ELSEVIER

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Original Article

Robot-assisted Laparoscopic Myomectomy Is an Improvement Over Laparotomy in Women with a Limited Number of Myomas

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ABSTRACT **Study Objective:** To compare surgical and immediate postoperative results of robot-assisted laparoscopic myomectomy vs myomectomy via laparotomy in patients with 3 myomas or fewer.
Design: Case-control (Canadian Task Force classification II-2).
Setting: University hospital.
Patients: Seventy-five women who had undergone robotic-assisted laparoscopic myomectomy were compared with patients who had undergone myomectomy via laparotomy.
Interventions: Medical records were reviewed for surgical and postoperative variables. Both groups had 3 myomas or fewer confirmed at preoperative magnetic resonance imaging or final pathology report.
Measurements and Main Results: No significant differences were observed between patients insofar as preoperative demographic data. There was a significant increase in mean duration of surgery for robotic-assisted myomectomy. There was a significant decrease in blood loss, change in hematocrit concentration on postoperative day 1, length of stay, number of days to regular diet, and febrile morbidity in robotic-assisted myomectomies. There were no significant differences in operative or postoperative complications.
Conclusion: Although robotic-assisted myomectomy took substantially longer, most of the other variables improved in comparison with similar procedures performed via laparotomy. Journal of Minimally Invasive Gynecology (2010) 17, 306–310

Keywords: Robotic assisted laparoscopic myomectomy; Myoma; Minimally invasive surgery

Since the first report of laparoscopic myomectomy by Semm [1], there has been debate about whether it is equivalent to myomectomy via laparotomy. Because most patients choose myomectomy as a means of uterine preservation to maintain fertility options, the most important result is the strength of the uterine scar after repair. Debate focuses on the quality of repair of the surgical incision. Hurst et al [2], in an exhaustive review of laparoscopic myomectomy, concluded that ''meticulous repair of the myometrium is essential for women considering pregnancy after laparoscopic myomectomy to minimize the risk of uterine rupture.'' When this surgery is performed via laparotomy, the defect is usually closed in layers. When the procedure is performed via laparoscopy, because of the limitations of fixed port placement, the repair is more likely to be completed using the bulk closure technique. The da Vinci robot (Intuitive Surgical, Inc., Sunnyvale, CA) enables 360-degree movement of the surgical head of the instrument. The enhanced surgical dexterity enables laparoscopic surgical closure of the uterine scar that can be done in layers and, therefore, better approximates that done via laparotomy. This was first reported by Advincula et al [3] in 2004.

The primary limitation of robotic surgery is lack of equivalent haptic perception to open surgery. Small intramural myomas not visible on the surface are unlikely to be found when the procedure is performed using a robot because of lack of manual palpation of the uterus. For this reason, when choosing patients as candidates for the robot-assisted laparoscopic approach, we limited it to patients with 3 myomas or fewer identified at preoperative magnetic resonance imaging

The authors have no commercial, proprietary, or financial interest in the products or companies described in this article.
Presented as a poster at the 35th Scientific Meeting of the Society of Gynecologic Surgeons, New Orleans, Louisiana, March 30–April 1, 2009.
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Submitted September 8, 2009. Accepted for publication January 14, 2010.
Available at www.sciencedirect.com and www.jmig.org

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doi:10.1016/j.jmig.2010.01.011

(MRI) to cause a deformity of the serosa and, therefore, able to be identified laparoscopically. If patients met this criteria and their uterus measured 20 weeks or less at examination, beginning in July 2005, they were offered robot-assisted laparoscopic myomectomy. The objective of this study was to compare the first 75 cases of robot-assisted laparoscopic myomectomy with a comparable cohort of patients who had undergone myomectomy via laparotomy.

Materials and Methods

From July 1, 2005, through July 1, 2008, 75 patients met the inclusion criteria and chose to undergo surgery via the robot-assisted procedure. Inclusion criteria consisted of a uterus less than or equal to 20 weeks in size at office examination and no more than 3 intramural myomas observed at preoperative MRI. Exclusion criteria included any substantial medical problems that limited the ability to undergo a prolonged laparoscopic procedure, and previous uterine surgery.

The goal for the robot-assisted laparoscopic procedures was to make them as similar as possible to those performed via laparotomy. Before uterine incision, all patients received subserosal injections of vasopressin, 20 U diluted in 50 mL of normal saline solution. In patients who underwent the robot-assisted procedure, this was performed with a spinal needle placed directly through the anterior abdominal wall or with a laparoscopic needle placed through the accessory port. In patients undergoing laparotomy, the uterine surgical incisions were closed with either 0 poliglecaprone 25 (Monocryl [Biosyn]) or 0 polyglactin 95 (Vicryl) sutures (both from Ethicon Inc., Somerville, NJ) per surgeon preference. In all patients undergoing robot-assisted laparoscopy, the incisions were closed with Vicryl sutures because of their greater ease of use laparoscopically compared with Monocryl sutures. All uterine incisions were covered with a cellulose film barrier (Interceed; Ethicon Inc.) at the end of the procedure. The procedures were performed in a university hospital. Myomectomies performed via laparotomy were completed by a variety of surgeons; most myomectomies and all robot-assisted laparoscopic procedures were performed by 1 surgeon (C.A.-W.). A senior gynecology resident participated in each case.

