Outcomes of Abdominal and Minimally Invasive Sacrocolpopexy: A Retrospective Cohort Study

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Objective: To compare perioperative and postoperative surgical outcomes between and among open and minimally invasive sacrocolpopexies (MISCs).

Methods: We performed a multicenter retrospective cohort study comparing abdominal sacrocolpopexy (ASC) and MISC from January 1999 to December 2010.

Results: A total of 1124 subjects underwent sacrocolpopexy, with 589 ASCs and 535 MISCs. Within the MISC group, 273 were laparoscopic (LSC) and 262 were robotic (RSC). Abdominal sacrocolpopexy was associated with greater overall complication rate compared with MISC (20.0% vs 12.7%; $P = 0.001$). After controlling for difference in length of follow-up, there was no significant difference in the rate of anatomical failure between the ASC and MISC groups. The MISC group had shorter hospitalization, less blood loss, but longer operative times compared with the ASC group. When comparing LSC to RSC, there was no difference in anatomic failures (7.7% vs 6.9%; $P = 0.74$). However, LSC was associated with more complications compared with RSC (18% vs 7%; $P < 0.02$). In addition, LSC had higher blood loss, less operative time, and shorter hospital stay compared with RSC.

Conclusion: Although anatomic results are similar, ASC is associated with a higher rate of complications compared with MISC.

Key Words: complications, sacral colpopexy, sacrocolpopexy

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The gold-standard surgical procedure for apical prolapse is the abdominal sacrocolpopexy (ASC).[1] Although success rates of 95% have been reported, the procedure is associated with significant morbidity, which has been estimated to be as high 17%.[2,3] New techniques of minimally invasive sacrocolpopexy (MISC) such as laparoscopic sacrocolpopexy (LSC) and more recently, robotic sacral colpopexy (RSC) have emerged as popular alternatives to the traditional open abdominal procedure. Studies have shown efficacy rates as high as 93% with the laparoscopic approach[4] and suggest decreased blood loss and shorter hospital stay compared with ASC.[5] However, LSC requires a high degree of technical ability, and RSC has only recently become more widely available. These factors, combined with the paucity of data regarding intraoperative and postoperative complications associated with both procedures, have limited the adoption of these minimally invasive techniques for apical prolapse repair.

To date, there have been no published studies adequately powered to detect a difference in perioperative and postoperative outcomes between the MISC and ASC approaches. Thus, the primary aim of this study was to compare intraoperative and immediate postoperative complication rates between ASC and MISC. Secondary aims were to compare operative time and length of hospital stay and to perform the same comparisons between LSC and RSC.

MATERIALS AND METHODS

After institutional review board approval at each site, we conducted a multicenter retrospective cohort study comparing the outcomes of ASC and MISC at 4 institutions with Female Pelvic Medicine and Reconstructive Surgery fellowship training programs in the United States. This article was written in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement.[6] We reviewed all procedures performed by Female Pelvic Medicine and Reconstructive Surgery subspecialists over an 11-year period (January 1999 to December 2010).

We searched hospital records and coding databases to identify all subjects that had undergone ASC and MISC using Current Procedural Terminology codes. We excluded women who underwent hysteropexy and women who had a previous sacrocolpopexy or a vaginal mesh repair. We reviewed inpatient and outpatient records including clinic notes, operative reports, and discharge summaries. We recorded patients' baseline demographic data including age, body mass index (BMI), race, parity, smoking status, medical comorbidities (as measured using the Charleston Co-morbidity Index [CCI]),[7] surgical history, and preoperative Pelvic Organ Prolapse Quantification (POPQ) examination data.[8] We recorded surgical information including surgical approach, concomitant surgical procedures, length of surgery, estimated blood loss, and intraoperative complications. Postoperative information was also recorded, including length of stay, change in hemoglobin, postoperative complications, and postoperative POPQ data.

