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Implementing robotic assisted myomectomy in surgical practice – a retrospective cohort study

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Abstract

Background: To compare surgical outcomes of patients with leiomyomas after robotic-assisted laparoscopic myomectomy (RALM), laparoscopic myomectomy (LsM), or laparotomic myomectomy (LtM) and to construct a useful algorithm for the best modus operandi for uterine leiomyomas.

Methods: Design: A retrospective chart review. Data included patient (age and BMI) and fibroid characteristics (number, measurements of the primary fibroid, type, and location), operating time, blood loss, hospitalization length, complications during and after surgery, and complications during posttreatment pregnancies. Comparisons were based on chi-square and two-sample *t* tests. Setting: University teaching hospital. Patients: Between 1 January 2009 and 31 December 2016, 51 RALMs, 84 LsMs, and 52 LtMs were performed at our institution. Interventions: Three different approaches of myomectomy were performed: robotic-assisted laparoscopy (RALM), laparoscopy (LsM), and laparotomy (LtM).

Results: There was no significant difference in the distribution of the location and the type of myoma between the three groups. The mean size of the largest myoma removed by LsM, RALM, and LtM was 60.9, 70.8, and 92.6 mm ($p < 0.05$), respectively. Surgical outcomes between the three modalities were comparable except for increased mean blood loss and postoperative bleeding and longer hospital stay for patients with LtM and for longer operation time when performing RALM.

Conclusion: RALM should replace open surgery if feasible and should not replace traditional laparoscopy unless other benefits are proven.

Keywords: Myomectomy, RALM, Laparoscopy, Laparotomy, Outcome

Introduction

Fibroids are the most common tumors of the female reproductive tract and can cause menorrhagia, dysmenorrhea, and infertility [1]. Only symptomatic fibroids require treatment by medical, surgical, or radiologically guided interventions [1–4]. The preferred surgical approach for myomectomy remains a point of discussion [5–9]. Laparotomic enucleation has less perioperative complications, shorter operative times, and better accessibility for multiple or posterior myomas, but also longer

hospitalization and more postoperative adhesions [5, 8]. Laparoscopy leads to lower morbidity rates, less adhesions, and faster recovery. Though, as stated by Bedient et al. and Nezhat et al., it is associated with less accessibility and difficulties in maintaining hemostasis and adequately suturing uterine incisions [6, 7]. The introduction of robotic-assisted laparoscopy surmounts some cons of laparoscopic myomectomy. During this procedure, a surgeon is seated comfortably and has a three-dimensional view. It creates a wider range of motion and improved dexterity and filters natural tremors. Easier suturing and better accessibility were also described [10–12]. A limitation in comparison with laparotomy is the lack of haptic perception [5]. According to current French guidelines, fibroids types 3–7 can be

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resected by laparoscopy or laparotomy depending on their size. Laparoscopy should be considered for myomas up to 8 cm. Myomas of ≥ 8 cm are an indication for open surgery [13]. This retrospective trial compares surgical outcomes after robotic-assisted laparoscopic (RALM), traditional laparoscopic (LsM), and laparotomic myomectomy (LtM). We attempt to construct a useful algorithm for clinicians regarding the best modus operandi of myomectomy for the different volumes and types of leiomyomas (focusing on types 3–6).

Materials and methods

We performed a retrospective chart review that included all patients who underwent myomectomy by robotic-assisted laparoscopy, traditional laparoscopy, or laparotomy for symptomatic leiomyomata in the period between 1 January 2009 and 31 December 2016. According to the performed surgical route, the patients were stratified into three groups. Although infertility may be considered a symptom of myomas, it was not the main symptom of patients included in our data. The indications for myomectomy were mainly menorrhagia and dysmenorrhea. As it was the surgical outcome that was studied in this review, data about the postoperative improvement of the symptoms was not gathered. The da Vinci robotic surgical system (Intuitive Surgical Inc. Sunnyvale, Ca) was used for performing the RALMs. Note that the robotic surgical system was only introduced as a treatment for fibroids in our institute on 31 August 2012. The patient groups withheld for the three different approaches included all eligible patients and were not matched to specific patient characteristics. Selection of patients for the different approaches was done based on the French guidelines [3]. RALM was chosen for fibroids too large for LsM in order to replace LtM. RALM was always performed by the same surgeon (JV), while the other procedures were also performed by other gynecologists. There was no comparison performed about the relationship between the surgical outcomes and the experience of the different surgeons. Though, they all had a surgical experience of over 5 years. Using the electronic medical records, data were compiled. The assembled information included patient (age and BMI) and fibroid characteristics (number, measurements and volume of the primary fibroid, type, and location), operating time, blood loss and decrease in hemoglobin, length of hospital stay, complications during and after surgery (organ perforation, thromboembolism, fever, infection, postoperative bleeding, peri- and postoperative need for blood transfusion, surgical revision and/or interventional radiology, and perioperative conversion to laparotomy), and complications during posttreatment pregnancies (uterine rupture and modus of delivery). The study protocol was approved by the KU/UZ Leuven

