108

Paraiso M F R[1], Jelovsek J E[1], Frick A[1], Chen C C G[2], Barber M D[1]
1. *Cleveland Clinic,* ***2.*** *Johns Hopkins*

CONVENTIONAL LAPAROSCOPIC VERSUS ROBOTIC-ASSISTED LAPAROSCOPIC SACRAL COLPOPEXY: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

The aim of this prospective single-blinded randomized controlled trial is to compare the perioperative, anatomic, functional, and quality of life outcomes of conventional laparoscopic and robotic-assisted laparoscopic sacrocolpopexy in patients with Stages 2-4 apical vaginal prolapse. The primary outcome measure was operative time from incision to closure. Our null hypothesis was that there would be no difference in operating time between the two techniques. Secondary outcomes included postoperative pain and activity, return to normal activities, perioperative complications, and anatomic and functional outcomes 6 months after surgery.

Study design, materials and methods

This is a single-center prospective single-blinded randomized controlled trial. CONSORT guidelines were followed and all participants completed an informed consent process. Subjects were eligible if they were $\geq$ 21 years of age, had post-hysterectomy vaginal apex prolapse with overall POP-Q Stage 2-4, and desired a minimally invasive approach to sacral colpopexy. Subjects were excluded if they were not candidates for general anesthesia, underwent a prior sacral colpopexy or rectopexy, had a suspicious adnexal mass or other factors that may indicate pelvic malignancy, reported a history of pelvic inflammatory disease, were morbidly obese (body mass index $\geq$ 40 kg/m^2), or were scheduled for a concomitant laparoscopic rectopexy with or without sigmoid resection. Randomization was stratified by surgeon and subjects were randomized to undergo either conventional laparoscopic sacrocolpopexy (L/S group) or robotically-assisted laparoscopic sacrocolpopexy (Robot group) using the da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA). Concomitant laparoscopic, anti-incontinence, or vaginal reconstructive procedures (for anterior or posterior prolapse) were performed at the primary surgeon's discretion. Subjects were blinded to treatment assignment for 12 months. All surgeries were performed by one of two surgeons who have extensive experience with laparoscopic sacrocolpopexy and had undergone training in robotic surgery. Each surgeon completed a minimum of 5 robotic-assisted sacrocolpopexy procedures prior to study initiation. Total time in the operating room, time under anesthesia, total operating time (incision to closure), total time to perform the sacrocolpopexy, time required to dock the robot, and time required for suturing during the sacrocolpopexy were recorded at the time of surgery by study personnel. 32 subjects in each arm (total n=64) were needed to detect a difference of 30 minutes or more in operating time between conventional laparoscopic versus robotic-assisted laparoscopic sacrocolpopexy with 90% power and a significance level of .05. During the six week postoperative period, the subjects completed a pain and activity diary that included amount of daily pain medication and activity level. They also completed validated surgical pain scales weekly and a validated postoperative activity scale at weeks 1, 2, and 4. Patients underwent a POP-Q examination and completed the Pelvic Floor Distress Inventory-20 (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7), Prolapse/Incontinence Sexual Questionnaire -12 (PISQ-12), and the EQ-5D at baseline and 6 months after surgery. Treatment groups were compared using the intent to treat principle.

Results

Seventy-six patients enrolled and 67 subjects were randomized and underwent surgery (L/S n= 32; Robot n = 35). Conversion to laparotomy or vaginal surgery occurred in two subjects in the L/S group (cystotomy (1), severe adhesions (1)) and three subjects in the Robot group (technical problems with the robot (1), severe adhesions (2)). Total time in the operating room, time under anesthesia, total operating time, total time for sacrocolpopexy, and total suturing time were all significantly greater in the robot-assisted group compared to the L/S group (see table). There was no significant association between the number of cases a surgeon performed and any of the studied times. No significant difference in the frequency of complications was noted between groups. There was no difference in length of stay or hospital pain medication requirement. Pain scale scores were similar on postoperative day 1 and week 1; however, subjects who received robotic-assisted surgery had significantly greater pain at rest and with activity during weeks 3 through 6 after surgery. The median (range) number of days requiring narcotic pain medication was similar (5.5 (0-14.3) vs. 4.5 (1-10.5), p=.77) between the two groups. However, median number of days using non-steroidal anti-inflammatory drugs (NSAIDS) was greater for the robotic-assisted group (19.5 (5-30) vs. 9.5 (0-12.8), p=.005). Both groups demonstrated significant improvements in anatomic outcomes and pelvic floor function six months after surgery without differences between groups.

OPERATING ROOM TIMES*

	Laparoscopic Sacrocolpopexy (n=32)	**Range**	**Robotic Sacrocolpopexy (n=35)**	**Range**	**Mean Difference (95% CI)**	**P**
Total Colpopexy Time	161 $\pm$ 47	90-232	227 $\pm$ 47	134-304	67 (44-90)	<.0001
Suturing Time	67 $\pm$ 15	42-107	98 $\pm$ 22	70-157	31 (22-42)	<.0001

Docking Time	n/a	n/a	14 ± 8	3-37	n/a	
Additional Procedure Time	43 ± 37	0-138	31 ± 30	0-149	-12 (-29-5)	.08
Anesthesia Time	255 ± 52	171-390	321 ± 52	234-389	66 (41-92)	<.0001
Total Case Time	198 ± 46	109-329	265 ± 50	191-381	68 (44-91)	<.0001

*Data are presented as mean minutes ± standard deviation.

Interpretation of results

All operating room time parameters measured were longer in the robotic-assisted group compared to the conventional laparoscopy group. There was no significant association between a surgeon's case volume and any of the measured operating times for either participating surgeon suggesting a lack of significant procedural learning that would affect operative time during the study. The robotic-assisted group also required NSAIDS for a significantly greater number of postoperative days and reported significantly greater pain at rest and at activity during postoperative weeks 3 to 6 compared to the conventional laparoscopic group. This may be a result of additional trocars, location of trocars, traction placed on the trocar, slightly larger incisions, and/or longer operative times in the robotic-assisted group.

Concluding message

In surgeons who are experienced with conventional laparoscopic sacral colpopexy, robotic-assistance results in longer operating times and increased pain weeks 3 through 6 after surgery compared to the conventional laparoscopic approach with no difference in anatomic or functional outcomes 6 months after surgery.

Specify source of funding or grant	**Internal funding from Cleveland Clinic**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov Indentifier:NCT00551993**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board of the Cleveland Clinic**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**