The primary outcomes were intraoperative and immediate postoperative complications expressed as the sum of all complications. Consequently, patients who had multiple complications were counted multiple times in the total. Intraoperative complications examined included conversion of a MISC to ASC, cystotomy, enterotomy, vascular injury, ureteral injury, intraoperative blood transfusion, and hemorrhage of greater than 500 mL. Intraoperative and postoperative outcomes in converted cases were analyzed in the ASC group, and conversion rates for MISC were reported separately. Postoperative complications included development of a deep venous thrombus (DVT) or pulmonary embolus (PE), ileus/small bowel obstruction, wound infection, ventral hernia formation, mesh erosion, and blood transfusion.

Secondary outcomes included operative time, blood loss, length of hospital stay, and anatomic success. Operative time was

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defined as the time of incision to the end of surgery. In addition to the estimated blood loss by the surgeon, we compared changes in preoperative and postoperative hemoglobin to evaluate the surgical blood loss. Anatomical success was defined as a prolapse at or above the hymen as described by Barber et al.[9] We also present failure rates for prolapse based on POPQ stage 2 or higher. Pelvic Organ Prolapse Quantification data points were collected retrospectively from the patients' most recent examinations.

Abdominal sacrocolpopexy was performed through either a Pfannenstiel or a midline vertical abdominal incision using techniques that have been described in the literature.[10] The MISC approach included LSC and RSC. In LSC, surgeons used a 5- or 10-mm camera port with a 10-mm port for extracorporeal knot tying and 2 additional 5-mm ports in various configurations. In RSC, a 12-mm camera port, 3 operative 8-mm robotic ports, and 1 to 2 laparoscopic assistance ports were used. The mesh used in all cases was type 1 (monofilament, macroporous) polypropylene. The practice of all surgeons operating at the time of case collection was to retroperitonealize the mesh.

Sample size calculations were based on a literature review, which revealed that patients who underwent ASC had a 31.2% risk of complications versus a 22.6% risk of complications in patients who underwent MISC.[1,4,5,11–13] Based on these results, we determined that 814 subjects would have 80% power to detect a difference in the rate of complications at an alpha of 0.05.

Statistical analyses were performed using SPSS for Windows version 19 (Chicago, IL). The normality of the data was tested by the Kolmogorov-Smirnov test. As some of the quantitative variables were not normally distributed, the Mann-Whitney test was used to analyze differences between groups. Comparisons of mean values of 2 groups for continuous variables were conducted using independent *t* tests, and 3 groups were compared using one-way analysis of variance. Categorical variables were compared using the Pearson χ^2 or Fisher exact test, as appropriate. Logistic regression model was preformed to assess the relation of developing complications with several parameters. Survival analysis with Kaplan-Meier model was preformed for estimating the survival function of the patients. $P \leq 0.05$ was considered statistically significant.

RESULTS

A total of 1124 subjects underwent sacrocolpopexy with 589 (52%) ASCs and 535 (48%) MISCs. The MISC approach included 273 (51%) LSCs and 262 (49%) RSCs, of which 13 (2.4%) were converted to open. Demographic data are presented in Table 1. There were no differences in mean age, BMI, parity,

