

Laparoscopic Compared With Robotic Sacrocolpopexy for Vaginal Prolapse

A Randomized Controlled Trial

Marie Fidela R. Paraiso, MD, J. Eric Jelovsek, MD, Anna Frick, MD, MPH,
Chi Chung Grace Chen, MD, and Matthew D. Barber, MD, MHS

OBJECTIVE: To compare conventional laparoscopic and robotic-assisted laparoscopic sacrocolpopexy for vaginal apex prolapse.

METHODS: This single-center, blinded randomized trial included participants with stage 2–4 posthysterectomy vaginal prolapse. Participants were randomized to laparoscopic or robotic sacrocolpopexy. The primary outcome was total operative time from incision to closure. Secondary outcomes were postoperative pain, functional activity, bowel and bladder symptoms, quality of life, anatomic vaginal support, and cost from a health care system perspective.

RESULTS: A total of 78 patients enrolled and were randomized (laparoscopic n=38; robotic n=40). Total operative time was significantly longer in the robotic group compared with the laparoscopic group (+67-minute difference; 95% confidence interval [CI] 43–89; $P<.001$). Anesthesia time, total time in the operating room, total sacrocolpopexy time, and total suturing time were all significantly longer in the robotic group. Participants in the robotic group also had significantly higher pain at rest and with activity during weeks 3 through 5 after surgery and required longer use of nonsteroidal anti-inflammatory drugs (median, 20 compared with 11 days, $P<.005$). The robotic group incurred greater cost than the laparoscopic group (mean difference +\$1,936; 95% CI \$417–\$3,454; $P=.008$). Both groups demonstrated significant improvement in vaginal support and functional outcomes 1 year after surgery with no differences between groups.

CONCLUSION: Robotic-assisted sacrocolpopexy results in longer operating time and increased pain and cost compared with the conventional laparoscopic approach.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, www.clinicaltrials.gov, NCT00551993.

(*Obstet Gynecol* 2011;118:1005–13)

DOI: 10.1097/AOG.0b013e318231537c

LEVEL OF EVIDENCE: I

In the United States, 7% of women require surgical intervention for pelvic organ prolapse by the age of 80 years.¹ Approximately 300,000 surgeries are annually performed to correct pelvic organ prolapse in the United States at a cost of greater than \$1 billion.^{1,2} Abdominal sacrocolpopexy, an operation in which the prolapsed vagina is suspended through a bridge of synthetic mesh to the sacrum, has been shown to have one of the highest long-term anatomic success rates (78–100%) among procedures for pelvic organ prolapse repair.³ Sacrocolpopexy has demonstrated higher efficacy compared with vaginal approaches for prolapse repair, but this is offset by a higher complication rate and longer postoperative recovery.⁴ Laparoscopic sacrocolpopexy has been adopted by many pelvic surgeons as a means to minimize surgical morbidity and quicken patient recovery.^{5–7} Retrospective studies comparing laparoscopic with abdominal sacrocolpopexy confirm similar anatomic outcomes, although the laparoscopic approach is associated with less blood loss and a shorter hospital stay.^{8–11}

Despite the clinical advantages of a laparoscopic approach, adoption of laparoscopic sacrocolpopexy has been limited secondary to the steep learning curve associated with attaining laparoscopic suturing and knot-tying skills. Robotic surgical systems have been developed with the goal of facilitating technically difficult procedures. Hence, many surgeons have turned to

From the Cleveland Clinic, Cleveland, Ohio.

Funded by the Cleveland Clinic Research Program Council and Cleveland Clinic Center for Surgical Innovation, Technology, and Education.

Corresponding author: Marie Fidela R. Paraiso, MD, Obstetrics, Gynecology, & Women's Health Institute, Desk A81, 9500 Euclid Avenue, Cleveland, OH 44195; e-mail: paraism@ccf.org.

Financial Disclosure

The authors did not report any potential conflicts of interest.

© 2011 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.

ISSN: 0029-7844/11



robotic-assisted surgery to offer patients a minimally invasive approach to sacrocolpopexy.

Although robotic-assisted surgery has been aggressively marketed and widely adopted across numerous surgical specialties in the United States, a recent MEDLINE search identified no completed randomized controlled trials comparing robotic with conventional laparoscopic procedures to date.¹² The objective of this study was to compare robotic sacrocolpopexy with laparoscopic sacrocolpopexy in the treatment of patients with posthysterectomy vaginal prolapse in a single-blinded randomized controlled trial.

MATERIALS AND METHODS

This single-center, blinded randomized controlled trial was approved by the Cleveland Clinic institutional review board and CONSORT (CONsolidated Standards of Reporting Trials) guidelines were followed. All women who presented with posthysterectomy vaginal apex prolapse at Pelvic Organ Prolapse Quantitative stages 2–4 from January 2007 to December 2009 who were at least 21 years of age and desired laparoscopic surgical management were eligible to participate. Patients were excluded if they were not candidates for general anesthesia, had a history of prior sacrocolpopexy, suspicious adnexal masses, a history of pelvic inflammatory disease, morbid obesity (body mass index [calculated as weight (kg)/[height (m)]²] of 40 or higher), or had a history of prior or concomitant surgery for rectal prolapse.

