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Postoperative Outcomes After Robotic Versus Abdominal Myomectomy

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ABSTRACT

Background and Objectives: Differences in postoperative outcomes comparing robotic-assisted laparoscopic myomectomy (RALM) with abdominal myomectomy (AM) have rarely been reported. The objective of this study was to compare surgical, quality-of-life, and residual fibroid outcomes after RALM and AM.

Methods: Consecutive patients who underwent RALM (n = 16) were compared with AM patients (n = 23) presenting with a uterine size of <20 weeks. Study patients participated in a telephone interview at 6 weeks and underwent a no-cost ultrasonographic examination at 12 weeks after surgery to obtain quality-of-life and residual fibroid outcomes. Medical records were reviewed to obtain surgical outcomes.

Results: Longer operative times (261.1 minutes vs 124.8 minutes, $P < .001$) and a 3-fold unfavorable difference in operative efficiency (73.7 g vs 253.0 g of specimen removed per hour, $P < .05$) were observed with RALM compared with AM. Patients undergoing RALM had shorter lengths of hospital stay (1.5 days vs 2.7 days, $P < .001$). Reduction of patient symptoms and overall satisfaction were equal. RALM patients were more likely to be back to work within 1 month (85.7% vs 45.0%, $P < .05$). Residual fibroid volume in the RALM group was 5 times greater than that in the AM group (17.3 cm^3 vs 3.4 cm^3, $P < .05$).

Conclusion: RALM and AM were equally efficacious in improving patient symptoms. Although operative times were significantly longer with RALM, patients had a quicker recovery, demonstrated by shortened lengths of stay and less time before returning to work. However, greater residual fibroid burden was observed with RALM when measured 12 weeks after surgery.

Key Words: Myomectomy, Noninvasive surgery, Robot-assisted laparoscopic myomectomy, Abdominal myomectomy, Myoma.

INTRODUCTION

Myomas are benign, monoclonal smooth muscle tumors of the myometrium.[1] They are the most common pelvic neoplasm, with an 80% incidence among premenopausal women.[2] Myomas cause significant morbidity and symptoms including abnormal uterine bleeding, pelvic pain, infertility, and urinary or bowel complaints.[1] For symptomatic women who wish to preserve their fertility, myomectomy is an appropriate therapeutic option.[3]

The advantages of smaller scars, decreased postoperative pain, less blood loss, and shorter hospital stays followed by more rapid return to normal activity associated with laparoscopic myomectomy compared with abdominal myomectomy (AM) have been well described.[4–6] However, laparoscopic myomectomy is surgically challenging and requires considerable training and expertise. The results of a large prospective multicenter trial and case reports of uterine rupture occurring in the second and third trimesters of pregnancy after laparoscopic myomectomy have led to recommendations cautioning against laparoscopic removal in patients with myomas >5 cm in diameter, multiple myomas, or deep intramural myomas.[6,7]

The use of robotic assistance greatly facilitates a surgeon's ability to perform laparoscopic myomectomy and expands the scope of eligible patients. Recent studies comparing robotic-assisted laparoscopic myomectomy (RALM) and AM have shown that the introduction of robotic technology may allow patients who typically would have undergone laparot-

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omy, because of large myoma size or location, to undergo a laparoscopic procedure with equivalent or better intraoperative and immediate postoperative outcomes.[4,8]

Clinically meaningful long-term outcomes associated with robotic-assisted gynecologic surgery are lacking in the present-day literature.[9] Outcomes beyond the immediate postoperative time frame have rarely been reported for RALM. In particular, symptom resolution, recovery time, residual fibroid burden, pregnancy rates, and patient satisfaction outcomes have yet to be reported.

Our objective in this study was to compare multiple patient outcomes after RALM with outcomes for a comparable control group of AM patients up to 3 months postoperatively. We first present data on comparative perioperative procedure outcomes including operative blood loss, complication rates (infection, gastrointestinal or genitourinary injury), and immediate postoperative pain. A 6-week postoperative telephone interview assessed patients' ratings of change in pain and symptoms, time to resumption of work, time to resumption of routine activities, and satisfaction. Finally, a 3-month postoperative ultrasonographic examination was used to compare residual fibroid burden after RALM with clinically similar patients who underwent AM.

