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One-Year Outcomes After Minimally Invasive Sacrocolpopexy

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Abstract

Objective—The primary aim of this study was to report anatomic, symptom, and quality of life outcomes in women with symptomatic stage 2 or greater prolapse 1 year after randomization to robotic and laparoscopic sacrocolpopexy.

Methods—This is a planned ancillary analysis of the Abdominal Colpopexy: Comparison of Endoscopic Surgical Strategies trial, a randomized comparative effectiveness trial comparing costs and outcomes of robotic and laparoscopic sacrocolpopexy at 2 academic medical centers. At baseline and 1 year after surgery, women underwent standardized assessment including validated subjective pelvic floor outcomes and physical examination with prolapse assessment.

Results—Sixty six (85%) of 78 randomized participants completed 1-year follow-up: 33 (87%) of 38 in the laparoscopic arm and 33 (83%) of 40 in the robotic arm ($P = 0.59$). Ninety-seven percent (32/33) in the laparoscopic group and 100% (33/33) in the robotic arm considered that their prolapse symptoms improved ($P = 0.999$). The cohort had significant improvement in all pelvic floor symptom and quality of life measures, which did not differ by treatment arm. Of women who were sexually active at 1 year, sexual function improved in both cohorts. No new serious adverse events, including mesh exposure or reoperation for prolapse, were identified between 6 months and 1 year after surgery. No women had a sacrocolpopexy mesh complication or reoperation for mesh exposure.

Conclusions—Minimally invasive sacrocolpopexy is associated with significant improvement in pelvic floor symptoms, anatomy, and sexual function. In addition, mesh exposure rates with

lightweight polypropylene mesh seem to be lower than those reported with multifilament and heavier polypropylene mesh.

Keywords

minimally invasive sacrocolpopexy; laparoscopic sacrocolpopexy; robotic sacrocolpopexy; mesh exposure; polypropylene mesh; outcomes

The efficacy and safety of minimally invasive surgery for pelvic organ prolapse, including short hospital stay, quick recovery, minimal blood loss, and decreased postoperative pain, continue to generate increasing numbers of both traditional laparoscopic and robotically assisted laparoscopic sacrocolpopexies.^{1,2} Anatomic and patient-reported symptom outcomes 1 year after open, robotic, and laparoscopic sacrocolpopexy are similar; however, these data are limited by a paucity of prospective randomized trial outcomes. Only 2 randomized trials report 1-year outcomes after laparoscopic and/or robotic sacrocolpopexy¹ and together include 29 women after robotic, 55 after laparoscopic, and 24 after open sacrocolpopexy.

Estimates suggest that women have a 14% lifetime risk of undergoing prolapse surgery³ and that surgery for pelvic organ prolapse will increase by 47% for the next 40 years.⁴ We can likely anticipate a commensurate increase in minimally invasive sacrocolpopexies for surgical management of prolapse, emphasizing the need for additional high-quality, prospective comparative outcome data to use when counseling patients.

The primary aim of this study was to report anatomic, symptom, and quality of life outcomes in women with symptomatic stage 2 or greater prolapse 1 year after randomization to robotic and laparoscopic sacrocolpopexy.

MATERIALS AND METHODS

This is a planned ancillary analysis of the Abdominal Colpopexy: Comparison of Endoscopic Surgical Strategies (ACCESS) trial (NCT01124916).^{2,5} Briefly, ACCESS was a randomized comparative effectiveness trial comparing costs and outcomes of robotic and laparoscopic sacrocolpopexy at 2 academic medical centers. A previous power calculation determined that 32 women in each arm would provide 95% power to detect a difference of at least US \$2500 difference in total charges. Women with symptomatic stage 2 or greater pelvic organ prolapse, including apical support loss to at least half the total vaginal length, planning minimally invasive sacrocolpopexy were randomized to laparoscopic or robotic routes of access. Detailed methods and primary outcomes were previously reported. Sacrocolpopexy was performed with 2 pieces of ultra-lightweight polypropylene mesh attached to the anterior and posterior vagina and the anterior longitudinal ligament using Gore-tex sutures. Concomitant supracervical hysterectomy, posterior colporrhaphy, and retropubic midurethral slings were allowed. Surgeon preference determined brand of mesh used and whether reperitonealization was performed.