All participants signed a written informed consent and underwent a standardized evaluation, including a structured urogynecologic history and physical examination with Pelvic Organ Prolapse Quantitative.¹³ Participants also completed several validated condition-specific and general quality-of-life questionnaires including the Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire-7, Prolapse/Incontinence Sexual Questionnaire, and EQ-5D.^{14–16} Assessment of baseline functional status was assessed using the Activity Assessment Scale, which they submitted during office visits at the Cleveland Clinic.¹⁷

Participants were assigned randomly in a 1:1 ratio to one of two treatment groups (laparoscopic sacrocolpopexy or robotic sacrocolpopexy). Treatment allocation was determined by a computer-generated randomization schedule with random block sizes (two to six) and stratified by surgeon. Treatment assignments were placed in consecutively numbered, opaque-sealed envelopes that were opened by the surgery scheduler immediately before scheduling the case because each procedure required different equipment that needed to be known before the day of surgery (on average this

occurred 42 days before surgery). Patients were blinded to their treatment assignment. Operating room and healthcare providers responsible for intraoperative and postsurgical care were informed not to discuss treatment assignment during the preoperative discussion or the postoperative period. Research staff administering and collecting the study questionnaires and outcomes were blinded to the participant's treatment group for the entire duration of the study.

Two attending surgeons (M.P., E.J.) enrolled all patients and were the primary surgeons in all procedures assisted by Female Pelvic Medicine and Reconstructive Surgery Fellows (including C.C. and A.F.). Both attending surgeons completed fellowship training in Female Pelvic Medicine and Reconstructive Surgery and were experienced in both laparoscopic and robotic sacrocolpopexy. Both received formal training by Intuitive Surgical Inc and had performed at least 10 robotic-assisted procedures before beginning trial enrollment. All participants received general anesthesia and underwent standard operative care. Each laparoscopic sacrocolpopexy was performed as previously described using two separate 4×15-cm pieces of polypropylene mesh.⁸ Four ports were used: one 5-mm umbilical port for the laparoscope; two 10/12-mm ports placed in bilateral lower quadrants; and one 5-mm port placed subcostally 9 cm lateral to the rectus muscle on either side (Fig. 1A). Knots were tied using extracorporeal knot-tying techniques.

Each robotic sacrocolpopexy was performed using the da Vinci Surgical System in a technique similar to conventional laparoscopy. Differences for the robotic approach included the port locations, the need to dock the robotic patient cart, and intracorporeal rather than extracorporeal knot tying. For the robotic approach, five ports were placed in a shallow “W” formation: one 12-mm umbilical port for the laparoscope; one 12-mm port placed subcostally lateral to the rectus muscle on the right side; and three 8-mm robotic ports placed in bilateral lower quadrants, two on the left and one on the right (Fig. 1B). The robotic patient cart was docked between the patient's legs. The entire sacrocolpopexy procedure was performed using robotic assistance in a manner similar to the laparoscopic technique outlined previously. Concomitant reconstructive procedures were performed at the primary surgeon's discretion.

Operating time was the primary outcome of the trial. For pelvic surgeons trained in both laparoscopy and robotics, the main impetus for electing a robotic sacrocolpopexy compared with a conventional laparoscopic approach is the improved dexterity, three-dimensional vision, and surgeon comfort afforded by the robot. Based on previous retrospective data, we did not



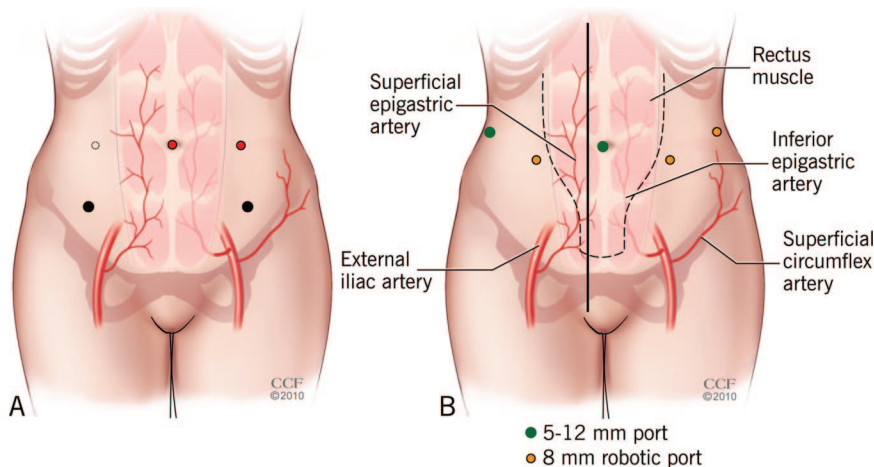


Fig. 1. Four ports were used in the laparoscopic approach to sacrocolpopexy (A): one 5-mm umbilical port for the laparoscope; two 10/12-mm ports placed in bilateral lower quadrants; and one 5-mm port placed subcostally 9 cm lateral to the rectus muscle on either side. Five ports were used in the robotic approach to sacrocolpopexy (B) placed in a shallow “W” formation: one 12-mm umbilical port for the laparoscope; one 12-mm port placed subcostally lateral to the rectus muscle on the right side; and three 8-mm robotic ports placed in bilateral lower quadrants, two on the left and one on the right. Reprinted with permission from the Cleveland Clinic Center for Medical Art and Photography © 2010–2011. All rights reserved.

Paraiso. *Laparoscopic and Robotic Sacrocolpopexy*. *Obstet Gynecol* 2011.

think these benefits would necessarily result in different clinical outcomes between the two groups.^{8–11} Thus, we chose operative time as the primary outcome because it was considered a proxy for surgical efficiency. The following operative parameters were recorded prospectively: time from initial incision to skin closure for all procedures (total operative time), total time the patient was in the operating room (operating room time), time that the patient was under anesthesia from beginning of induction to extubation (anesthesia time), and time for specific parts of the case including robotic cart docking (docking time only applicable to robot), sacrocolpopexy suturing, sacrocolpopexy, and concomitant procedures. Perioperative complications (intraoperative through the sixth postoperative week) as well as long-term complications (beyond 6 weeks) were documented.