MATERIALS AND METHODS

Sample Selection and Protocol

This study was approved by the Northwestern University Institutional Review Board. It used a prospective case-control design, comparing consecutive patients who underwent RALM with a cohort of AM patients with equivalent uterine sizes. We sought to recruit at least 15 patients for each arm based on a two-group χ^2 test with a $P = .05$ two-sided significance level and 80% power to detect the difference in clinically significant residual fibroids of 25% for AM versus 75% for RALM (odds ratio, 0.1). From January 2011 through March 2012, we monitored the operating room schedule and subsequently identified eligible participants with a verified primary *International Classification of Diseases* procedure code of 68.29 and a principal diagnosis code of 208.XX, with RALM patients further identified with procedure code 17.42. Once an eligible patient was identified, permission to contact the patient was obtained from the attending surgeon. To ensure comparison of patients with equivalent operative complexity, AM patients were selectively approached based on a preoperative ultrasonographic uterine size $<$20 weeks, which was found to be a key predictor of the likelihood of undergoing RALM in a previous propensity score matching study at our institution.[8] Operative technique, RALM or AM, was determined by the patient's physician. All patients had their surgery performed at Northwestern Memorial Hospital, a large academic medical center with most patients being cared for by private groups of physicians.

Patients consented to have their medical records reviewed, participate in a telephone interview at 6 weeks, and undergo a no-cost ultrasonographic examination at 12 weeks after surgery. All follow-up ultrasonography scans were obtained at a single ultrasonographic facility and read by a single study investigator (L.C.) who was blinded to patients' procedure type. Doppler interrogation was used to distinguish residual fibroids from postoperative changes with the presence of significant peripheral color flow expected to be seen with fibroids.

Medical Record Review

Preoperative clinical and demographic characteristics including patient age, body mass index, uterine size by weeks' gestation, number and dimensions of fibroids from preoperative imaging reports, and indications for surgery (pain, bleeding, gastrointestinal or genitourinary dysfunction, or infertility) were obtained from electronic medical record review. Surgical times, specimen weights, number of fibroids removed, operative blood loss, complication rates (infection, gastrointestinal or genitourinary injury), narcotic use, and immediate postoperative pain were also abstracted from medical records. Uniform discharge criteria, which include stable vital signs, ability to ambulate without assistance, ability to void, adequate diet intake, and adequate pain control with oral pain medications, were applied to determine discharge readiness.

Telephone Interview Ratings

Study investigators (A.G. and A.H.) called all enrolled patients at approximately 6 weeks postoperatively. Patients were first asked to rate their prior symptom severity on a 0 to 10 scale. Next, patients were asked to rate their pain "when they first came home from the hospital" on a 0 to 10 scale, to rate their pain "at its worst" and "right now" using Likert scale items ("mild" to "excruciating"), and to indicate when they stopped taking narcotic pain medication postoperatively. Patients were then asked to describe in days, weeks, or months their time of return to "routine daily activities" and return to "paid employment." Finally, patients were asked to rate their symptoms "now"

as compared with before surgery. The difference in each patient's preoperative versus postoperative symptoms rating was calculated and compared by procedure type.

Measurement of Residual Fibroids

To estimate residual fibroid volume from imaging reports, we assumed fibroids to be spherical. The radius was estimated to be half of the mean of the length, width, and depth measurements for each fibroid (0.5 × [length + width + depth]/3). The volume of each imaged fibroid was then summed to obtain an estimate of total residual fibroid volume for each patient. RALM and AM patients were compared by total number of residual fibroids categorized by size and location, as well as by mean residual fibroid volume.

Data Analysis

Clinical, demographic, and telephone response outcomes for RALM and AM patients were compared by use of χ^2 tests for categorical measures or *t* tests or Wilcoxon rank sum tests for continuous measures. We used multiple logistic regression to test the effect of procedure type on the likelihood of residual fibroid volume >5 cm^3, controlling for patients' preoperative uterine size and the number of fibroids removed. All analyses were performed with IBM SPSS software, version 20 (IBM, Armonk, Illinois, USA).

