Factors influencing surgical outcomes of laparoscopic myomectomy. A propensity-score matched analysis

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Abstract

Introduction: To evaluate factors influencing surgical choice in performing uterine myomectomy by comparing laparoscopic and open approach surgery.

Material and methods: We analyzed women undergoing uterine myomectomy in our hospital. Patients were divided into two groups: patients who underwent laparoscopic myomectomy (group A) and patients who underwent laparotomic myomectomy (group B). We matched 1: 1 women in these two groups to compare the effects of the procedures on each outcome according to a propensity-matched score analysis.

Results: 460 myomectomies were performed in the study period: 361 cases by laparoscopy (group A) and 99 cases by laparotomy (group B). We found lower estimated intraoperative blood loss (200 ml group A vs. 300 ml group B, < 0.0001) and a smaller decrease in hemoglobin value on the first postoperative day (1.7 g/dl group A vs. 2.2 g/dl group B, < 0.0001) with the laparoscopic approach. The propensity score matching estimated that to obtain an equivalent outcome, we required an average of 2 myomas and an average diameter of 8 cm in laparoscopy and 10 cm in laparotomy. Moreover, the variables mostly associated with a laparotomic conversion were the presence of a myoma > 8 cm and association with the presence of more than 2 myomas.

Conclusions: Despite some proposals from previous studies, there are no specific guidelines regarding the best surgical procedure for myomectomy. Our data confirm that the choice of surgical technique should consider the patient characteristics and the surgeon experience to reduce longer operating times and more significant blood loss.

Key words: laparoscopy, myomectomy, propensity score, gynecological surgery, LPS.

Introduction

Uterine myomas represent the most frequent tumor of the female genital tract and affect up to 30% of women of reproductive age, including up to 77% of cases considering histological evidence of post-hysterectomy samples [1, 2]. Clinical symptoms are usually related to the number, position and size of the masses, and the most common are abnormal uterine bleeding, pelvic pain and infertility [3, 4].

The therapeutic approach could be medical with selective progesterone receptor modulators that interact with progesterone receptors and reduce the growth [5] or, in cases with severe symptoms, a surgical approach should be considered [6].

The first definitive positive results in favor of a laparoscopic surgical approach were published 20 years after the first laparoscopic myomectomy performed by Semm in 1979 [7–9]. The advantages of the above technique are those related to minimally invasive surgery, including shorter hospitalization times, reduced post-operative pain, and reduced intraoperative blood loss compared to laparotomic myomectomy [10]. However, laparoscopic myomectomy is a more technically challenging procedure and is associated with possible complications that must always be evaluated and compared with expected clinical benefits [9, 11, 12].

In recent years, many authors have proposed some 'rules' to help correct decision-making in choosing myomectomy surgery. For example, Saccardi *et al.* suggested that clinical parameters indicating a preference for a laparoscopic myomectomy approach include a dominant myoma diameter ≤ 8 cm and/or fewer than 3 my-

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omas to be removed [10]; moreover, a combination of dominant myoma diameter > 10 cm and uterine volume > 600 cm³ was found to be predictive of complications for minimally invasive myomectomy [13]. However, other authors concluded that the laparoscopic approach is safe independently of size, number, and location when performed by experienced surgeons [14]. Thus, there is no unanimity in this field, although surgical feasibility must be evaluated concerning clinical benefit.

Given the above, we performed a propensity-score matched analysis on patients who underwent myomectomy, to understand the conditions that might influence surgical outcomes.

Material and methods

General information

We performed a retrospective cohort study of patients who underwent myomectomies at our hospital, IRCCS, Humanitas Clinical and Research Center, Rozzano (Milan), Italy, in the period from June 2009 to June 2019. We included relevant demographic, anamnestic, clinical and operative data. The study protocol was *a priori* defined, according to the STROBE guidelines [15]. Enrolled patients were allocated to two different study groups: group A, patients who underwent laparoscopic myomectomy, and group B, patients who underwent laparotomic myomectomy.

Operative variables included in the analysis were: operative time, intraoperative estimated blood loss, need for blood transfusion, the opening of the endometrial cavity during the procedure, conversion to laparotomy in the case of laparoscopy, intraoperative complication (defined as an organ or vascular injury), and length of hospital stay.

Among specific variables related to the myomectomy, we considered the number of removed myomas, the diameter of the larger removed myoma, and overall weight of the removed myomas. Finally, postoperative outcomes were recorded in terms of early (< 30 days) and long-term (> 30 days) complications.

