred in either group.

There were no reports of de novo SUI. The percentage of patients affected by SUI decreased significantly in both groups after the treatment at the 12-month follow up: incidence (compared with preoperative incidence) decreased from 47.7% to 27.3% in the L-SCP group (*P*=0.047) and from 15.9% to 0% in the R-SHP group (*P*=0.005).

Patient's reported outcome data, 12 months after the surgery, was statistically better in the L-SCP group (*P*=0.034): 36 (81.8%) and 43 (97.8%) women had PGI-I scores less than 3, in R-SHP and L-SCP, respectively. No significant differences regarding postoperative urinary function at 12 months, evaluated through ICQ-SF, were recorded. Forty-four women (21 in R-SHP group and 23 in L-SCP, *P*=0.831) were sexually active at 12 months after the intervention but only four patients complained of an FSDS score of 11 or above, without any statistical difference between the two groups (Table 3).

During the follow up, we recorded seven cases of relapse (8%): two in the L-SCP group and five in the R-SHP (*P*=0.393) (Table 4; Figure 2). No patient needed reoperation. No women in the R-SHP group experienced postmenopausal bleeding during the follow up.

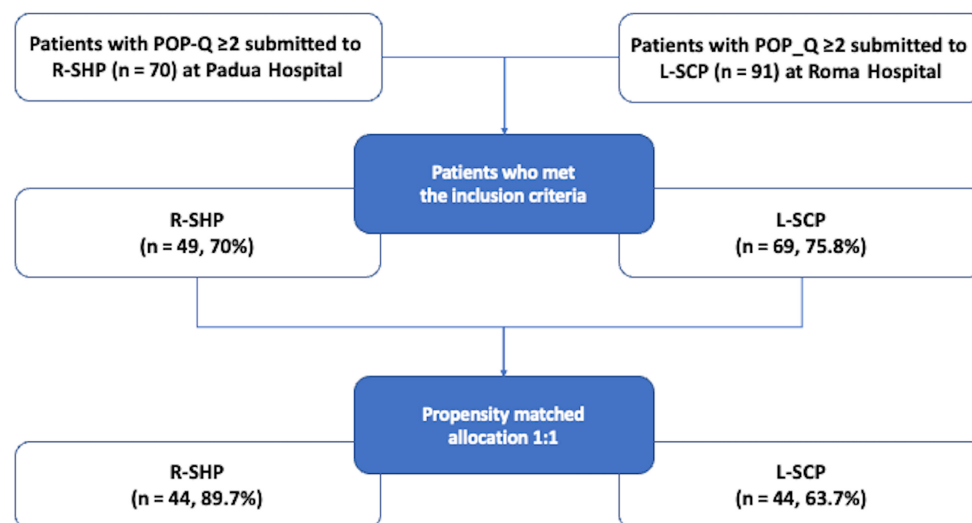


FIGURE 1 Flow diagram of propensity-match analysis.

TABLE 1 Baseline patient characteristics.^a

Variables	R-SHP (cases)	L-SCP (controls)	P-value
All cases	44	44	-
Age, y	66 (48-77)	64 (41-71)	0.202
Body mass index ^b	27 (19.3-33.6)	26 (19.0-31.2)	0.352
No. of vaginal deliveries	2 (0-3)	2 (1-4)	0.414
Menopausal	38 (86.4)	37 (84.1)	0.752
Prolapse at presentation (POP-Q stage):			
Anterior	2 (0-4)	2 (0-4)	0.886
> 2	16 (36.3)	17 (38.6)	0.826
Apical	2 (0-4)	2 (0-4)	0.599
> 2	10 (22.7)	13 (29.5)	0.469
Posterior	1 (0-3)	1 (0-3)	0.09
> 2	1 (2.2)	3 (6.8)	0.308
Stress urinary incontinence	7 (15.9)	21 (47.7)	0.002
Previous operations for pelvic floor dysfunction	4 (9.0)	6 (13.6)	0.737
Previous pelvic surgery	8 (18.1)	6 (13.6)	0.770

Abbreviations: L-SCP, sub-total hysterectomy + sacrocolpopexy; POP-Q, Pelvic Organ Prolapse Quantification system; R-SHP, sacral hysteropexy.

^aData are presented as median (interquartile range) or as number (percentage).

^bBody mass index is calculated as weight in kilograms divided by the square of height in meters.