RESULTS

Patient Demographic Characteristics and Immediate Postoperative Outcomes

A total of 23 patients undergoing RALM were identified during our enrollment period. Three patients refused to participate and 4 were lost to follow-up, leaving 16 patients who underwent RALM for analysis. There were 49 eligible AM patients with uteri sized <20 weeks reflecting about 12% of all AM patients during the study period. Eleven AM patients refused to participate and 15 did not complete the study, leaving 23 matching AM patients for comparison. None of the patients undergoing RALM were pretreated with gonadotropin-releasing hormone analogues. Gonadotropin-releasing hormone use before AM could not be accurately ascertained from the available records because of patient recruitment from multiple providers.

Comparative patient characteristics are presented in **Table 1**. Though not statistically significant, there was a trend for patients in the RALM group to have a lower body mass index, be younger, and have a smaller preoperative uterine size. RALM patients were significantly more likely to have pressure symptoms and infertility as indications for their surgery. Immediate postoperative outcomes are presented in **Table 2**. RALM patients had significantly longer surgical times (261.1 minutes for RALM vs 124.8 minutes for AM, $P < .001$), with a 3-fold unfavorable difference in operative efficiency defined as grams of specimen removed per hour of operative time (73.7 g for RALM vs 253.0 g for AM, $P < .05$). However, though not statistically significant, the number of fibroids removed ($P = .08$) and specimen weight removed were greater in the AM group. There were no differences in complication rates and maximal pain scores, but fewer RALM patients received intravenous hydromorphone postoperatively. RALM patients had significantly shorter lengths of hospital stay (1.5 days for RALM vs 2.7 days for AM, $P < .001$).

Table 1.
Preoperative Characteristics for AM and RALM Patients

	Mean (SD)/Frequency (%)	
	AM (n = 23)	RALM (n = 16)
Age (y)	35.2 (5)	33.8 (5)
Body mass index	27.3 (7.5)	23.6 (3.8)
Uterine size (wk)	15.7 (2.7)	14.4 (3.9)
No. of preoperative fibroids imaged	2.4 (1.4)	2.7 (1.4)
Volume of imaged preoperative fibroids (cm^3)	400.1 (362.9)	372.3 (201.4)
Indications for surgery		
Bleeding	17 (73.9)	7 (43.8)
Pain	5 (21.7)	7 (43.8)
Genitourinary, fertility, gastrointestinal[a]	6 (26.1)	10 (62.5)

[a] $P < .05$.

Self-Reported Outcomes at 6 Weeks

The 6-week postoperative telephone interview results are presented in **Table 3**. Although there was no difference between groups in percentage of patients describing their pain at worst as "distressing or excruciating," there was a trend of fewer RALM patients reporting any pain at 6 weeks and a higher percentage of RALM patients (81.2% for RALM vs 69.6% for AM) who had discontinued use of narcotic medications within 1 week after surgery. RALM patients had quicker returns to routine activity, which did

Table 2.
Postoperative Outcomes for AM and RALM Patients

	Mean (SD)/Frequency (%)	
	AM (n = 23)	RALM (n = 16)
Surgical time (min)[a]	124.8 (31.6)	261.1 (56.3)
Specimen weight (g)	483.8 (582.5)	318.6 (154.0)
Operative efficiency (g of specimen weight removed per OR[c] hour)[b]	253.04 (307.84)	73.71 (33.58)
Fibroids removed	4.6 (3.8)	2.8 (1.9)
Estimated blood loss (cm^3)	445.7 (389.9)	415.6 (413.8)
Hemoglobin level postoperatively	9.4 (1.7)	9.5 (1.9)
Maximum pain score	6.6 (1.8)	5.6 (2.4)
Percentage with any complications	4 (17.4)	2 (12.5)
Percentage taking IV[c] hydromorphone	22 (95.7)	12 (75.0)
Length of stay[a]	2.7 (0.7)	1.5 (0.8)

[a] $P < .001$.

[b] $P < .05$.

[c] IV = intravenous; OR = operating room.