Medical Research Ethical Commission on 1 March 2018 (MP003022).

Statistical analysis

Statistical significance was calculated by using a two-sample *t* test for continuous measures. Dichotomous measures were compared by using the χ^2 test. *P* values less than .05 were considered statistically significant.

Results

Between 1 January 2009 and 31 December 2016, 51 RALMs, 52 LtMs, and 84 LsMs were performed at our institution. Table 1 shows the differences between the patients undergoing RALM, LsMs, and LtMs concerning age and body mass index. The only significant difference in distribution was the mean age between RALM and LsM and between LsM and LtM. Patients in RALM and LtM groups are younger compared to the laparoscopy group. No significant difference in BMI was observed between the different groups. Note however that the upper limit for BMI in the RALM group was 41.

Fibroid characteristics are shown in Table 1 and Figs. 1 and 2. The differences in distribution of the mean size of the largest fibroids and the mean number of fibroids were all significant except when comparing the number of fibroids between RALM and LsM (Table 1). An average of two myomas was removed by RALM and LsM in comparison with an average of 4.5 by LtM. The mean size of the largest myoma removed by LsM, RALM, and LtM was 60.9, 70.8 and 92.6 mm, respectively.

Data about fibroid characteristics are comparable between the different modalities. There is no significant difference observed in the distribution of the location of the myoma between the three groups (Fig. 1). The same observation was made for the distribution of the different types of fibroids (Fig. 2). One type 1 and one type 2 fibroid were removed by robotic-assisted laparoscopy. The largest diameter of these fibroids was 6 and 10 cm, respectively. In both cases, the uterine cavity was opened. These fibroids were not transmural types, as this would alter their classification.

When comparing the different approaches, no significant difference was observed for the mean blood loss between the RALM and LsM group, where the data of the laparotomy group showed significantly more blood loss. There was also no significant difference in hospital stay between RALM and LsM. Women in the laparotomy group had a significantly longer hospital stay compared to RALM and LsM. Operation time was significantly longer with RALM, and this was also observed when comparing LsM to LtM. (Table 2) Differences in denominators are due to missing data.

Table 1 Demographic characteristics of patients undergoing myomectomy and fibroid characteristics

	RALM	LsM	LtM	RALM vs LsM <i>P</i> value	RALM vs LtM <i>P</i> value	LsM vs LtM <i>P</i> value
Patient						
Age, years*	34/51 (21–58)	37/84 (25–59)	35/52 (20–58)	.02	.87	.03
BMI*	25/51 (18–41)	24/84 (18–38)	25/52 (18–37)	.21	1.00	.20
Fibroid						
Size of largest (mm) ^o	70.8/49 (13–114)	60.9/84 (4–147)	92.6/51 (7.2–250)	.03	.01	.00
Number ^o	1.9/51 (1–7)	2.2/84 (1–7)	4.5/52 (1–30)	.38	.00	.01

LsM laparoscopic myomectomy, LtM laparotomic myomectomy, RALM robotic-assisted laparoscopic myomectomy

*Values are presented as mean (min–max)

^oValues are presented as mean/n (min–max)