Participants were asked to rate their pain on the Surgical Pain Scales 24 hours after surgery and on a weekly basis through the sixth postoperative week.¹⁷ The pain scales consisted of visual analog scales requesting the patient rate their pain between “no pain sensation” and “most intense pain imaginable” at rest and with normal activity. Participants also were asked to rate the “unpleasantness” of their pain. Amounts of narcotic and nonsteroidal anti-inflammatory drugs (NSAIDs) used during the hospitalization were also assessed daily through the 6-week visit. The Activity Assessment Scale measured participants’ functional status 1, 2, and 4 weeks after surgery. Participants also rated their return to normal activities using a nonanchored 10-cm visual

analog scale at weeks 1–6 after surgery. Six months and 1 year after surgery, participants underwent a physical examination with Pelvic Organ Prolapse Quantitative measurements by a member of the research team, who did not participate in the surgery and was blinded to treatment assignment. The Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire-7, Prolapse/Incontinence Sexual Questionnaire, EQ-5D, and Activity Assessment Scale were readministered at 6 months and 1 year.

A priori, we determined that 32 participants in each group were needed to detect a difference of 50 minutes or more in operating time between laparoscopic compared with robotic groups with greater than 90% power and a significance level of .05 using a two-sided two-sample *t* test. A difference of 50 minutes and assumed standard deviations of 60 minutes for laparoscopic and robotic operative times were chosen based on previously published literature.^{7,8,18}

Primary and secondary outcomes were analyzed according to the original treatment assignment (intent to treat). The analysis of the primary outcome (operative time) was performed using the Student’s *t* test and included all participants who were randomized and underwent surgery. To evaluate the potential influence of those participants who were randomized but withdrew before surgery, we also performed this comparison for all randomized patients imputing the missing operative time data of those participants who did not undergo surgery using the method of Brown, whereby the



missing values are imputed with the median value of the control (laparoscopic) group and compared using the Wilcoxon rank-sum test.¹⁹ The relationship between the cumulative number of cases performed by each surgeon and the operating room times (learning curve) were assessed using Pearson's correlation coefficient. Secondary outcomes (postoperative pain, functional activity, bowel and bladder symptoms, quality of life, anatomic vaginal support, and cost from a healthcare system perspective) were compared using two-sided Pearson's chi square for dichotomous variables and two-sided Student's *t* tests for parametric continuous variables or Wilcoxon rank-sum test for nonparametric continuous or ordinal variables. Variables were assessed for normality using quantile–quantile plots. Number of days using pain medications (NSAIDs and narcotics) were compared using time-to-event analysis and analyzed using the log-rank test.

Costs were considered from a healthcare system perspective and did not include costs incurred to the

individual patient or additional societal costs. Cost data were collected from the health systemwide cost-based accounting system for the surgery, hospitalization, and surgery-related inpatient and outpatient care through the 6-week postoperative visit. The cost-based accounting system uses a formula to calculate the estimated total costs for the procedure based on estimated direct and indirect costs. Costs did not include the initial purchase and maintenance costs of the da Vinci robot or the laparoscopic equipment. All charges are presented in 2011 U.S. dollars. Costs were compared between robotic and laparoscopic sacrocolpopexy using two-sided *t* tests. Statistical analysis (authors M.D.B. and A.F.) was performed with JMP 8.0.

RESULTS

Seventy-eight patients were enrolled and randomized in this trial: 38 to laparoscopic sacrocolpopexy and 40 to robotic sacrocolpopexy. Allocation and follow-up are displayed in Figure 2. Thirty-three patients underwent