Surgical technique

Three experienced gynecologists performed the surgical procedures. Based on global uterine volume, open myomectomy was performed by abdominal longitudinal or transverse (according to Kustner incision) incision. Myoma removal was performed respecting the pseudocapsule and suturing the hysterotomy breach in a double layer non-locking section, using a polyglyconate monofilament (Maxon 0, Medtronic Italia S.p.A.). Laparoscopy myomectomy was performed using a Hasson trocar and three ancillary trocars. A uterine incision was carried out with a monopolar hook, along with enucleation of the mass with a tenaculum and bipolar dissector, minimizing the use of electrocoagulation to preserve the myometrium integrity. The myometrial wall was sutured with monofilament polyglyconate suture (Maxon 0, Medtronic Italia S.p.A.) in a double layer. Tissue fragmentation and extraction was performed through the technique of power tissue morcellation (Versator tissue morcellation system, Veol Medical Technologies) in combination with an isolated containment bag (MorSafe tissue morcellation bag, Veol Medical Technologies); this system was routinely used in all laparoscopic myomectomies in order to prevent tissue dissemination in the peritoneal cavity [16].

Statistical analysis

Given the non-randomized nature of the study, we performed a propensity-matched analysis to estimate the effects of the treatment by accounting for the covariates that predict receiving the treatment. The propensity score was defined as the estimated probability of a patient having open surgery vs. laparoscopy and was developed through a binary logistic regression. The model included the following pre-operative variables: age, body mass index, previous vaginal delivery, previous cesarean section, previous myomectomy, history of other previous gynecological or abdominal procedures, concomitant adnexal pathology, the diameter of the larger myoma and the number of myomas.

Women who finally underwent open surgery (electively or after intraoperative conversion) were matched 1 : 1 to women who underwent laparoscopy. Calipers of width equal to ± 0.2 SD of the logit of the P defined as ln (PS/1-PS) were used for matching [17].

Normality testing (D'Agostino and Pearson test) was performed to determine whether data were sampled from a Gaussian distribution. Chi-square and Fisher's exact tests were used to analyze proportions, as appropriate. Student's test and the Mann-Whitney *U* test were performed to compare continuous parametric and non-parametric variables, respectively.

A p-value < 0.05 was considered statistically significant. Statistical analysis was performed with SPSS version 20.0 (IBM Corp.) for Mac OS X.

Ethics approval

The proposed treatment and possible alternative approaches were explained to the patients, and written informed consent was obtained from each subject involved following local legislation and the Declaration of Helsinki. All data were collected independently by an internal review board since it concerned a validated technique and an observational, non-interventional study.

Results

In the study period, a total of 460 myomectomies were performed: 361 cases with a laparoscopic approach (group A) and 99 cases by laparotomy (group B). Baseline characteristics and surgical outcomes are detailed in Table 1.

Based on the comparison of the preoperative variables, a greater number of patients with previous myomectomy was recorded in group B (4.7% group A vs. 11.1% group B). We found that operative times were similar in the two groups (110 minutes group A vs. 105 minutes group B, p = 0.87). Estimated intraoperative blood loss was lower with the laparoscopic approach (200 ml group A vs. 300 ml group B, < 0.0001), and we found a smaller decrease in hemoglobin value on the first postoperative day (1.7 g/dl group A vs. 2.2 g/dl group B, < 0.0001). In contrast, group B patients showed longer hospitalization (< 0.0001). There were no differences in terms of complications or post-operative transfusions (Table 2). In all cases, the definitive histological diagnosis was benign leiomyoma.

Propensity score matching

To achieve a comparison that can simulate randomization of the two groups, 86 patients in both groups were matched with a propensity score matching test, according to the surgical approach. We found that, with similar group characteristics, to obtain an equivalent outcome, we should consider an average of 2 myomas and an average diameter of 8 cm in laparoscopy and 10 cm in laparotomy. The results are shown in Table 3.

According to these findings, we performed a subgroup analysis, assigning the patients with one myoma < 7 cm to group A1 (n = 116) and patients with at least two myomas, of which at least one > 8 cm, to group A2 (n = 53) (Table 4). The latter group represented the maximum limit size found in the matching analysis.

In group A2, the operative time was \geq 2 hours in most cases (56.6% vs. 19%, < 0.0001), with more significant intraoperative blood loss (200 ml vs. 150 ml, < 0.0001) and an increased probability of conversion to laparotomy (13.2% vs. 2.7%, < 0.0001), compared to patients of group A1.

Moreover, we performed the univariate and multivariate analysis according to factors that potentially impact surgical outcomes. The factors chosen were the risk of laparotomic conversion during laparoscopic myomectomy (Table 5), operative time \geq 2 hours (Table 6), intraoperative blood loss > 500 ml (Table 7), and the risk of loss of more than three mg/dl hemoglobin in the first postoperative day (Table 8).