Peri- and postoperative complications are shown in Table 3. The perioperative complications showed the same surgical outcomes between the three modalities. The uterine cavity of four patients of each group was opened during the myomectomy. Injury of the bowel or bladder was described for two and one patients, respectively, undergoing traditional laparoscopy. Conversion to laparotomy was necessary in four and eight patients undergoing RALM and LsM, respectively. In the RALM group, three conversions were necessary because of difficulties in the mobilization of the uterus. For the fourth patient, the surgery was converted because of the bleeding of the epigastric artery. In one patient, the lateral incision was enlarged because of the impossibility of morcellation of the myoma due to the hardness of the tissue. This patient was not included in the data of conversion to laparotomy. Conversion to laparotomy in the LsM group was decided perioperatively because of the large volume of and difficult accessibility to the fibroma in six cases. In one patient, the reason for conversion was multiple adhesions caused by previous surgery. The eighth case with conversion was due to a liquefied myoma, and because of this, the surgeon experienced difficulties in recognizing the plane of dissection between healthy myometrium and the myoma causing slow

laparoscopic progression and ample loss of blood. While looking at postoperative complications, the only significant difference described was more postoperative bleeding when comparing open surgery to traditional laparoscopy and a higher need for blood transfusion when comparing open surgery to RALM and LsM separately. This result was also demonstrated when comparing the drop in postoperative hemoglobin levels. A significant fall was noticed in the LtM group in comparison to the RALM and LsM group. All other postoperative complications showed the same surgical outcomes.

Revision surgery was performed for divergent reasons. In the RALM group, relook laparotomy was performed in one patient because of sepsis and a second patient was thought to have a postoperative bleeding. Both investigations were negative. Four patients who initially had traditional laparoscopy needed relook surgery. Three of these patients had peritonitis of which one was caused by a surgically infected hematoma and two by perforation of the bowel. Both patients with bowel perforation (one of the rectum and one of the small intestines) had a history of abdominal surgery with extensive adhesions. The fourth patient had a postoperative bleeding at the cleavage plane of the myoma for which additional suturing was necessary. The cause of revision surgery after

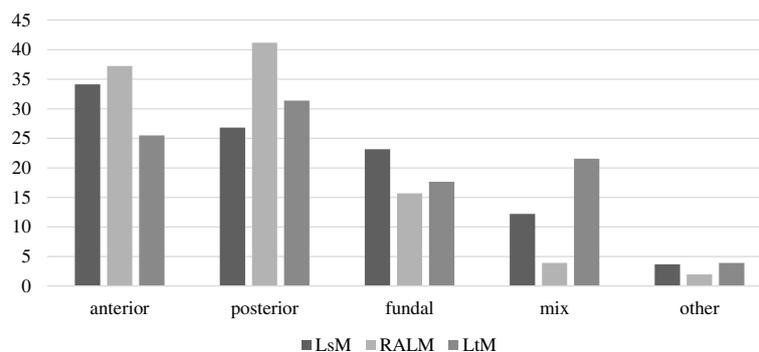


Fig. 1 Location of the myoma (%). LsM, laparoscopic myomectomy; LtM, laparotomic myomectomy; RALM, robotic-assisted laparoscopic myomectomy

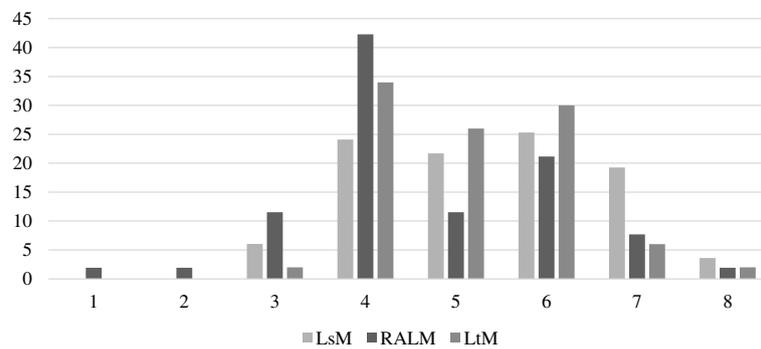


Fig. 2 Type of the myoma (%). LsM, laparoscopic myomectomy; LtM, laparotomic myomectomy; RALM, robotic-assisted laparoscopic myomectomy