TABLE 2 Perioperative data.^a

Variables	R-SHP (cases)	L-SCP (controls)	P-value
Operative time, min	175 (75-275)	180 (110-264)	0.117
Estimated blood loss, mL	30 (0-200)	30 (0-200)	0.326
Hospital stay, day	2 (1-6)	2 (1-7)	0.101
Concomitant incontinence procedure	2 (4.5%)	6 (13.6%)	0.266
Bilateral salpingo-oophorectomy	40 (90.1)	38 (86.4)	0.450
Intraoperative complications	1 (2.3%)	0	1
Postoperative complications ^b	4 (9.1%)	1 (2.3%)	0.343

Abbreviations: L-SCP, sub-total hysterectomy + sacrocolpopexy; R-SHP, sacral hysteropexy.

^aData are presented as median (interquartile range) or as number (percentage).

^bNo major postoperative complications were recorded (≥ 3 according to Clavien-Dindo scale).

TABLE 3 Postoperative outcomes.^a

Variables	R-SHP (cases)	L-SCP (controls)	P-value
FSDS ≥ 11			
Yes	2 (10.5)	2 (8.7)	0.667
No	19 (90.5)	21 (91.3)	
ICIQ SF ≥ 6			
Yes	3 (6.8)	10 (22.7)	0.071
No	41 (93.2)	34 (77.3)	
Subjective satisfaction ^b			
Yes	36 (81.8)	43 (97.8)	0.034
No	8 (18.2)	1 (2.2)	
Stress urinary incontinence	0	12 (27.3)	0.000

Abbreviations: FSDS, Female Sexual Distress Scale (≥ 11 is pathologic value); ICIQ-SF, Incontinence Questionnaire—Short Form (≥ 6 is pathologic value); L-SCP, sub-total hysterectomy + sacrocolpopexy; R-SHP, sacral hysteropexy.

^aData are presented as number (percentage).

^bMeasured using the Patient Global Impression of Improvement (< 3).

TABLE 4 Pattern of recurrent prolapse according to surgical approach.^a

Variables	Total	R-SHP (cases)	L-SCP (controls)	P-value
All cases	88	44	44	-
Recurrences ^b				
Anterior	5 (5.7)	3 (6.8)	2 (4.5)	0.393
Apical	1 (1.1)	1 (2.2)	-	0.314
Posterior	1 (1.1)	1 (2.2)	-	0.314

Abbreviations: L-SCP, sub-total hysterectomy + sacrocolpopexy; R-SHP, sacral hysteropexy.

^aData are presented as number (percentage).

^bPelvic Organ Prolapse Quantification system score ≥ 2 .

4 | DISCUSSION

Literature lacks high-level evidence-based data on the potential benefits of uterine preservation compared with hysterectomy during surgery for prolapse correction.

To our knowledge, this is the first propensity-matched study that compared R-SHP and L-SCP in a large cohort of women. Our data confirm that R-SHP and L-SCP are both effective and safe methods for prolapse repair.

A recent survey has shown that the number of women candidates for POP surgery who preferred uterine preservation is steadily increasing.¹⁴ Several reasons may explain this preference: the desire to maintain fertility and body image, convictions about the adverse effects on sexual function, and concerns about the risks of hysterectomy.