Table 3.
Six-Week Postoperative Telephone Interview Results for AM and RALM Patients

	Mean (SD)/Frequency (%)	
	AM (n = 23)	RALM (n = 16)
Postoperative pain		
Worst pain described as distressing, horrible, or excruciating	10 (43.5)	7 (43.8)
Mild or discomforting pain at 6 wk	13 (56.5)	5 (31.2)
Interview		
Pain at 6 wk (0–10 scale)	1.22 (0.4)	1.19 (0.4)
Discontinued narcotic medications within 1 wk	16 (69.6)	13 (81.2)
Return to household and leisure/recreational activities within 1 wk	9 (39.1)	9 (56.2)
Returned to work within 1 mo (n = 34 employed)[a]	9 (45.0)	12 (85.7)
Most severe preoperative symptoms (0–10 scale)	8.1 (1.8)	8.1 (1.6)
Most severe symptoms at 6 wk (0–10 scale)	5.0 (3.1)	4.2 (2.8)
Change in most severe symptoms (0–10 scale)	3 (3.0)	4.1 (2.6)
Change in symptoms (0–10 scale)		
Heavy bleeding	–3.4 (3.6)	–4.0 (3.4)
Abdominal pain or pressure	–2.6 (4.1)	–5.2 (2.2)
Urinary symptoms (including frequency and urgency)	–5.2 (2.5)	–5.9 (2.0)
Gastrointestinal symptoms (including constipation and rectal pressure)	–4.5 (2.4)	–6.0 (2.7)
Other symptoms	–3.2 (4.3)	–4.5 (2.5)
"Very satisfied" with surgery	19 (82.6)	13 (81.2)

[a] $P < .05$.

not reach statistical significance. However, among the 34 women who were employed, a significantly greater proportion of RALM patients were back to work within 1 month (85.7% for RALM vs 45.0% for AM, $P < .05$). Regardless of symptom type, RALM and AM were equally efficacious, with a mean reduction of the worst symptom by 3 points in the AM group and 4.1 points in the RALM group on a 10-point scale. Overall satisfaction was no different, with 82.6% of AM patients and 81.2% of RALM patients being "very satisfied."

Residual Fibroid Outcomes

Comparative residual fibroid outcomes are presented in **Table 4**. The mean aggregate residual fibroid volume in the RALM group was 5 times greater than that in the AM group (17.3 cm^3 for RALM vs 3.4 cm^3 for AM, $P < .05$). Seventy-eight percent of patients undergoing AM versus 56% of patients undergoing RALM had either no or clinically insignificant residual fibroid volume (<5 cm^3) detected 12 weeks after surgery ($P = .03$). RALM patients had a mean of 2.2 residual fibroids found compared with 1.2 for AM patients; this difference did not reach statistical significance ($P = .13$). In patients with the greatest residual fibroid volume (>10 cm^3), 6 of 7 were in the RALM group, representing >37% of all RALM patients. Most residual fibroids were <2 cm in diameter in both groups.

Table 4.
Comparative Residual Fibroid Outcomes for AM and RALM Patients[a]

	Mean (SD)/Frequency (%)	
	AM (n = 23)	RALM (n = 16)
Mean total imaged residual fibroid volume (cm^3)[a]	3.4 (5.2)	17.3 (31.3)
Residual fibroid volume by category[a]		
<5.00 cm^3	18 (78.3)	9 (56.2)
≥5.00 cm^3 but <9.99 cm^3	4 (17.4)	1 (6.2)
≥10 cm^3	1 (4.3)	6 (37.5)
Mean No. of residual fibroids imaged per patient	1.2 (1.1)	2.2 (1.9)
Total No. of residual fibroids imaged	28	35
Fibroids <1 cm in diameter	3	1
1-cm-diameter residual fibroids	20	20
2-cm-diameter residual fibroids	5	10
3-cm-diameter residual fibroids	0	4
Any residual subserosal fibroid	3 (13)	6 (37.5)
Any intramural fibroid count	16 (69.6)	10 (62.5)
Any submucosal fibroid count	1 (4.3)	0

[a]$P < .05$.

There were no AM patients with residual fibroids of 3 cm in diameter, whereas this size was present in 4 RALM patients. Most residual fibroids were intramural in location in both groups.