All robot-assisted procedures were performed via 4 laparoscopic ports. A 12-mm port was placed in the umbilicus through which the binocular camera was placed and attached to 1 of the arms of the robot. This was controlled by the primary surgeon from the remote booth. Two 8-mm ports were placed bilaterally in the lower quadrants, lateral to the rectus muscle. Arms of the robot were attached to both of these ports, and instruments were placed that were also controlled by the primary surgeon. An additional 12-mm port was placed in the left lower quadrant, lateral to the rectus muscle and either superiomedial or superiolateral to the 8-mm port. The position of this port differed only in an initial attempt to determine which location enabled greater ease of assistance from the resident at the surgical table. This port was used only by the assistant and enabled placement of the morcellator for removal of the detached myomas.

As a comparison group, we used a subset of patients who had undergone myomectomy via laparotomy. These patients were from our previously published study that examined the use of routine ketorolac postoperatively to reduce the incidence of postoperative fever [4]. The study was performed before the availability of robot-assisted laparoscopic myomectomy; thus, none of the patients were offered this technique. We identified 50 patients from this study who had 3 myomas or fewer at final pathologic analysis and who preoperatively would have also met criteria for robot-assisted myomectomy. This subgroup was used to compare surgical and postoperative outcomes with those in the robot-assisted laparoscopic myomectomy group.

Review of medical records was approved by our institutional review board (IRB). Statistical analysis was performed using commercially available software (SPSS Inc., Chicago, IL), the χ^2 test, and independent-sample t tests. Significance was set at $p = .05$.

Results

During the study, all 75 patients who met criteria for the robot-assisted procedure elected to that procedure. There were no conversions to laparotomy, and the results in all 75 patients were included for analysis.

Demographic data for the study patients and the historical cohort are given in Table 1. There were no significant differences between the groups in age, race/ethnicity, body mass index, parity, or preoperative depo-leuprolide use. Depo-leuprolide was not routinely used preoperatively before either type of surgery. It was, however, used in patients with a hematocrit concentration less than 30 to improve that concentration before surgery or had been administered by other physicians before patients were seen by the surgeon at our institution. Only 1 patient in the robot-assisted group received depo-leuprolide because she had a uterus 24 weeks in size but otherwise met criteria for the robot-assisted laparoscopic procedure. She received one 3-month dose, and the uterus decreased in size to 18 weeks, thereby making her a candidate for the robot-assisted procedure. Six patients in the laparotomy group received at least 1 dose of depo-leuprolide.

Operative and postoperative variables between the 2 groups are given in Table 2. There was a significant increase in duration of surgery when performed with the robot-assisted laparoscopic method, which was primarily attributed to the increased setup time required to dock and position the robot and instruments and the time required for morcellation of the myoma. No patient in either arm of the study had any anesthetic complications or developed a deep venous thrombosis. Neither the number of myomas removed nor the aggregate myoma weight differed between groups, which suggests that the surgical challenges were comparable.

The robot-assisted technique demonstrated significantly less estimated mean (SD) blood loss (226.32 [154.11,

Table 1
Demographic Data

	Robot-Assisted Group N=75 (st. dv) [95% CI]	Laparotomy Group N=50 (st. dv.) [95% CI]	P value
Mean Age (yrs)	36.48 (7.22) [22.33,50.63]	37.16 (5.35) [28.28, 46.14]	0.83
BMI (mean)	21.66 (3.69) [14.42, 28.89]	20.39 (4.10) [12.35, 28.43]	0.58
Ethnicity			
Caucasian	48	32	
African American	22	16	
Other	5	2	0.72
Parity (mean)	0.07 (0.36) [-0.64, 0.78]	0.08 (0.32) [-0.55, 0.71]	0.86
Pre-op Lupron doses (monthly average)	0.04 (0.5) [-0.79, 0.87]	0.60 (1.59) [-2.51, 3.72]	0.09