We considered patients' age > 40 years, BMI > 30 kg/m^2 , previous cesarean section, previous myomectomy, concomitant adnexal pathology, myoma size $\geq 8 \text{ cm}$, > 2 myomas, and these last two variables considered together.

Table 1. Baseline characteristics and surgical outcomesof the whole population undergoing myomectomy

Parameters	<i>N</i> = 460
Age (years)	37.7 (22.3–49.2)
BMI [kg/m²]	22.0 (16.2–64.5)
Obese (BMI \geq 30 kg/m ²)	37 (8.0%)
Previous vaginal delivery (N)	70 (15.2%)
Previous caesarean section (N)	40 (8.7%)
Previous myomectomy (N)	28 (6.1%)
History of other previous gynecological procedures (N)	102 (22.2%)
History of other previous abdominal procedures (N)	102 (22.2%)
Concomitant adnexal pathology (N)	61 (13.3%)
Operative time (min)	109 (30–280)
Intraoperative blood loss [ml]	200 (10–2000)
Hemoglobin drop on 1 st post-operative day [g/dl]	1.8 (0.1–5.4)
Transfusions (N)	9 (2.0%)
Opening of the endometrial cavity (N)	12 (2.6%)
Number of removed myomas	1 (1–18)
Diameter of the larger myoma removed [cm]	7 (1–30)
Overall weight of the removed myomas [g]	131.5 (10–5460)
Conversion to laparotomy (N)	25 (5.4%)
Intraoperative complications (N)	0
Hospital stay [days]	3 (1–8)
Early post-operative complications $(\leq 30 \text{ days} > G2)$ (N)	3 (0.7%)
Late post-operative complication (> 30 days > G2) (N)	0

Data are expressed as median (range), percentage (%) or absolute number (N).

The variables most strongly associated with a laparotomic conversion were the presence of a myoma > 8 cm (*p*-value in univariate analysis 0.02; *p*-value in multivariate analysis 0.008) and the presence of > 2 myomas (*p*-value in univariate analysis 0.03; *p*-value in multivariate analysis 0.03) (Table 5).

For evaluation of operative time ≥ 2 hours (Table 6), an association in univariate analysis was found with the variables age (*p*-value 0.006), history of a previous myomectomy (*p*-value 0.036), the presence of > 2 myomas (*p*-value \leq 0.0001) and the presence of 2 myomas with at least one > 8 cm (*p*-value 0.0008); in multivariate analysis, age > 40 years (*p*-value 0.009) and the presence of > 2 myomas (*p*-value 0.01) maintained the significance (Table 6). Furthermore, based on the uni-multivariate analysis regarding the presence of predictor variables for intraoperative blood loss > 500 ml,

Parameters	Group A n = 361 (78.5%)	Group B n = 99 (21.5%)	<i>p</i> -value
Age (years)	37.6 (22.3–49.2)	38.2 (22.5–48.7)	0.42ª
BMI [kg/m²]	22.0 (16.2–64.5)	21.7 (17.3–58.1)	0.86 ^a
Obese (BMI \geq 30 kg/m ²)	27 (7.5%)	10 (10.1%)	0.41 ^b
Previous vaginal delivery (N)	57 (15.8%)	13 (13.1%)	0.64 ^b
Previous caesarean section (N)	29 (8.0%)	11 (11.1%)	0.32 ^b
Previous myomectomy (N)	17 (4.7%)	11 (11.1%)	0.03 ^b
History of other previous gynecological procedures (N)	75 (20.8%)	27 (27.7%)	0.18 ^b
History of other previous abdominal procedures (N)	78 (21.6%)	24 (24.2%)	0.59⁵
Concomitant adnexal pathology (N)	54 (15.0%)	7 (7.1%)	0.04 ^b
Operative time (min)	110 (40–252)	105 (30–280)	0.87 ^a
Operative time \geq 2 hours (N)	145 (40.2%)	38 (38.4%)	0.82 ^b
Intraoperative blood loss [ml]	200 (10–1200)	300 (10–2000)	< 0.0001 ^a
Intraoperative blood loss \geq 500 ml (N)	37 (10.2%)	19 (12.2%)	0.02 ^b
Hemoglobin drop on 1 st post-operative day [g/dl]	1.7 (0.1–5.4)	2.2 (0.3–4.8)	< 0.0001ª
Transfusions (N)	5 (1.4%)	4 (4.0%)	0.11 ^b
Opening of the endometrial cavity (N)	9 (2.5%)	3 (3.0%)	0.73 ^b
Number of removed myomas	1 (1–18)	1 (2–16)	< 0.0001ª
Diameter of the larger myoma removed [cm]	7 (1–15)	10 (1–30)	< 0.0001ª
Overall weight of the removed myomas [g]	110 (10–765)	325 (30–5460)	< 0.0001ª
Transfusions (N)	0	0	> 0.99 ^b
Hospital stay [days]	3 (1–8)	3 (2–7)	< 0.0001ª
Early post-operative complications (\leq 30 days > G2) (N)	3 (0.8%)	0	> 0.99 ^b
Late post-operative complication (> 30 days > G2) (N)	0	0	> 0.99 ^b