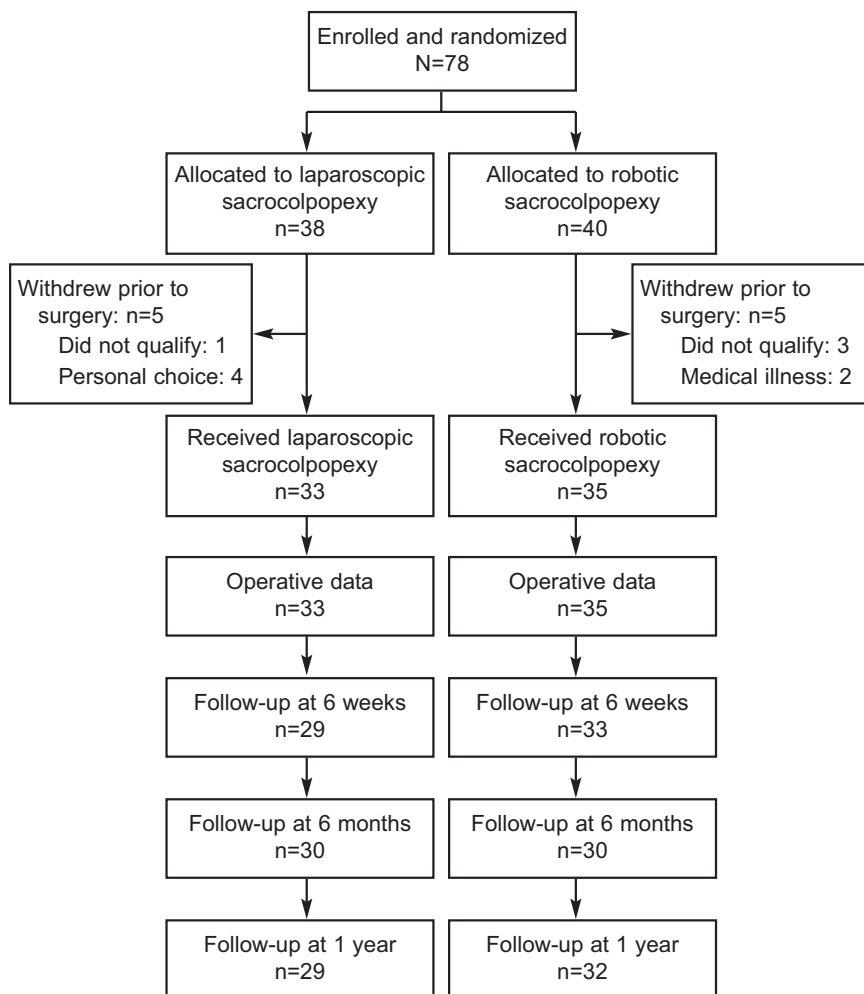


Fig. 2. Allocation and follow-up in the trial.

Paraiso. Laparoscopic and Robotic Sacrocolpopexy. Obstet Gynecol 2011.



Table 1. Patient Demographics and Baseline Data

| | Laparoscopic Sacrocolpopexy (n=38) | Robotic Sacrocolpopexy (n=40) |
|--------------------------------------|------------------------------------|-------------------------------|
| Age (y) | 60±11 | 61±9 |
| Parity | 2 (0–7) | 3 (1–5) |
| Body mass index (kg/m ²) | 29±5 | 29±5 |
| Hormone therapy use | 19 (59) | 13 (41) |
| Race | | |
| White | 34 (92) | 36 (90) |
| African American | 2 (6) | 2 (5) |
| Other | 1 (2) | 2 (5) |
| Insurance status | | |
| Private | 27 (77) | 27 (69) |
| Medicaid or Medicare | 7 (20) | 12 (31) |
| None | 1 (3) | 0 (0) |
| Charlson Comorbidity Index | | |
| 0 | 29 (81) | 33 (83) |
| 1 | 3 (8) | 2 (5) |
| Greater than 1 | 4 (11) | 5 (12) |
| Current smoker | 2 (6) | 4 (10) |
| Prior hysterectomy | 37 (97) | 36 (90) |
| Prior pelvic reconstructive surgery | 16 (42) | 23 (58) |

Data are mean±standard deviation, median (range), or n (%). No statistically significant differences were noted between laparoscopic and robotic arms for other variables. Numbers do not add to total N as a result of missing data.

laparoscopy with one participant requiring conversion to laparotomy for a large iliac aneurysm obstructing the presacral space and one participant undergoing conversion to a vaginal approach as a result of an obliterated cul de sac from previous rectosigmoid diverticulitis. Thirty-five patients underwent robotic surgery with three intraoperative conversions to an alternative ap-

proach: one laparotomy for repair of two cystotomies and injury to the sigmoid colon and two laparoscopies for robot malfunction (one for a dysfunctional robotic arm and another for console limited to vision through one eyepiece that could not be resolved). Beyond this, there were no protocol violations.

There were no differences in demographic and preoperative anatomic and functional data between groups (Table 1). Concomitant incontinence surgery among the laparoscopic and robotic groups was performed in 23 (70%) compared with 25 (71%), rectocele repair in 16 (48%) compared with 10 (29%), adhesiolysis greater than 45 minutes in 17 (52%) compared with 14 (40%), and conversion to laparotomy or vaginal approach in two (7%) compared with three (9%), respectively. There were no differences between groups in type or number of concomitant procedures performed with sacrocolpopexy.

Operating room times are listed in Table 2. There were significantly longer operative times in the robotic group compared with the laparoscopic group in all parameters measured: sacrocolpopexy time (mean difference +67 minutes, 95% confidence interval [CI] 43–89, *P*<.001), sacrocolpopexy suturing time (mean difference +31 minutes, 95% CI 20–41, *P*<.001), total operative time (mean difference +66 minutes, 95% CI 43–90, *P*<.001), operating room time (mean difference +66 minutes, 95% CI 42–91, *P*=.001), and anesthesia time (mean difference +65 minutes, 95% CI 40–89, *P*<.001). Imputing the missing operative time data for the nine patients who were randomized but did not undergo surgery did not change these results (mean total

Table 2. Operative Times and Hospital Data

| | Laparoscopic Sacrocolpopexy (n=33) | Median (Range) | Robotic Sacrocolpopexy (n=35) | Median (Range) | Mean Difference (95% CI) | <i>P</i> |
|------------------------------------|------------------------------------|-----------------|-------------------------------|----------------|--------------------------|----------|
| Sacrocolpopexy time (min) | 162±47 | 155 (90–232) | 227±47 | 224 (134–304) | 67 (43–89) | <.001 |
| Sacrocolpopexy suturing time (min) | 68±16 | 66 (42–107) | 98±22 | 93 (70–157) | 31 (20–41) | <.001 |
| Docking time (min) | N/A | N/A | 14±8 | 12 (3–37) | N/A | N/A |
| Additional procedure time (min) | 44±37 | 47 (0–138) | 31±31 | 21.5 (0–149) | -12 (-29 to 4) | .14 |
| Total operating time (min) | 199±46 | 196 (109–329) | 265±50 | 257 (191–381) | 66 (43–90) | <.001 |
| Anesthesia time (min) | 256±52 | 248 (171–390) | 321±52 | 305 (234–465) | 65 (40–89) | <.001 |
| Operating room time (min) | 284±49 | 279.5 (192–402) | 349±51 | 340 (278–479) | 66 (42–91) | <.001 |
| Hospital stay (h) | 34±11 | 29 (15–65) | 43±37 | 36 (19–240) | 9 (-4 to 23) | .17 |

CI, confidence interval; N/A, not applicable.