Table 2
Operative and Post-operative Variables

	Robot-Assisted Group N=75 (st. dv) [95% CI]	Laparotomy Group N=50 (st. dv.)	P value
Duration (min)	192.32 (68.22) [58.61, 326.03]	138.56 (55.24) [30.28, 246.83]	0.010
EBL	226.32 (154.11) [-271.73, 724.37]	459.00 (441.06) [-405.48, 1323.48]	0.009
Δ in Hct	5.11 (2.88) [-0.53, 10.75]	7.09 (4.14) [-1.02, 15.20]	0.050
Number of fibroids	2.35 (1.50) [-2.09, 6.79]	1.68 (0.79) [0.13, 3.22]	0.110
Fibroid mass (gms)	321.16 (243.87) [-156.82, 799.14]	331.54 (348.30) [-351.12, 1014.22]	0.840
Length of stay (days)	0.51 (0.67) [-0.80, 1.82]	3.28 (1.09) [1.14, 5.41]	0.000
Time to reg. diet (days)	0.85 (0.37) [0.12, 1.54]	2.30 (0.54) [1.24, 3.35]	0.000
Febrile morbidity (%)	1.33	38	0.000

58.61−326.03] mL vs 459.00 [441.06,−405.48-1323.48] mL; p = .009) and a smaller change in postoperative hematocrit concentration (5.11% [2.88%, –.53-10.75] vs 7.09% [4.14, – 1.02 -15.20]; p = .05). However this was not clinically significant because none of the patients in either group required a transfusion.

Length of stay was significantly decreased in the robot-assisted group (0.51 [0.67] days vs 3.28 [1.09] days; p = .001). The first 21 patients were routinely admitted to the hospital after the procedure, and discharged on postoperative day 1. Only 1 patient required a longer admission for pain control. Secondary to a change in policy by insurance companies, the last 54 patients were scheduled as outpatients and then given the option of admission after evaluation postoperatively in the recovery room. Of these patients, 40 elected to be discharged, and 14 remained and were discharged on postoperative day 1. In addition, time to tolerating a regular diet and percentage of patients with febrile morbidity was also decreased in the robot-assisted group. There were no significant differences in operative or postoperative complications.

Discussion

Surgeons constantly strive for more minimally invasive options for common procedures in an effort to decrease patient discomfort and recovery time. While this is an admirable goal, it is important to balance this with patient safety, both during the procedure and postoperatively. In addition, in attempting to be minimally invasive, the reliability of the surgical outcome must not be compromised. The standard for myomectomy surgery involves a layered closure of the uterus. While there has not been a good study comparing single-layer closure with multiple-layer closure after myomectomy, recent data from Durnwald and Mercer [5] demonstrated a significant increase in the percentage of women with uterine windows in the cesarean section scar at second cesarean section when the first was closed using single-layer vs 2-layer closure. Although the uterus is not in the same state during myomectomy, similar principles may be applied to myometrial healing in both cases.

We know from case reports that there is risk of uterine rupture in pregnancy with either technique, to our knowledge, no large randomized study has conclusively proved the benefit of one technique over the other. Three randomized controlled trials have compared laparoscopic vs abdominal myomectomy [6–8]. These studies demonstrated the benefits of laparoscopic surgery such as decreased postoperative pain, less blood loss, and shorter hospital stay; however, they did not provide much information about the risk of uterine rupture in pregnancy.

Two recent studies compared traditional laparoscopic vs robot-assisted myomectomy. Bedient et al [9]concluded that robot-assisted myomectomy was comparable to traditional laparoscopic techniques insofar as operating time, blood loss, length of stay, and complications. However, there were fewer uterine incisions and improved layered closure of the uterus, which may provide potential benefit against uterine rupture. Nezhat et al [10] concluded that there was no advantage of robot-assisted laparoscopic myomectomy compared with standard myomectomy. Both studies are limited in that they were not randomized and were retrospective.

There are several limitations to the present study; in particular, it is not a randomized control trial. However, the control group selected for this study was quite comparable to the group who underwent the robot-assisted procedure, but it cannot be known whether these patients would have opted for the robot-assisted procedure had it been offered to them at the time or if the procedure could have been completed for them successfully without conversion to laparotomy. In addition, while the senior surgeon (C.A.-W.) has no recollection of excluding patients for the robot-assisted approach because of an office examination that may have led to concern

about the ability to achieve completion via laparoscopy, this bias may have existed. Long-term clinical outcomes are not available. Given that myomectomy is a uterus-sparing procedure, fertility is an important outcome. Our IRB did not give permission to contact patients after the procedures. Therefore, the exact number of women who subsequently became pregnant is not known; however, anecdotally, we know of at least 10 patients who became pregnant after robotic myomectomy. We hope to ask our IRB in the future to provide this important long-term data.

It was not surprising that the duration of surgery was significantly greater for the robot-assisted procedure. This was due in part to the increased setup time required in robot-assisted laparoscopy and the time required to morcellate the myomas for removal once the uterus was repaired. This study represents the first 75 patients offered this surgical technique by the primary surgeon, and the procedure time has decreased as the surgeon has acquired more experience. The mean surgical time for the last 20 procedures was 176 minutes, resulting in an operative time closer to that of laparotomy. However, this is a substantial decrease from the first 15 cases, in which the mean surgical time was 231 minutes. It is possible that the surgical time will continue to decrease with increased experience, and may become comparable to that for laparotomy.