Figure 1 displays the frequency of residual fibroids found per patient by procedure type. There were no residual fibroids seen 12 weeks after surgery for 7 AM procedures (30.4%) and 2 RALM procedures (18.8%). We found 5 fibroids in 1 patient and 6 fibroids in 2 patients, all in the RALM group. These 3 patients were aged 32, 30, and 24 years, and all had at least 4 fibroids identified preoperatively. Their uteri were 16, 18, and 20 weeks in size, respectively, and the specimens removed were 412 g, 609 g, and 315 g in aggregate, respectively. The operative times for these 3 procedures were 279, 301, and 305 minutes, respectively. All but one of these sizes, weights, and times exceeded the respective means in the RALM group.

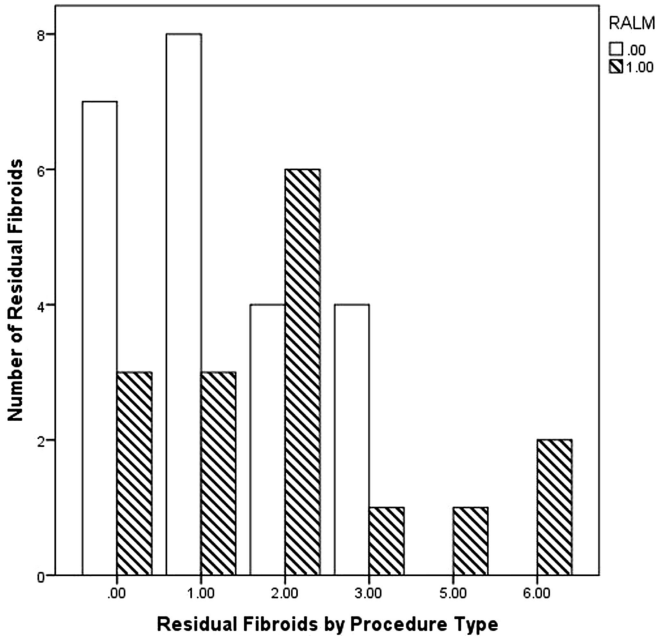

Figure 1. Number of residual fibroids imaged 12 weeks after surgery for 16 RALM patients (hatched bars) and 23 matched AM patients (white bars).

Logistic regression analysis testing the association of procedure type with the likelihood of having a residual fibroid volume >5 cm^3 was estimated controlling for preoperative uterine size and number of fibroids removed. Each additional fibroid removed was associated with an approximately 40% greater odds of having >5 cm^3 of residual fibroid volume ($P = .03$). RALM patients had a 10.5 times greater odds of having >5 cm^3 of residual fibroids ($P = .03$).

DISCUSSION

The emergence of robotic technology to assist surgeons in performing complex laparoscopic procedures has allowed patients who typically would have undergone laparotomy in the past to now undergo laparoscopic myomectomy.[4,8,10] Lack of equivalent haptic perception and extended operative time are challenges that surgeons encounter when performing RALM compared with AM. We undertook this study to determine whether these challenges would negatively impact the effectiveness of RALM in removing fibroids and ultimately lead to poorer clinical outcomes. We also hoped to identify risk factors for less effective fibroid removal with RALM.

Hypothetically, small intramural myomas, not visible laparoscopically but palpable manually, may be missed during

RALM but removed if one is performing AM. Also hypothetically, surgeon fatigue or patient safety concerns may lead surgeons to intentionally leave fibroids not thought to be clinically significant when operative times become extended. The potential result of these hypothetical scenarios is residual fibroids that may contribute to a patient's risk of suboptimal symptom relief or recurrent symptoms and subsequent need for reoperation. Reoperation rates after RALM have not yet been reported, but it would be fair to assume that they may be higher than reoperation rates after AM if the postoperative residual fibroid burden is greater. The 5-year cumulative rates of recurrence and need for future surgery after AM have been reported to be 62% and 9%, respectively.[11]

In this prospective analysis of 16 patients undergoing RALM compared with 23 uterine size–matched patients undergoing AM, statistically significant differences were found indicating a higher likelihood of residual fibroids after RALM. The clinical significance of these differences is uncertain. Most residual fibroids were ≤2 cm in diameter. The mean cumulative residual fibroid volume of 17 cm^3 after RALM is equivalent to a fibroid that is 3.17 cm in diameter. It has been suggested that fibroids do not predictably cause morbidity until their diameter is >5 cm.[1]