Data are mean±standard deviation unless otherwise specified.

Measured times may overlap and thus are not additive components of time.

Anesthesia time: time that the participant was under anesthesia from beginning of induction to extubation. Docking time: docking applicable only to the robotic approach. Laparoscopic suturing time: time from start of suturing mesh on the vagina to closure of the peritoneum over the mesh. Operating room time: time the participant was in the operating room. Other procedure time: time from incision to closure of other procedures. Sacrocolpopexy time: time from incision to closure of sacrocolpopexy. Total operating time: time from incision to skin closure of all procedures.



Table 3. Intraoperative and Postoperative Complications

| Complication | Laparoscopic Sacrocolpopexy (n=33) | Robotic Sacrocolpopexy (n=35) | P |
|---|------------------------------------|-------------------------------|------|
| Intraoperative | | | |
| Cystotomy | 2 (6) | 2 (6) | >.99 |
| Enterotomy | 0 | 1 (3) | .49 |
| Corneal abrasion | 0 (0) | 1 (3) | >.99 |
| Postoperative | | | |
| Urinary tract infection | 3 (9) | 5 (14) | .71 |
| Small bowel obstruction | 0 (0) | 2 (6) | .49 |
| Wound infection | 0 (0) | 2 (6) | .49 |
| Erosion | 0 (0) | 2 (6) | .49 |
| Abdominal wall pain necessitating trigger point injection | 0 (0) | 3 (9) | .24 |
| Abscess | 1 (3) | 1 (3) | >.99 |

Data are n (%) unless otherwise specified. One of the erosions was from tension-free vaginal tape.

case time with imputed values: 199 compared with 265 minutes, $P<.001$) There were no differences among groups with respect to additional procedure times. Analysis of the relationship between the cumulative number of cases performed and the operating room times (learning curve) yielded no significant correlations between the case number and total case time when stratified by laparoscopic compared with robotic approach or when each approach was stratified by surgeon (correlation coefficients .03 and .12, $P=.48$ and .89 for each surgeon). Thus, operative time did not appear to decrease with additional operative experience for either laparoscopic or robotic cases. Finally, there were no differences between groups with respect to intraoperative complications and postoperative complications as summarized in Table 3.

Six-week postoperative visual analog scales for pain at rest, pain with activity, and unpleasantness of pain are summarized in Figure 3. Participants who underwent robotic sacrocolpopexy rated their pain at rest and during normal activities as significantly greater and had greater unpleasant pain than laparoscopy participants from weeks 3–5 after surgery. Individuals who underwent robotic sacrocolpopexy required NSAIDs significantly longer after surgery than those who underwent the laparoscopic approach (median days [interquartile range] on NSAIDs=20 [9–36] compared with 11 [3–21] days, $P<.005$), whereas narcotic use (6 [1–15] compared with 6 [2–13] days, $P=.92$) and return to normal activi-

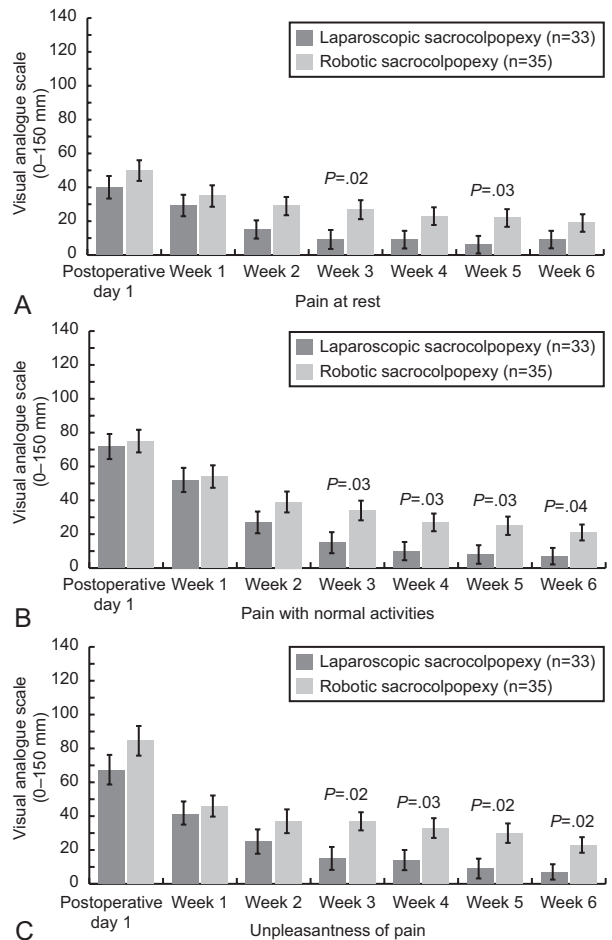


Fig. 3. Six-week postoperative visual analog scale scores (error bars indicate standard error) for pain at rest (A), pain with activity (B), and unpleasantness of pain (C) between laparoscopic and robotic sacrocolpopexy.

Paraiso. Laparoscopic and Robotic Sacrocolpopexy. *Obstet Gynecol* 2011.

ties and activity assessment scale scores were similar between groups (Table 4).

Postoperative Pelvic Organ Prolapse Quantitative stage and quality-of-life questionnaires at baseline, 6 months, and 1 year after surgery are summarized in Tables 5 and 6, respectively. There were no differences in anatomic outcome or quality-of-life measures between the laparoscopic and robotic groups.