At baseline and 1 year after surgery, all study participants underwent a standardized physical examination including pelvic organ prolapse quantification (POP-Q)⁶ and completed a series

of validated pelvic floor symptom and quality of life questionnaires, including the Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ),⁷ and Pelvic Organ Prolapse/Incontinence Sexual Questionnaire.⁸ The PFDI has 3 subscales to assess bother from prolapse (POPDI), urinary (UDI), and colorectal-anal (CRADI) symptoms; POPDI and UDI subscale ranges from 0 to 300 and the CRADI 0 to 400 with higher scores indicating greater bother. The PFIQ has similar subscales to assess quality of life impact from prolapse, urinary, and colorectal-anal symptoms, which range from 0 to 400. The Pelvic Organ Prolapse/Incontinence Sexual Questionnaire is a validated measure designed to evaluate sexual function in women with prolapse and urinary incontinence. Participants also completed the Patient Global Impression of Improvement (PGI-I)⁹ at 1 year to assess their impression of their overall prolapse symptom improvement after surgery. The PGI-I is a 7-item scale ranging from “very much better” to “very much worse.” For the purposes of analyses, responses of “very much better” and “much better” were considered “improved,” responses of “a little better,” “no change,” and “a little worse” were considered “unchanged,” and responses of “much worse or very much worse” were considered “worse.”

Mean and standard deviations were computed for continuous data. Differences between baseline and 1-year outcomes across groups were tested by way of generalized linear regression and included covariance structure estimation to account for repeated measures over time. Regression diagnostics were used to confirm data distributions and the presence of any overly influential outliers. A *P* value of 0.05 was considered significant. All analyses were performed with SAS 9.3.

RESULTS

Seventy-eight women were randomized and underwent the assigned surgery (38 laparoscopic and 40 robotic). Sixty six (85%) of participants completed 1-year follow-up: 33 (87%) of 38 in the laparoscopic arm and 33 (83%) of 40 in the robotic arm (*P* = 0.59). Participant's mean(SD) age was 59.5(9.9)years, the majority was white, and approximately 20% had previous prolapse surgery (Table 1). Forty-five women (58%) underwent concomitant supracervical hysterectomy, 47 (60%) underwent retropubic midurethral sling, and 5 (6%) underwent posterior repair.

Ninety-seven percent (32/33) of women in the laparoscopic group and 100% (33/33) in the robotic arm considered their prolapse symptoms “improved” on the PGI-I, whereas 1 woman in the laparoscopic and none in the robotic arm considered her prolapse symptoms unchanged. The PGI-I scores did not differ between treatment groups (*P* = 0.999).

Table 2 shows baseline and 1-year POPQ, PFDI, PFIQ, and PISQ scores for the entire cohort and the robotic and laparoscopic groups. The cohort had significant improvement in all symptom and quality of life measures, which did not differ by treatment arm. The proportion of women who were sexually active in the past 3 months did not differ among treatment arms at baseline or 1 year after surgery; similarly, the proportion of women who reported sexual activity in the past 3 months did not increase from baseline 1 year after surgery. Of women who were sexually active at 1 year, sexual function improved in both cohorts.

No new serious adverse events, including mesh exposure or reoperation for prolapse, were identified 1 year after surgery. There were 3 reoperations for bowel complications (1 port-site hernia and 2 small bowel obstructions), which all occurred in the first 6 to 8 weeks after surgery. No women had a sacrocolpopexy mesh complication or reoperation for mesh exposure. One patient had asymptomatic Gortex suture erosion, which did not require further treatment.

DISCUSSION

Despite the increasing rates of minimally invasive sacrocolpopexy, few prospective data report comprehensive pelvic floor outcomes beyond 6 months after surgery. In fact, a recent systematic review comparing laparoscopic and robotic sacrocolpopexy, which included studies with as few as 3 months of follow-up, found only 3 prospective studies of high enough quality to include in their analysis.¹⁰ We report validated anatomic and patient-oriented outcomes 1 year after laparoscopic and robotic sacrocolpopexy in a cohort of women enrolled in a multicenter randomized trial. Women undergoing minimally invasive sacrocolpopexy had significant improvement in all endpoints, including global improvement in their pelvic symptoms, bother, and quality of life related to urinary, bowel, and prolapse symptoms, sexual function, and anatomic outcomes. Rates of minimally invasive sacrocolpopexy have increased substantially for the past decade.^{11–13} Using 2001–2011 Medicare claims data, Wang et al¹³ found that the annual volume of sacrocolpopexy averaged 100 to 180 cases per year from 2004 to 2007. This increased to 1720 cases in 2011. The majority (at least 80%) of sacrocolpopexies were performed laparoscopically or robotically, further emphasizing the need for longer term prospectively obtained outcomes.