A decrease in estimated blood loss and change in hematocrit concentration represent 2 improvements associated with the robot-assisted approach. During laparoscopy, the surgical field is continuously subjected to externally increased pressure from the carbon dioxide used for abdominal distention; as a result, bleeding from small arterioles and veins is likely suppressed. In addition, dissection of the uterus is usually performed with a bipolar grasper through 1 port and a monopolar hook through the other. Bleeding is magnified by the laparoscope, and is more likely to be managed more quickly with either type of coagulation. While in this study there was no clear clinical benefit to decreased blood loss, as no patients received a transfusion, it may have contributed to the early discharge from the hospital for patients who underwent the robot-assisted procedure.

Unexplained fever is a known adverse effect of myomectomy. In a previous study [4], it was demonstrated that administration of ketorolac can significantly reduce the incidence of postoperative fever after and, hence, the additional workup and treatment that is often given to treat this phantom condition. In the present study, 19 patients in the laparotomy group exhibited a temperature greater than 101.0°F during their hospital stay. Only 10 of the 19 developed this temperature during postoperative day 1. The only found source of infection in any of these patients was a positive urine culture in 1 patient. All cultures were performed via spontaneous voiding, and in 9 of the 10, the culture was positive for common vaginal contaminates. Only 2 patients had a white blood cell count greater than 12. Even knowing that most of these fevers do not truly represent infection, 13 of the 19 patients received additional antibiotic therapy.

Only 1 patient in the robot-assisted group demonstrated a temperature higher than 101.0°F postoperatively. Perhaps that these temperature elevations were not detected inasmuch as all but 1 patient who underwent the robot-assisted procedure were discharged within 24 hours of completion of the procedure. These patients were told to monitor their temperature at home if they felt warm, but may not have detected temperatures higher than 101.0°F as well as would have occurred in the hospital. While infection can occur after surgery, the greatest risk seems to be in the skin incision. Given the small size of the incisions in the robot-assisted approach, this risk is likely decreased. It is probable that many of the patients in the laparotomy arm were unnecessarily treated with antibiotics and, therefore, were subjected to the additional risks of superfluous antibiotic therapy. Because none of the patients in the robot-assisted group had an elevated temperature, none were subjected to this risk.

Other than febrile morbidity, there were no other complications in the laparotomy group. The only complication in the robot-assisted group was in 1 patient who developed a supra-fascial hematoma from the right lateral port site. She remained hospitalized for 3 days to manage flank pain. Her hematocrit concentration stabilized at 27.9 on postoperative day 1, and she did not require a transfusion or any other therapy other than additional pain medication. The hematoma resolved spontaneously postoperatively.

A previous study by Advincula et al [11] compared both surgical outcomes as well as the financial effect of myomectomy by traditional laparotomy compared with the robot-assisted technique. This study had similar surgical outcomes including decreased estimated blood loss and length of stay. The financial comparison demonstrated that the initial hospital charges are higher and physician reimbursement is lower for robot-assisted surgery. However, as the costs secondary to depreciation of the robot decrease in combination with lower complication rates, length of stay, and nursing costs, robot-assisted technology may become the lower financial option. We did not perform a cost-benefit analysis in this study. One of the primary arguments against robot-assisted procedures and a reason that it is not more readily available for patients across the United States is its cost. The robot alone costs approximately $1 500 000. The instruments average between $200 and $250 per use, and we used 4 instruments per procedure. The instruments can each be used 10 times before the robot will no longer allow their use, and the average cost of each instrument is $2000 to $2500. Because most of the instruments used in laparotomy are reusable, the per-case operative cost is likely to be significantly higher for the robot-assisted procedure. However, the cost of cell saver is $1000 to $2000, and this currently only applies to laparotomy. More significant is the decrease in length of hospital stay and the lack of use of patient-controlled anesthesia. Both of these tremendously decrease the total hospital cost of the robot-assisted approach vs the laparotomy approach. A potentially quicker return to work may also increase the overall cost-effectiveness of the robot-assisted

technique. A full cost-effective analysis is planned for this technique in the future.

Myomectomy performed via a robot-assisted laparoscopic technique seems to be an improvement over laparotomy in a subset of patients with a small number of myomas for a variety of operative and immediately postoperative variables. Although operative time was longer, a decrease in blood loss, length of hospital stay, and patient discomfort make this an appealing option in patients with 3 myomas or fewer at preoperative MRI and a uterus that is less than 20 weeks in size. Further evaluation of the cost-effectiveness of the robot-assisted approach is necessary. A randomized trial would also better confirm the usefulness of this technique.

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