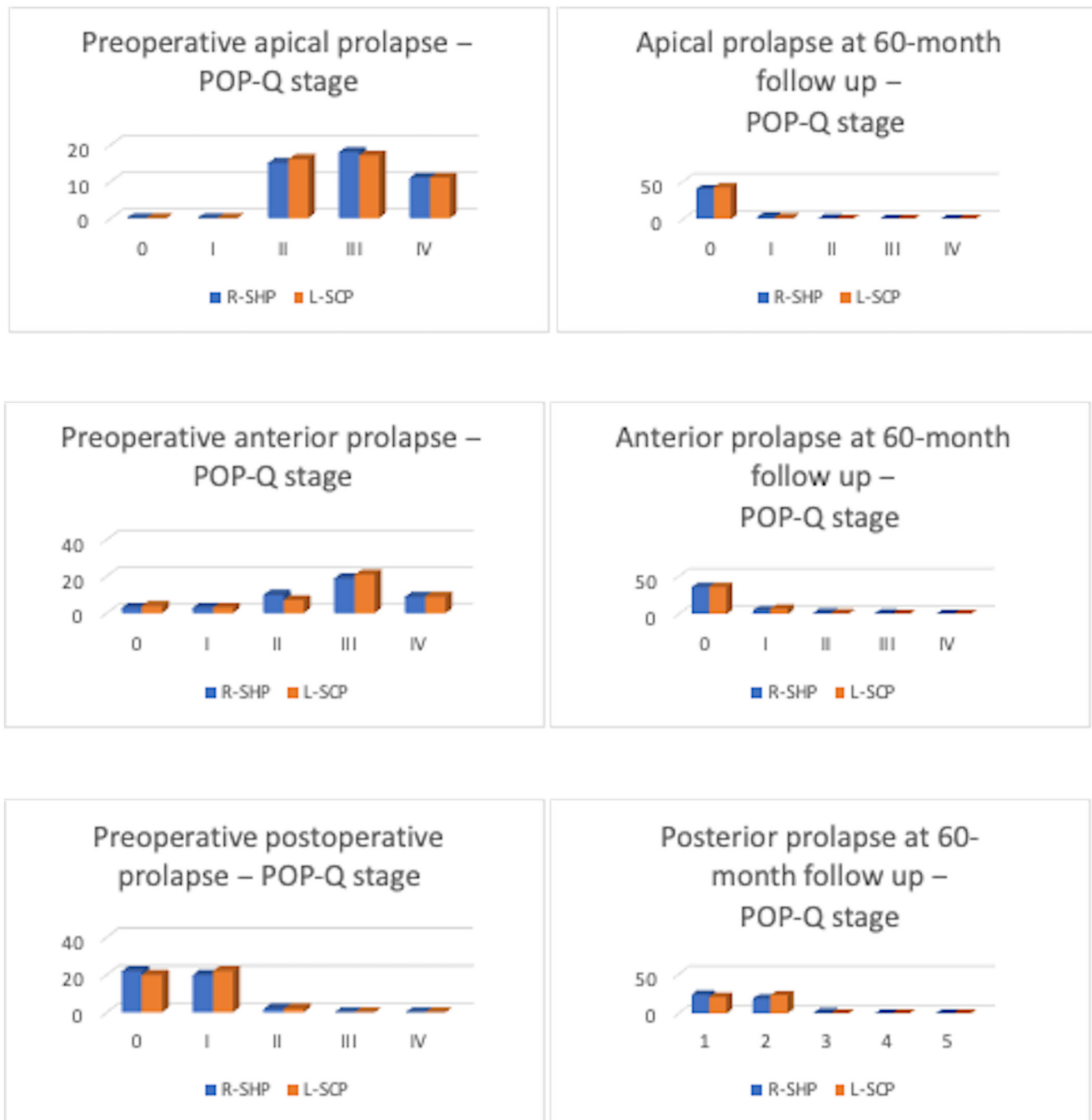


FIGURE 2 Anatomical success rate for anterior, apical, and posterior compartments.

Patients undergoing sacrohysteropexy must continue to monitor the uterus, but the main disadvantage is that the eventual subsequent hysterectomy, in women who have undergone a previous hysteropexy, is more complex and demanding for the surgeon.¹⁵ During preoperative counseling, patients should be informed about this issue.

In our series, no women experienced uterine disorders during the follow up that required reoperation. We highlight that all patients had an extensive evaluation before surgery to exclude uterine disorders.

Surgical outcomes are the most important aspect to consider when counseling before POP surgery. In the literature, controversial

results^{5,13} were found depending on the definition of success after surgery used, but it is currently agreed that patients' subjective satisfaction should be more relevant than anatomical success in urogynecology.¹⁶

In our study, at the 12-month follow up, subjective satisfaction, measured with PGI-I scores greater than 3 at 12 months, was high (more than 80%) in both cohorts, confirming the efficacy of these procedures. According to the study by Gracia et al.⁵ in our cohort the rate of PGI-I scores of 3 or greater was significantly higher in the L-SCP cohort. Anatomical outcomes were highly satisfactory in both groups, confirming the efficacy of these procedures. Our study was

characterized by a longer follow up (60 months) compared with previous studies.^{5,13,17} In the L-SCP group, the success rates for the apical, anterior, and posterior vaginal compartments were 100%, 95.5%, and 100%, respectively; whereas in the R-SHP group, the success rates were 97.8%, 93.5%, and 97.8% for the apical, anterior and posterior vaginal compartments, respectively. These results were not statistically different between the cohorts. For the R-SHP group the recurrence rate slightly, but not significantly, increased. These results overlap with those published by Campagna et al.¹³ but differ from those presented by Garcia et al.⁵ In their prospective observational study, the overall success rate was significantly higher in their laparoscopic subtotal hysterectomy plus cervicopexy group, compared with their laparoscopic sacral hysteropexy group; however, this result could be justified by a small sample size in which 15 cases of laparoscopic sacral hysteropexy were compared with 30 cases of laparoscopic subtotal hysterectomy.⁵