TABLE 1. Demographic Information

	ASC (n = 589)	MISC (n = 535)	*P*	LSC (n = 273)	RSC (n = 262)	*P*
Sites						
Washington Hospital (263)	50	213		105	108	
University of Pennsylvania (470)	336	135		0	135	
University of Oklahoma (206)	148	58		39	19	
Case Western Reserve (186)	57	129		129	0	
*Age	58.8 ± 10	57.8 ± 11	0.42	56.5 ± 10	59.3 ± 11	*<0.01*
95% CI of the difference	−2.1 to 0.27			0.99–4.6		
*BMI	27.3 ± 5	27 ± 5	0.2	26.7 ± 5	27.3 ± 5	0.21
95% CI of the difference	−0.87 to 0.33			−0.32 to 1.44		
Ethnicity†						
White	75%	79%	*<0.01*	84%	75%	0.07
Black	12%	8%		9%	16%	
Other	15%	13%		7%	9%	
Parity‡	2.65 ± 1.4	2.58 ± 1.2	0.06	2.7 ± 1.3	2.4 ± 1.2	*0.01*
95% CI of the difference	−0.23 to 0.084			−0.48 to −0.06		
CCI‡	0.47 ± 0.8	0.33 ± 0.8	*0.01*	0.31 ± 0.7	0.37 ± 0.8	0.35
	−0.23 to −0.03			−0.06 to 0.19		
Smoking status†						
None	43%	64%	*<0.01*	64%	64%	*0.01*
Previous	15%	19%		23%	16%	
Current	42%	17%		13%	20%	
Prior abdominal surgery†	76%	56%	*<0.01*	67%	43%	*<0.01*
Menopausal†						
No	17%	27%	*<0.01*	30%	24%	0.2
Yes	83%	73%		70%	76%	
HRT†						
No	78%	83%	*<0.01*	76%	89%	*<0.01*
Yes	22%	17%		23%	11%	

*Independent *t* test.

†χ^2 association of variables.

‡Mann-Whitney test.

CI, confidence interval.

TABLE 2. Primary Outcome

Intraoperative and Postoperative Complications*	ASC (n = 589)	MISC (n = 535)	P	LSC (n = 273)	RSC (n = 262)	P
Cystotomy	4%	2%	*<0.01*	2.5%	1.5%	0.7
Enterotomy	0.2%	0.7%	0.4	1.4%	0.00%	0.54
Vascular injury	0.33%	0%	0.5	0.00%	0.45%	1
Ureteral injury	0.33%	0%	0.5	0.00%	0.00%	–
Intraoperative transfusion	0.33%	0%	0.5	0.00%	0.00%	–
Hemorrhage >500 mL	2.2%	1.1%	0.14	1.8%	0.3%	0.21
Conversion to open	–	–	–	4%	0.4%	*<0.01*
DVT/PE	1.5%	1%	0.3	3%	0.00%	*<0.01*
Ileus/SBO	5%	2%	*<0.01*	1.8%	1.5%	1
Wound infection	1.9%	1.3%	0.12	1.5%	1.1%	1
Ventral hernia	0.7%	0.2%	0.61	0.00%	0.4%	0.49
Mesh erosion	2.6%	3.21%	0.21	4%	1.9%	0.2
Blood transfusion	1.2%	0.5%	0.4	1%	0.00%	0.25
All complications	20.0%	12.7%	*<0.01*	18%	7%	*<0.01*

*Fisher exact test.

and preoperative POP-Q stage 3 or higher (70.9% vs 66.4%; $P = 0.21$) between ASC and MISC. The MISC group was more likely to be white, nonsmokers, premenopausal, with fewer prior abdominal surgeries, and a lower CCI compared to the ASC group. Compared with the MISC subgroups, the RSC cohort had a lower parity but was older and more likely to be menopausal.

Abdominal sacrocolpopexy was associated with greater overall complication rate when compared to MISC (20.0% vs 12.7%; $P = 0.001$; Table 2). This difference remained after multivariate logistic regression. Regression analysis including smoking, menopausal status, prior abdominal surgery, hormone replacement, age, and BMI demonstrated that prior abdominal surgery was the only independent predictive value for possible complication after surgery (odds ratio, 2.3 [95% confidence interval, 1.44–3.68]; $P < 0.0001$). Intraoperative cystotomy (4% vs 2%; $P = 0.001$) and postoperative ileus/small bowel obstruction (5% vs 2%, $P = 0.001$) were more common in the ASC group than in the MISC group.