Robotic sacrocolpopexy (mean \$16,278±\$3,326) cost more than laparoscopic sacrocolpopexy (mean \$14,342±\$2,941) with a mean difference of +\$1,936 (95% CI, \$417–\$3,454, $P=.008$). The discrepancy in cost was driven primarily by the difference in operating room costs (mean difference +\$1,667, 95% CI \$448–\$2,885, $P=.008$), because hospitalization (mean difference +\$271, 95% CI –\$419 to \$963, $P=.43$)



Table 4. Activity Scales

| | Laparoscopic Sacropopexy (n=33) | Robotic Sacropopexy (n=35) | <i>P</i> |
|---|---------------------------------------|----------------------------------|----------|
| Return to normal activities (0–100 mm visual analog scale) | | | |
| Week 1 | 22 (0–80) | 21 (0–86) | .86 |
| Week 2 | 35 (0–85) | 40 (0–96) | .82 |
| Week 3 | 55 (2–100) | 49 (5–100) | .49 |
| Week 4 | 71 (2–100) | 65 (10–100) | .67 |
| Week 5 | 76 (0–100) | 77 (19–100) | .99 |
| Week 6 | 88 (2–100) | 85 (13–100) | .43 |
| Activity Assessment Scale (0 [no limitation] to 100 [severely limited]) | | | |
| Week 1 | 28 (4–68) | 28 (2–67) | .41 |
| Week 2 | 12 (0–64) | 20 (0–75) | .18 |
| Week 4 | 2.5 (0–48) | 7 (0–70) | .17 |
| Month 6 | 0 (0–22) | 0 (0–64) | .45 |

Data are median (range) unless otherwise specified.

and 6-week postoperative care (mean difference –\$3, 95% CI –\$100 to \$94, *P*=.95) costs were similar between the two groups.

DISCUSSION

Physicians and patients often embrace new technologies before their clinical and economic implications are fully understood.²⁰ The number of robotic-assisted procedures performed worldwide nearly tripled between

2007 and 2010, from 80,000 to 205,000, whereas the number of da Vinci robotic systems sold grew from 800 to approximately 1,400 over a similar time period.²⁰ This increase across a range of surgical subspecialties is largely driven by robotic surgery's touted benefits of enhanced surgeon dexterity, three-dimensional vision, motion scaling, improved ergonomics, and direct-to-consumer marketing.²¹ However, it remains unclear if the addition of robotic assistance translates into better clinical outcomes when compared with conventional laparoscopy. A recent MEDLINE search from 1996–2011 using the terms “robotic surgery,” “randomized trial,” and “randomized controlled trial” identified no completed randomized controlled trials comparing robotic and conventional laparoscopic procedures to date. This is the first randomized clinical trial comparing robotic with conventional laparoscopic surgery in gynecology. This study demonstrates that despite its widespread adoption, a robotic-assisted approach to sacropopexy results in a longer operating time, increased postoperative pain, and significant added expense with no clear advantage in pelvic floor function or anatomy 1 year after surgery compared with a conventional laparoscopic approach.

The excess operative time observed with the robotic-assisted approach is consistent with recently published retrospective data.²² Given that robotic assistance is advocated as a means of facilitating the more technically difficult aspects of the procedure such as suturing, it is notable that suturing took an additional 31 minutes in robotic-assisted cases. Docking the robot, a step unique to the robotic approach, accounted for only 14 of the additional 67 minutes required to complete a

Table 5. Anatomic Data*

| | Baseline | | 6 Months | | 1 Year | |
|--|---------------------------------------|----------------------------------|---------------------------------------|----------------------------------|---------------------------------------|----------------------------------|
| | Laparoscopic Sacropopexy (n=36) | Robotic Sacropopexy (n=39) | Laparoscopic Sacropopexy (n=26) | Robotic Sacropopexy (n=28) | Laparoscopic Sacropopexy (n=23) | Robotic Sacropopexy (n=26) |
| Pelvic Organ Prolapse Quantitative stage | | | | | | |
| 0–1 | 0 (0) | 0 (0) | 23 (88) | 26 (93) | 21 (91) | 23 (88) |
| 2 | 11 (31) | 11 (28) | 3 (12) | 2 (7) | 2 (9) | 3 (12) |
| 3 | 22 (61) | 27 (69) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| 4 | 3 (8) | 1 (3) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Pelvic Organ Prolapse Quantitative measurement | | | | | | |
| Ba | 2 (–3 to 9) | 2 (–3 to 5) | –3 (–3 to –1) | –3 (–3 to 0.5) | –3 (–3 to 0) | –2 (–3 to –1) |
| Bp | 0 (–3 to 9) | 1 (–3 to 5) | –3 (–3 to –1) | –3 (–3 to 0) | –3 (–3 to 0) | –3 (–3 to 0) |
| C | 0 (–5 to 7) | 0 (–4 to 6) | –10 (–11 to –7) | –9 (–11 to –6) | –10 (–11 to –5) | –9 (–11 to –6) |
| TVL | 9 (7–11) | 9 (6–11) | 10 (8–11) | 10 (7–11) | 10 (8–12) | 10 (7–11) |

Ba, most dependent point of the anterior vaginal wall 3 cm above the hymen to the apex; Bp, most dependent point of the posterior vaginal wall 3 cm above the hymen to the apex; C, measurement of the vaginal apex in relationship to the hymen; TVL, total vaginal length.

* There are no statistically significant differences between laparoscopic and robotic values for any of these parameters at baseline, 6-month, or 12-month follow-up.