laparotomy was postoperatively subcutaneous ($n = 2$) or intra-abdominal bleeding (diffuse ($n = 1$), cleaving plane of the myoma ($n = 2$), or meso of the small intestines ($n = 1$)). The postoperative complications classified as others after RALM comprise atrial fibrillation, ketoacidosis, and sepsis without focus. After LsM, the other complications included colitis, a perforation of the vagina after concomitant resection of a deep rectovaginal endometriosis nodule, a surgically infected intra-abdominal hematoma and an abscess of the Douglas with a septic shock within the same patient. Pneumonia, neutropenia without focus, and a wound problem without infection were described as other complications after open surgery. Postoperative necessity for radiologically guided intervention was described in three cases, twice after RALM and in one patient who had open surgery. In all three cases, the reason for the embolization of the uterine artery was the persistent loss of blood vaginally or in the drainage system and hemodynamic instability.

Information about posttreatment pregnancies was gathered, although the fulfillment of pregnancy wish and long-term obstetrical follow-up was not the purpose of the review. The data showed that 36 children were born in 26 patients after surgical treatment. (Table 4) One rupture of the uterus during labor was described for which a secondary C-section was performed in a patient who initially had a traditional laparoscopic myomectomy for a single subserosal posterofundal myoma with a maximal diameter of 10 cm. During the LsM, no complication or perforation of the uterus was described.

Before the introduction of robotic-assisted laparoscopy, myomectomy was performed by laparoscopy in 65.3% and by laparotomy in 34.7%. When looking at the change in practice for myomectomies after utilization of the robot, we observed a decrease in open surgery of 41.8% and the number of traditional laparoscopy reduced even more (65.5%). RALM was performed in 51% of the cases.

Discussion

The data about fibroid characteristics were as expected as the surgeons chose the mode of surgery for the patients included in the trial. A general weakness of a retrospective review is the inability to compare groups as group characteristics are set data. To create comparable groups upfront could lead to an unethical surgical situation. Another infirmity is the discrepancy in surgical techniques when comparing the surgical outcomes of the different modalities. However, when looking at the distribution of the location and the different types of fibroids between the three groups in our review, no significant differences were observed. Hence, the results can be critically judged as the three modalities have somewhat comparable fibroid characteristics. As it is a retrospective trial, we can conclude that the current way of choosing an approach seems warranted as complications are not higher and even lower in the laparoscopy or RALM group. Postoperative bleeding and the need for blood transfusion tend to be higher in the laparotomy group. These findings are comparable with the

Table 2 Surgical factors

	RALM	LsM	LtM	RALM vs LsM <i>P</i> value	RALM vs LtM <i>P</i> value	LsM vs LtM <i>P</i> value
Operating time (min)*	196.5/51 (60–420)	123.1/74 (30–283)	98.4/44 (30–230)	< .001	< .001	.01
Blood loss (ml)*	322/50 (50–1500)	319/67 (0–2000)	525.2/44 (20–4000)	.96	.07	.06
Hospital stay (<i>n</i>)*	4.3/51 (2–16)	4.9/84 (1–11)	6.4/52 (3–16)	.10	< .001	.001

LsM laparoscopic myomectomy, LtM laparotomic myomectomy, RALM robotic-assisted laparoscopic myomectomy

*Values are presented as mean/*n* (min–max)

Table 3 Perioperative and postoperative complications

	RALM n = 51	LsM n = 84	LtM n = 52	RALM vs LSM P value	RALM vs LtM P value	LsM vs LtM P value
Perioperative complications						
Bladder perforation	0	1 (1.2)	0	.32	–	.32
Bowel perforation	0	2 (2.4)	0	.16	–	.16
Uterine perforation	4 (7.8)	4 (4.8)	4 (7.7)	.49	.49	.51
Conversion to laparotomy	4 (7.8)	8 (9.5)	–	.74	–	–
Postoperative complications						
Thromboembolism	0	0	1 (1.9)	–	.32	.32
Fever (> 38 °C)	2 (3.9)	4 (4.8)	3 (5.8)	.82	.67	.80
Wound infection	1 (2)	1 (1.2)	0	.74	.32	.32
Postoperative bleeding	2 (3.9)	1 (1.2)	7 (13.5)	.36	.09	.02
Blood transfusion	4 (7.8)	10 (11.9)	14 (26.9)	.44	.01	.04
Revision surgery	2 (3.9)	4 (4.8)	6 (11.5)	.82	.15	.18
Radiologically guided intervention	2 (3.9)	0	1 (1.9)	.16	.55	.32
Others	3 (5.9)	4 (4.8)	3 (5.8)	.78	.98	.80