In addition, patients who underwent ASC had shorter operative times (222 vs 296 minutes; $P < 0.02$), greater blood loss (187 ± 142 vs 122 ± 146 mL; $P < 0.01$) and longer length of hospitalization (2.9 ± 1.6 vs 1.3 ± 1 days; $P < 0.01$; Table 3). On multivariable analysis, ASC remained independently associated with higher estimated blood loss and length of hospitalization after controlling for variables that may affect these outcomes (ie, number of previous abdominal procedures, additional procedures, POPQ stage, and CCI). While there was no difference in vaginal mesh erosion between the ASC and MISC groups, erosions occurred more frequently in patients who had total hysterectomy versus those who had a supracervical hysterectomy (4.8% vs 0.6%; $P < 0.01$). The rate of women who underwent supracervical hysterectomy was significantly lower in the patients who had ASC compared with those who had MISC (54% vs 65%; $P < 0.01$); however, even after controlling for the type of hysterectomy, there was no difference in vaginal mesh erosion between the ASC and MISC groups.

The ASC group had longer follow-up time compared to the MISC group (14 vs 8 months; $P < 0.01$), but there were fewer patients with follow-up POP-Q data (Table 3). The ASC group had a higher anatomical failure using both definitions (prolapse at or beyond hymen, 15.1% vs 7.4%; $P < 0.001$ and stage 2 or higher-stage prolapse, 25.3% vs 14.2%; $P < 0.001$), which was driven primarily by failure in the posterior wall using stage 2

TABLE 3. Secondary Outcomes

	ASC (n = 589)	MISC (n = 535)	P	LSC (n = 273)	RSC (n = 262)	P
Estimated blood loss, mL	150 (10–1500)	100 (2–2500)	*<0.01*	100 (2–2500)	100 (10–1000)	0.77
95% CI of the difference	−82 to −48			−42 to 7.4		
Change in Hemoglobin, grams/dL	2.3 (−4.9–5.8)	2.1 (0–5.4)	*0.01*	2.2 (0.1–5.4)	2 (0–4.60)	*0.004*
95% CI of the difference	−0.26 to −0.03			−0.45 to −0.09		
Length of surgery	222 (73–678)	295.5 (94–604)	*0.02*	272 (94–451)	316 (149–604)	*<0.0001*
95% CI of the difference	68.4–86.5			34.28–60.9		
Hospital stay	3 (0–27)	1 (0–16)	*0.01*	1 (0–5)	1 (1–16)	*0.005*
95% CI of the difference	−1.7 to −1.5			0–0.36		
Follow-up, mo	14 (8–74)	8 (6–147)	*<0.01*	8.0 (5–147)	8.0 (1–41)	0.89
Number of patients with follow-up data	290	496		246	250	
Anatomic failures						
At or beyond hymen	15.1%	7.4%	*<0.001*	6.5%	8.4%	0.49
Stage 2 or higher	25.3%	14.2%	*<0.001*	11.3%	17.2%	0.069