Table 6. Quality-of-Life Data

| | Baseline | | 6 Months | | 12 Months | |
|--|---------------------|----------------|---------------------|----------------|---------------------|----------------|
| | Laparoscopic (n=38) | Robotic (n=40) | Laparoscopic (n=30) | Robotic (n=30) | Laparoscopic (n=29) | Robotic (n=32) |
| Pelvic Floor Distress Inventory-20 | 117 (17–248) | 128 (0–267) | 29 (0–71) | 22 (0–101) | 38 (0–226) | 44 (0–161) |
| Prolapse Subscale | 46 (8–87) | 50 (0–100) | 8 (0–33) | 0 (0–67) | 8 (0–67) | 6 (0–67) |
| Colorectal Subscale | 22 (0–86) | 31 (0–84) | 9 (0–37) | 7 (0–53) | 6 (0–84) | 18 (0–67) |
| Urinary Subscale | 50 (0–100) | 44 (0–100) | 8 (0–42) | 8 (0–71) | 8 (0–84) | 8 (0–67) |
| Pelvic Floor Impact Questionnaire | 40 (0–262) | 63 (0–271) | 0 (0–67) | 0 (0–138) | 0 (0–167) | 0 (0–124) |
| Prolapse Subscale | 12 (0–80) | 21 (0–100) | 0 (0–67) | 0 (0–138) | 0 (0–56) | 0 (0–62) |
| Colorectal Subscale | 4 (0–81) | 14 (0–100) | 0 (0–24) | 0 (0–48) | 0 (0–60) | 0 (0–33) |
| Urinary Subscale | 24 (0–100) | 28 (0–100) | 0 (0–22) | 0 (0–62) | 0 (0–61) | 0 (0–62) |
| Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 | 19 (4–38) | 20 (3–36) | 12 (5–27) | 16 (2–25) | 11 (3–22) | 16 (3–27) |
| EQ-5D | .82 (.38–1.0) | .80 (.26–1) | 1 (.71–1) | 1 (.52–1) | .84 (.43–1) | 1 (.47–1) |
| EQ-5D Visual Analog Scale | 75 (0–94) | 80 (22–100) | 89 (40–100) | 90 (30–100) | 85 (20–98) | 90 (30–100) |
| Activity Assessment Scale | 18 (0–53) | 16 (0–71) | 0 (0–23) | 0 (0–65) | 0 (0–43) | 0 (0–31) |

Data are median (range).

There are no statistically significant differences between laparoscopic and robotic values for any of these parameters at baseline, 6-month, or 12-month follow-up.

robotic sacrocolpopexy. Thus, other aspects of the robotic approach such as instrument placement and exchange, robotic arm adjustment, and team communication likely contribute to the observed discrepancy in operative time and should be considered in future trials of robotic surgery.

Although many surgeons assume robotic-assisted surgical techniques are easier to learn than advanced laparoscopic skills, multiple studies show that this benefit may only pertain to novice surgeons.^{23,24} In multiple studies evaluating new technically challenging tasks, novice surgeons demonstrated increased proficiency with robotic surgery when compared with a conventional laparoscopic approach, whereas experienced surgeons demonstrate equal proficiency between the two approaches. These findings give credence to the argument that robotic assistance appears to eliminate the early learning curve for novices but may not provide advantages for experienced laparoscopic surgeons. The expertise in both minimally invasive routes for sacrocolpopexy in our institution is not only uncommon among individual surgeons, but also in training programs. The fact that operative time did not appear to decrease with additional operative experience for either laparoscopic or robotic cases in our hands supports similar expertise in both routes. Although many educators believe that advanced conventional laparoscopy is difficult to teach, we believe that novice surgeons would be ideally served by comprehensive training in both advanced laparoscopic surgery and robotic training. Many surgeons have used robotic-assisted laparoscopy as a stepping stone to advanced conventional laparoscopy.

Although participants in this trial undergoing robotic and laparoscopic sacrocolpopexy had similar peri-

operative morbidity, anatomic, and functional outcomes up to 1 year after surgery, the robotic group reported more pain with activity 3–5 weeks postoperatively and had a longer duration of postoperative NSAID use. The increase in pain experienced by the robotic group may be the result of the additional operating port required by the robotic cases, the larger size or different location of the robotic trocars, longer operating time, or the robotic rather than manual manipulation of the trocars throughout a longer procedure. Because polypropylene mesh was implanted in all of the patients for sacrocolpopexy, we do not believe that it was the mesh itself that caused the difference in postoperative pain between groups.

The excess expense associated with robotic assistance (+\$1,936) is consistent with published data and largely reflects increased costs incurred in the operating room with similar hospitalization and postoperative care costs observed between the two groups.^{25,26} However, this provides a conservative estimate of cost differences, because inclusion of the approximate \$1.85 million purchase price and \$100,000 of annual maintenance costs of the Intuitive da Vinci Surgical System exceeds the costs associated with the purchase and maintenance of conventional laparoscopic equipment and would further inflate the added expense observed with the robotic approach.

The strengths of this investigation include its prospective, randomized design, use of validated questionnaires, and 1-year follow-up of women undergoing a minimally invasive sacrocolpopexy procedure. Both patients and providers performing follow-up examinations were also blinded to the participant's treatment assignment. A limitation of the study is that it is inadequately powered to assess for small differ-



ences in surgical morbidity or long-term anatomic or functional outcomes. The study also includes patients treated in a high-volume academic referral center and reflects the outcomes of surgeons with both advanced laparoscopic and robotic skills, who are responsible for training fellows, residents, and medical students and as such may not be readily generalizable to other clinical settings. Finally, surgeon ergonomics and comfort were not assessed.