Data are shown as n (%) of patients

LsM laparoscopic myomectomy, LtM laparotomic myomectomy, RALM robotic-assisted laparoscopic myomectomy

results of Barakat et al. [14]. A suggested disadvantage of RALM was longer operation time, which was also significantly longer in our study and with Barakat et al. [14]. This will probably remain one of the challenges of the robotic surgery; however, we expect that it should improve as surgical experience with robots increases. Note that when comparing laparoscopy to open surgery, significantly longer operation times were also observed.

The results from this retrospective trial, of course, support our own approach to myomas, but by comparing the surgical outcomes based on the small number of patients in this review, we attempted to construct a useful algorithm for clinicians for the best modus operandi of myomectomy for the different volumes and the different types of fibroids, mainly focusing on types 3 to 6. In our opinion, single fibroids up to 7 cm or multiple fibroids with a cumulative diameter up to 15 cm are indications for traditional laparoscopic myomectomy. This was supported by our findings. For cases with a single myoma of 8 to 11 cm, RALM should be considered. Single myomas of 12 cm or larger and multiple fibroids with a cumulative diameter more than 20 cm should perhaps be resected by

open surgery. Laparoscopy and mini-laparotomy are the modalities of choice for an anterior fibroid. In case of a posterior fibroid, RALM seems to be the best modality, although it is also depending on size.

The topic of morcellation is not covered by the extent of this review; however, it should be noted that not all resected fibroids were morcellated. Some were removed in an Alexis® Contained Extraction System through a small incision. However, it should be noted that even the enucleation of fibroids causes spilling. A study by Sandberg et al. showed tissue spillage from leiomyomata during conventional open myomectomy as leiomyoma cells were found in the cytology of post-myomectomy washings [15].

The shift in surgery from laparotomy and laparoscopy to RALM is probably due to several facts. First, traditional laparoscopy was only performed for fibroids up to 7 cm before the introduction of RALM, and second, the University hospital is registered as a training center for RALM, making more myomas being selected for RALM, as easy cases should be performed when introducing a new technique.

Table 4 Posttreatment pregnancy information

	Pregnancies*	Modus of partus ^o			Uterine rupture
		Vaginal	Prim C-section	Sec C-section	
RALM	5 (5)	4/5 (80)	0/5	1/5 (20)	0/5
LsM	17 (12)	7/17 (41.2)	7/17 (41.2)	3/17 (17.6)	1/17
LtM	14 (9)	5/14 (35.7)	9/14 (64.3)	0/14	0/14

LsM laparoscopic myomectomy, LtM laparotomic myomectomy, Prim primary, RALM robotic-assisted laparoscopic myomectomy, Sec secondary

*Values are presented as n (number of patients)

^oValues are presented as n (%)

The cost of the different surgical approaches was not covered by the extent of this trial because of the limitations of the cost database of our institution.

Conclusion

Robotic surgery was introduced with the intent to convert open cases to a minimally invasive procedure. Our observations also indicate that RALM should replace some open surgery when feasible but may not replace conventional laparoscopy unless significant advantages of RALM over laparoscopy are proven. Until now, however, there are no studies showing significant and clinically relevant benefits for RALM over laparoscopy. The suggested algorithm is valuable for those who are experienced in both myomectomy and robotic surgery.

Abbreviations

BMI: Body mass index; KU/UZ Leuven: Catholic University/University Hospital Leuven; LsM: Laparoscopic myomectomy; LtM: Laparotomic myomectomy; RALM: Robotic-assisted laparoscopic myomectomy

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

JV contributed to the project development, data analysis, and manuscript editing and is the responsible surgeon. SA contributed to the data collection, data analysis, manuscript writing, and statistical analysis. SH contributed to the project development, data analysis, and manuscript editing. DT contributed to the project development. All authors read and approved the final manuscript.

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Approval Belgian Ethical Committee: 01/03/2018 - MP003022.

This article does not contain any studies with animals performed by any of the authors.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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