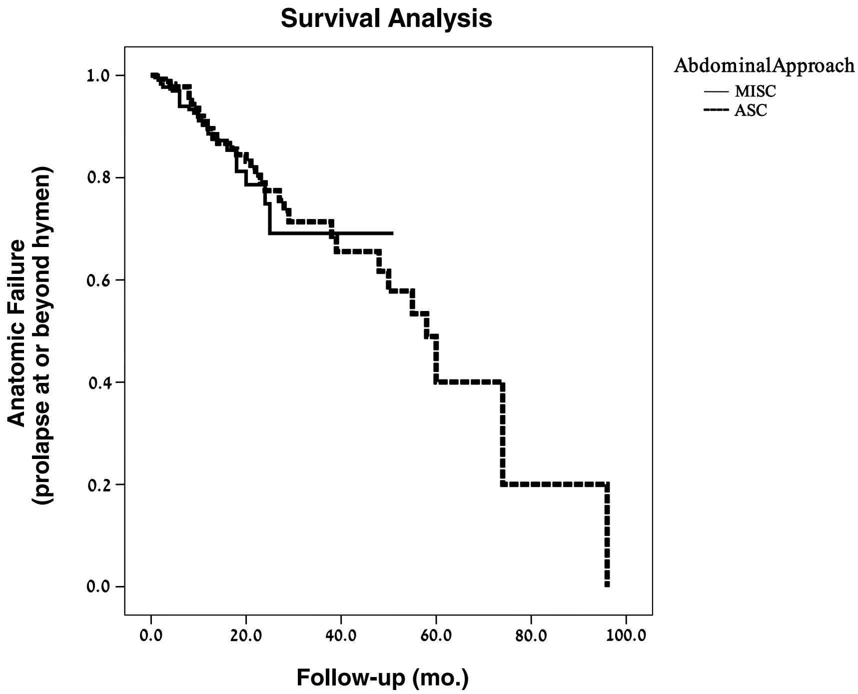

FIGURE 1. Survival analysis.

or higher (16.3% vs 9.6%; $P < 0.01$). However, to adjust for the longer follow-up in the ASC group, a survival analysis was performed. After censoring for outliers, there was no difference in the onset of recurrence between the 2 groups, supporting similar failure rates for the ASC and MISC groups (Fig. 1).

Laparoscopic sacrocolpopexy was associated with a greater overall complication rate compared with RSC (18.0% vs 7.0%; $P < 0.01$; Table 2). Patients who underwent LSC were more likely to have their procedure converted to open (4.0% vs 0.4%; $P < 0.01$) and were more likely to develop a DVT/PE (3.0% vs 0.0%; $P < 0.01$). Follow-up time and the number of patients available for follow-up were similar for the LSC and RSC groups (Table 3). There was no statistically significant difference in anatomic failure rates (6.5% vs 8.4%; $P = 0.49$) between these 2 techniques. However, LSC was associated with shorter operative time (272 vs 316 minutes; $P < 0.001$) and shorter length of hospitalization.

DISCUSSION

This retrospective multicenter cohort study represents the largest cohort of patients who underwent sacrocolpopexy in the literature. We found a higher rate of complications in patients who underwent ASC compared to MISC group (20.0% vs 12.7%; $P = 0.001$). The distinction between open and minimally invasive surgery was echoed in a meta-analysis of 27 randomized clinical trials comparing operative laparoscopy to laparotomy for benign gynecological conditions, which found the overall risk of complications to be significantly lower in the laparoscopy group (relative risk, 0.59; 95% confidence interval, 0.50–0.70).[14] In addition, in a systematic review of all approaches to sacrocolpopexy, Diwadkar et al[3] found an overall complication rate of 17.1%, which was similar to our study. However, in this study, the sacrocolpopexy group was heterogeneous and included patients who received standard ASC and sacrohysteropexies by laparoscopy or laparotomy.

Intraoperative cystotomy (4.8% vs 2.1%; $P < 0.01$) and postoperative ileus/SBO (4.8% vs 1.8%; $P = 0.02$) were the only complications that were more common in the ASC compared to the MISC groups. Cystotomies were higher in the ASC group despite the fact that more procedures, and specifically more sling procedures, were performed in the MISC group. However, patients in the ASC group were more likely to have had a previous abdominal surgery compared to the MISC group (76% vs 56%; $P < 0.01$), which increases the complexity of the case and the risk of injury to adjacent organs. This factor, combined with an abdominal incision, also increases the risk of ileus/SBO. In contrast, Paraiso et al[15] found no difference in the rate of cystotomy or postoperative ileus/SBO between ASC and LSC. However, both our study and the study by Paraiso et al were not powered to detect these differences.

Intraoperative hemorrhage was more common in the ASC group compared to the MISC group, but the difference was not statistically significant. Hemorrhage was defined as an estimated blood loss of greater than 500 mL, which was arbitrarily chosen. If this is removed from the composite complication score, the difference in overall complications was still greater in the ASC group (16.1% vs 11.4%; $P = 0.023$).