In this prospective randomized trial, robotic-assisted sacrocolpopexy was associated with longer operative times, increased postoperative pain, and additional expense without improvement in any clinical outcome measure during the perioperative period, 6 months, or at 1-year follow-up when compared with the conventional laparoscopic approach. Although robotic surgical systems may accelerate the learning curve of less experienced surgeons appropriately interested in offering patients a minimally invasive approach to sacrocolpopexy, it does not offer a clear advantage for surgeons experienced in advanced laparoscopy. Given the substantial added costs of robotic assistance, it is important for physicians, medical training programs, and health systems to consider the implications of widespread adoption of robotic technology and the relative use when compared with conventional laparoscopy. Future investigations are warranted to discern the best applications for robotic technology in benign gynecologic surgery.

REFERENCES

- Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997;89:501-6.
- Subak LL, Waetjen LE, van den Eeden S, Thom DH, Vittinghoff E, Brown JS. Cost of pelvic organ prolapse surgery in the United States. *Obstet Gynecol* 2001;98:646-51.
- Nygaard IE, McCreery R, Brubaker L, Connolly AM, Cundiff G, Weber AM, et al. Abdominal sacrocolpopexy: a comprehensive review. *Obstet Gynecol* 2004;104:805-23.
- Maher C, Baessler K, Glazener CM, Adams EJ, Hagen S. Surgical management of pelvic organ prolapse in women: a short version Cochrane review. *Neurourol Urodyn* 2008;27:3-12.
- Cosson M, Rajabally R, Bogaert E, Querleu D, Crepin G. Laparoscopic sacrocolpopexy, hysterectomy, and burch colposuspension: feasibility and short-term complications of 77 procedures. *JLS* 2002;6:115-9.
- Nezhat CH, Nezhat F, Nezhat C. Laparoscopic sacral colpopexy for vaginal vault prolapse. *Obstet Gynecol* 1994;84:885-8.
- Ostrzenski A. Laparoscopic colposuspension for total vaginal prolapse. *Int J Gynaecol Obstet* 1996;55:147-52.
- Paraiso MF, Walters MD, Rackley RR, Melek S, Hugney C. Laparoscopic and abdominal sacral colpopexies: a comparative cohort study. *Am J Obstet Gynecol* 2005;192:1752-8.
- Klauschie JL, Suozzi BA, O'Brien MM, McBride AW. A comparison of laparoscopic and abdominal sacral colpopexy: objective outcome and perioperative differences. *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:273-9.
- Hsiao KC, Latchamsetty K, Govier FE, Kozlowski P, Kobashi KC. Comparison of laparoscopic and abdominal sacrocolpopexy for the treatment of vaginal vault prolapse. *J Endourol* 2007;21:926-30.
- Geller EJ, Siddiqui NY, Wu JM, Visco AG. Short-term outcomes of robotic sacrocolpopexy compared with abdominal sacrocolpopexy. *Obstet Gynecol* 2008;112:1201-6.
- Reza M, Maeso S, Blasco JA, Andradas E. Meta-analysis of observational studies on the safety and effectiveness of robotic gynaecological surgery. *Br J Surg* 2010;97:1772-83.
- Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996;175:10-7.
- Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol* 2005;193:103-13.
- Barber MD, Kuchibhatla MN, Pieper CF, Bump RC. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. *Am J Obstet Gynecol* 2001;185:1388-95.
- Rogers RG, Coates KW, Kammerer-Doak D, Khalsa S, Qualls C. A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14:164-8; discussion 168.
- McCarthy M Jr, Jonasson O, Chang CH, Pickard AS, Giobbie-Hurder A, Gibbs J, et al. Assessment of patient functional status after surgery. *J Am Coll Surg* 2005;201:171-8.
- Elliott DS, Frank I, DiMarco DS, Chow GK. Gynecologic use of robotically assisted laparoscopy: sacrocolpopexy for the treatment of high-grade vaginal vault prolapse. *Am J Surg* 2004;188(suppl):52S-6S.
- Brown MB. A test for the difference between two treatments in a continuous measure of outcome when there are dropouts. *Control Clin Trials* 1992;13:213-25.
- Barbash GI, Glied SA. New technology and health care costs—the case of robot-assisted surgery. *N Engl J Med* 2010;363:701-4.
- Shukla PJ, Scherr DS, Milsom JW. Robot-assisted surgery and health care costs. *N Engl J Med* 2010;363:2174; author reply 2176.
- Tan-Kim J, Menefee SA, Luber KM, Nager CW, Lukacz ES. Robotic-assisted and laparoscopic sacrocolpopexy: comparing operative times, costs, and outcomes. *Female Pelv Med Reconstr Surg* 2011;17:44-9.
- Yohannes P, Rotariu P, Pinto P, Smith AD, Lee BR. Comparison of robotic versus laparoscopic skills: is there a difference in the learning curve? *Urology* 2002;60:39-45; discussion 45.
- Chandra V, Nehra D, Parent R, Woo R, Reyes R, Hernandez-Boussard T, et al. A comparison of laparoscopic and robotic assisted suturing performance by experts and novices. *Surgery* 2010;147:830-9.
- Patel M, O'Sullivan D, Tulikangas PK. A comparison of costs for abdominal, laparoscopic, and robot-assisted sacral colpopexy. *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:223-8.
- Judd JP, Siddiqui NY, Barnett JC, Visco AG, Havrilesky LJ, Wu JM. Cost-minimization analysis of robotic-assisted, laparoscopic, and abdominal sacrocolpopexy. *J Minim Invasive Gynecol* 2010;17:493-9.