No differences in postoperative urinary and sexual function were reported between the two groups evaluated with standardized questionnaires; indeed, in both groups an improvement of SUI was registered. After counseling, 28.6% of patients with preoperative SUI chose to undergo a concomitant incontinence procedure. All these patients improved their SUI but also 5/5 women in R-SHP and 3/15 in L-SCP improved their incontinence without additional procedures.

Christmann-Schmid et al.¹⁸ showed that more than two-thirds of women with POP and concomitant SUI undergoing sacrocolpopexy can be spared unnecessary subsequent anti-incontinence surgery if a two-step approach is chosen in a well-informed group of patients. A recent Cochrane review suggested that in women with POP and SUI, concomitant placement of MUS probably decreases postoperative SUI and should be discussed at preoperative counseling.¹⁹

In our opinion, the decision should be individualized, balancing risks and benefits of combined abdominal prolapse surgery with concurrent placement of MUS.

The number of patients with stress incontinence was higher in the L-SCP group both before and after the surgery, but without determining a significant difference in the number of patients with a pathological value on the Incontinence Questionnaire.

In contrast to current literature,^{13,20} no difference in operative time was recorded. Gagyor et al.²⁰ reported a median difference between groups of only 5 min. Our median operative time is shorter than reported by other authors. In a recent study, Mach et al.²¹ reported a mean operative time of 197 min for robotic sacropexies. Serror et al.²² compared laparoscopic and robot-assisted sacrocolpopexy and described an inferior strict operative time (median 125 min versus 220 min; $P < 0.001$) in the second group but this time advantage was not maintained when comparing overall operating room time (215 min versus 220 min). They defined "strict operating time" as the time for port insertion plus procedure and excluding the preparation and docking of the robot and "overall operating time" as total time in the operating theater.²² In our study, we considering operating time as the interval between the skin incision and its closure, including docking of the robot.

According to the study by Campagna et al.¹³ no differences in terms of estimated blood loss and hospital stay were shown.

Regarding estimated blood loss, as previously reported, in our technique uterine arteries were closed at their origin, with a reduction of bleeding during the hysterectomy.

Considering perioperative complications, which were similar between the two groups of patients, no major intraoperative or postoperative complications were recorded.

Several studies have shown a lower incidence of mesh exposure in sacrohysteropexy than in sacrocolpopexy with total hysterectomy,²³ but this difference was not found with supracervical hysterectomy.^{3,24,25} In the group of L-SCP, all patients were submitted to subtotal hysterectomy and no case of mesh exposure was recorded in our series, according to published data.⁵

Our data confirm that both techniques had a high success rate, low intraoperative and postoperative complications and low prolapse recurrence rates. We think that women's preferences based on a wide information of all surgical procedures is a key factor to be considered when selecting the type of surgical approach.

This study has several limitations, including a relatively small sample size and the retrospective design of the study. Other limitations might be related to the different learning curves of the two techniques and the multi-surgeon nature of this study.

To promote standardization between the various centers, it would also be useful to compare the vaginal and laparoscopic approaches in the treatment of symptomatic POP, both with preservation and removal of the uterus. Prospective studies are necessary to evaluate the most appropriate surgical approach to POP.

However, its strength lies in the fact that it is the first propensity-matched study comparing R-SHP and L-SCP, using validated questionnaires and objective evaluation and with a long follow up. Obviously, further prospective trials are needed to confirm our results.

In conclusion, our findings demonstrate that both procedures are safe and effective in the treatment of POP. Menopausal patients and perimenopausal patients who no longer desire uterine preservation will be encouraged to consider L-SCP. R-SHP can be offered as an alternative in women who are strongly motivated to preserve the uterus in the absence of abnormal uterine findings at the preoperative evaluation.

AUTHOR CONTRIBUTIONS

GV, AM, GS, AE, and FDM designed the study; MA, GP, GC, FM, and MS collected the data and SR, LD, GV, and MM analyzed the data; GV, MA, AM, GP, FM, MM, and MS wrote the manuscript and GS, AE, FDM, GC, LD, and SR edited it. All authors approved the final manuscript draft.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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