Operative efficiency is unfavorable when comparing RALM with AM. Nezhat et al[12] reported that RALM required a significantly prolonged surgical time over standard laparoscopic myomectomy, as well as AM, for myomas of similar size. Nash et al[8] similarly reported that with respect to operative efficiency, defined as grams of specimen removed per unit of surgical time, RALM becomes significantly less efficient than AM as specimen size increases. In our study the mean efficiency of RALM (73.7 g removed per hour) was 3 times lower than that of AM (253.0 g removed per hour). It is certainly possible that surgeons may be more likely to terminate procedures before removal of all known fibroids when operative times become prolonged and potentially concerning. Therefore, one can postulate that a large anticipated specimen weight may be a significant risk factor for residual fibroids when considering RALM versus AM.

The mode of preoperative uterine imaging and fibroid mapping may influence the risk of residual fibroids after myomectomy. The sensitivity to detect uterine fibroids has been reported to be 2-fold greater with magnetic resonance imaging compared with transvaginal ultrasonography (80% vs 40%).[13] Given the limited tactile sensation appreciated during robotic-assisted surgery, accurate preoperative fibroid mapping is essential. Unfortunately, this study did not have adequate power to show a difference in residual fibroid status when comparing preoperative imaging modalities; however, on the basis of our findings, we would recommend consideration of preoperative magnetic resonance imaging evaluation for those patients with large uteri considering RALM.

Despite the increased residual fibroid volumes and numbers after RALM, there was no difference in patient-reported symptom relief when we compared AM with RALM. Significant advantages were observed in the RALM group with respect to postoperative recovery outcomes. RALM patients required less intravenous narcotic use in the hospital and less oral narcotic use at home. With smaller operative incisions and less narcotic use, RALM patients were able to return to daily activities and employment more quickly than AM patients, which for many patients was an important component of postsurgical healing.

Limitations of this study include its small sample size from one medical center and a significant number of patients who either refused to participate or were lost to follow-up. Our study is also an observational study that cannot adequately control for potentially important unmeasured differences in patient groups and selection bias. However, using data from a previous propensity score matching study at our institution,[8] we were able to match, with a highly selected AM group from a large pool of candidates, for patients who likely could have undergone RALM had their surgeons been trained to perform RALM. In addition, we did not include traditional laparoscopic myomectomy in our comparison because of the small number of cases at our institution in the period studied. Laparoscopic myomectomy may overcome the lack of haptic feedback associated with robotic procedures and, therefore, may have varied residual fibroid volumes, but further research is required to determine this. It is also uncertain whether complete fibroid removal was an operative goal for all cases. At times, it may be more appropriate to intentionally not remove clinically insignificant fibroids to limit the number of uterine incisions and potential complications to future fertility. Lastly, we recognize that surgical outcomes data may vary greatly depending on surgeon skill and experience. Our medical center is not a referral center for robotic surgery, which would be expected to perform a much higher volume of robotic myomectomies. The surgeons who performed the RALM cases in this study were all highly skilled laparoscopic surgeons who have been in private practice for >12 years but first started to perform RALM in 2008. Therefore, the outcomes reported in this study may be dissimilar to those expected from a referral

center but may be more generalizable to the typical gynecologic practice in the community. Although our results need to be validated in a randomized controlled trial, these initial findings contribute to our understanding of surgical outcomes after RALM.

In conclusion, RALM and AM were equally efficacious in improving patient symptoms. Although operative times were significantly longer with RALM, patients had a quicker recovery, demonstrated by shortened lengths of stay, less narcotic use, and less time before returning to work. However, patients undergoing RALM had higher residual fibroid burden outcomes compared with patients undergoing AM when measured by ultrasonography 12 weeks after surgery. This difference was most evident in those patients who had large uteri, large surgical specimens, and prolonged operative times. Accurate preoperative evaluation of the number and size of fibroids is essential in estimating the risk of residual fibroids after myomectomy. In counseling patients seeking RALM, the risks of residual fibroids and recurrence of symptoms, as well as the potential need for reoperation, should be discussed and balanced with the numerous surgical and patient satisfaction benefits of minimally invasive surgery. Ultimately, surgeons can minimize these risks with appropriate preoperative evaluation, counseling, and patient selection.

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