We found no sacrocolpopexy mesh exposures 1 year after sacrocolpopexy with an ultra-lightweight polypropylene mesh, in contrast to previous studies using multifilament and heavier polypropylene meshes.^{14,15} A multicenter study of open sacrocolpopexy reported a 5% mesh exposure rate on average 1 year after surgery (mean interval from surgery to erosion was 313 days [range, 45–744] days),¹⁴ which increased to 10.5% by 6 years after surgery.¹⁵ Approximately half of sacrocolpopexy procedures were done with woven polyester or expanded polytetrafluoroethylene, and half with heavier, less porous, stiffer polypropylene meshes than used in our study (Gynemesh; Ethicon Women's Health and Urology, Cincinnati, Ohio). Recent studies using ultralight polypropylene meshes reported 1-year mesh erosion rates similar to our findings.^{16,17} Two prospective studies, which followed 261 women for 1 year after sacrocolpopexy with ultra-lightweight polypropylene meshes (Alyte Y-mesh graft, C.R. Bard, Covington, GA, and Restorelle Y Smartmesh, Coloplast A/S, Humlebæk, Denmark) also reported no cases of vaginal mesh exposure. Even if one assumes that mesh exposure rates double over time, similar to earlier reported data, mesh exposures after ultra-lightweight polypropylene meshes would remain significantly lower than those in previous reports using multifilament meshes, suggesting that older data may not be applicable to current meshes.

Our study is strengthened by the prospective design, including validated subjective outcomes and in-person visits with pelvic examinations at both 6 months and 1 year after surgery, which allows for comparisons with similar studies and inclusion in future systematic reviews

and meta-analyses. The study was also designed to prospectively collect mesh exposure rates, one of the most concerning adverse outcomes associated with sacrocolpopexy.

An important limitation of this study is our inability to report comparative outcomes 1 year after robotic and laparoscopic sacrocolpopexy. The primary study outcome was cost differences between laparoscopic and robotic sacrocolpopexy; therefore, although we can report meaningful outcomes on minimally invasive sacrocolpopexy, we are underpowered to report differences between the 2 routes. Fortunately, both anatomic and subjective measures of success were high in both arms suggesting there is likely no meaningful difference between the routes of access. However, we did find an increased cost with robotic surgery, which was primarily related to the robot purchase price and maintenance rather than surgical costs.

In conclusion, minimally invasive sacrocolpopexy is associated with significant improvement in pelvic floor symptoms, anatomy, and sexual function. Its additional, mesh exposure rates with lightweight polypropylene mesh seem to be lower than those reported with multifilament and heavier polypropylene mesh.

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TABLE 1

Baseline Demographics of Study Population

	Entire Group	Robotic	Laparoscopic	<i>P</i>
Age, mean (SD)	59.5(9.9)	58.5(10.5)	60.6(9.2)	0.35
BMI, mean (SD)	27.7(5.7)	28.3(6.6)	27(4.70)	0.29
Race, %				0.68
White	91	88	95	
African American	6	10	3	
Previous UI surgery, %	15	13	18	0.54
Previous POP surgery, %	21	21	20	0.99
Previous hysterectomy, %	42	35	50	0.25

UI indicates urinary incontinence.

TABLE 2

Baseline and 1-Year Anatomic, Symptom, and Quality of Life Outcomes

	Entire Group		Robotic		Laparoscopic		Time P^*	Treatment $P^\dagger$
	Mean (SD)		Mean(SD)		Mean(SD)			
	Baseline	1 y	Baseline	1 y	Baseline	1 y		
POP-Q Ba	2.5(1.9)	−2.3(1.0)	2.6(2.0)	−2.2(1.1)	2.5(1.8)	−2.5(0.8)	<0.001	0.815
POP-Q Bp	−0.2(3.0)	−2.3(0.9)	−0.5(2.9)	−2.2(0.94)	0.21(3.0)	−2.4(0.8)	<0.001	0.743
POP-Q C	0.5(3.8)	−8.1(3.5)	0.25(3.6)	−7.6(4.6)	0.74(3.9)	−8.7(1.5)	<0.001	0.424
UDI	104(59)	28(36)	110(59)	31(34)	97(60)	25(37)	<0.001	0.350
POPDI	122(62)	36(40)	127(63)	41(45)	117(61)	31(33)	<0.001	0.570
CRADI	94(71)	46(48)	90(72)	52(53)	99(72)	40(42)	<0.001	0.991
UIQ	113(96)	20(42)	128(94)	23(41)	98(96)	18(43)	<0.001	0.140
POPIQ	99(94)	7(20)	114(102)	10(26)	83(84)	3(8)	<0.001	0.088
CRAIQ	67(88)	24(47)	67(90)	28(57)	68(88)	20(36)	0.001	0.798
PISQ total	18.1(6.0)	11.8(3.0)	17.0(6.5)	11.4(3.1)	19.2(5.5)	12.2(2.9)	<0.001	0.195
Sexually active	55 (41/74)	47 (29/62)	55 (21/38)	48 (15/31)	56 (20/36)	45 (14/31)	0.173	0.799

* P value represents comparison by outcome for each group from baseline to 1 year (within groups over time).

† P value represents comparisons between robotic and laparoscopic surgery group at 1 year. UIQ indicates Incontinence Impact Questionnaire; POPIQ, Prolapse Impact