In our study, complications of mesh were similar between the groups. However, mesh erosions were more common in patients who underwent concomitant total hysterectomy compared to supracervical hysterectomy (4.8% vs 0.6%; $P < 0.01$). Previous studies support this finding of higher erosion rate with total hysterectomies, and authors have suggested that a vaginal incision and devascularization of the cuff at the time of hysterectomy may account for the increased erosion rate seen in this cohort.[3,15] However, these findings are complicated by the retrospective nature of our study and the longer follow-up for the ASC compared to the MISC group. Research has shown that mesh erosion can occur at variable times during recovery, ranging from weeks to years.[16–18] The short-term follow-up may mask a larger erosion rate in the MISC group. In addition, we did not collect the specific mesh or suture used to attach the mesh, which may adversely affect our outcomes.

Patients who underwent ASC had greater blood loss and longer length of hospitalization than those who underwent MISC. Several factors may contribute to these findings. Patients who had ASC were more likely to have a higher CCI and a greater number of previous abdominal surgeries, both of which may increase blood loss and the length of hospitalization.

We found a higher anatomical failure rate in the ASC group compared to the MISC group; however, this could be due to the longer follow-up time in the ASC group and the high lack of follow-up in the ASC group. Using survival analysis, we found no difference in the time to prolapse recurrence between the ASC and MISC groups (Fig. 1). This finding is consistent with previous studies, which have shown no difference in the overall rate of anatomic failure among the various sacrocolpopexy approaches.[2,4,15] In addition, when comparing anatomic failures between RSC and LSC, we found no difference (6.9% vs 7.7%; $P = 0.74$). A recent blinded randomized trial comparing robotic to laparoscopic sacrocolpopexy by Paraiso et al found similar anatomic failures (12% vs 9%) at 1 year.[15]

As in the previous study by Paraiso et al, we found a statistically significant difference in operative times between the MISC techniques, which accounted for nearly 1 more hour in the operating room for the RSC group.[15,19] This difference has been previously associated with docking, suturing, and instrumentation. It may also reflect the fact that our data were collected during the early adoption phase for RSC at many institutions. Whereas the operative times may be reduced with experience, studies have shown that they often remain elevated.[15] Of note, this longer time did not result in an increase in hospital stay or postoperative complications.

Laparoscopic sacrocolpopexy had an increased risk of overall complications compared to RSC (18% vs 7%; $P < 0.02$), which was primarily driven by the increased rate of conversion to laparotomy and DVT/PE. The rate of conversion was 2.4% (13/535), which is consistent with the published literature.[5,11,15] However, the rate of conversion in the robotic group was extremely low. This difference is likely due to the criteria used to define conversion, which was limited by the retrospective nature of our study. Robotic docking was required for conversion to be counted. Consequently, planned robotic cases that were started laparoscopically but aborted secondary to dense adhesion would be counted as a laparoscopic conversion, which skews the rate to the laparoscopic group. Patients who underwent LSC were also more likely to experience a DVT/PE, which may be secondary to the increased use of hormone replacement therapy in this population (23% vs 11%; $P < 0.01$).

The strengths of this investigation are the number of cases collected and the heterogeneity of the techniques used for mesh placement, which improve its generalizability. We also used a robust definition for complications that included multiple adverse events. Limitations of this study are its retrospective nature, which introduces detection bias and adversely affects follow-up. For example, not all patients who returned for follow-up had a POPQ examination or a standardized approach to evaluate mesh complications. In addition, we used a composite complication score, which may not account for all adverse events. Finally, our definition of failure did not include subjective data, which were inconsistently available.

In summary, in this large cohort of women who underwent sacrocolpopexy, we found that ASC is associated with a higher rate of perioperative and postoperative complications compared to MISC. The MISC group had shorter length of hospitalization, less blood loss, and longer operative times. Within the MISC group, RSC was associated with fewer complications compared to LSC. The rate of vaginal mesh erosion was low in all groups but higher in women having total hysterectomy compared to supracervical hysterectomy. There was no difference in anatomic failure with any sacrocolpopexy approach.

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