Table 2. Comparison of population and surgical result of patients undergoing myomectomy with laparoscopic (group A) vs. open technique (group B)

^a – Mann-Whitney *U* test, ^b – Fisher's exact test

Data are expressed as median (range), percentage (%) or absolute number (N).

there was an association with concomitant adnexal surgery (*p*-value 0.06), but it was not significant in multivariate analysis (Table 7). Finally, investigating the variables that could predict the risk of loss of more than three mg/dl hemoglobin in the first post-operative day (Table 8), only the presence of a myoma of at least 8 cm was associated in univariate (*p*-value 0.04) and multivariate (*p*-value 0.02) analysis.

Discussion

Our findings revealed that a myomectomy with at least two myomas, one of which is more than 8 cm, might be challenging, and a laparotomic approach should be preferred.

These results agree with results proposed in 2014 in the Saccardi study [10]. However, the comparison showed instead how the approach to a patient with at least two myomas, of which one is more than 8 cm, must consider that the laparoscopic choice may be more complex both in terms of operating times and in terms of increased intraoperative blood loss.

The propensity score was estimated using logistic regression, accounting for the baseline covariates that influence the assignment of a procedure. Two subjects from two different cohorts but with a similar propensity score have a similar probability of undergoing either of the two procedures, and therefore they can be statistically interchanged as controls for each other. The univariate-multivariate sub-analyses demonstrate instead how the presence of an 8 cm myoma and the presence of an 8 cm myoma associated with over two myomas are statistically significantly associated with the risk of laparotomic conversion during laparoscopic myomectomy. Uni-multivariate analysis of the operating time over two hours shows that the number of enucleations and sutures increases when there are more than two myomas. These times inevitably add up in surgical procedures. The presence of a myoma over 8 cm is not significant. We hypothesized that this might be associated with rigidity of the myometrium wall, which can make myoma enucleation and myometrial suturing more difficult for the age variable. A previous myomectomy and the presence of a fibroid of over 8 cm are statistical-

Parameters	Group A <i>n</i> = 86	Group B <i>n</i> = 86	<i>p</i> -value
Age (years)	38.1 (24.5–46.9)	39.2 (22.5–49.2)	0.80 ^a
BMI [kg/m ²]	21.6 (17.3–37.8)	21.6 (16.3–43.0)	0.81ª
Obese (BMI \ge 30 kg/m ²)	7 (8.1%)	6 (7.0%)	> 0.99 ^b
Previous vaginal delivery (N)	13 (15.1%)	10 (11.6%)	0.65 ^b
Previous caesarean section (N)	6 (7.0%)	9 (10.5%)	0.59 ^b
Previous myomectomy (N)	10 (11.6%)	10 (11.6%)	> 0.99 ^b
History of other previous gynecological procedures (N)	25 (29.1%)	24 (27.9%)	> 0.99 ^b
History of other previous abdominal procedures (N)	21 (24.4%)	19 (22.1%)	0.85 ^b
Concomitant adnexal pathology (N)	5 (5.8%)	9 (10.5%)	0.42 ^b
Operative time (min)	120 (43–252)	111 (30–212)	0.60ª
Operative time \geq 2 hours (N)	43 (50.0%)	34 (39.5%)	0.22 ^b
Intraoperative blood loss [ml]	200 (10–1200)	200 (50–1000)	0.81ª
Intraoperative blood loss \geq 500 ml (N)	10 (11.6%)	12 (14.0%)	0.82 ^b
Hemoglobin drop in 1st post-operative day [g/dl]	1.8 (0.1–4.6)	2.2 (0.3–4.8)	0.81ª
Transfusions (N)	2 (2.3%)	4 (4.7%)	0.62 ^b
Opening of the endometrial cavity (N)	1 (1.2%)	4 (4.7%)	0.37 ^b
Number of removed myomas	2 (1–14)	2 (1–12)	0.71ª
Diameter of the larger myoma removed [cm]	8 (3–15)	10 (1–20)	0.88ª
Overall weight of the removed myomas [g]	142 (16–540)	236 (30–1380)	0.93ª
Intraoperative complications (N)	0	0	> 0.99 ^b
Hospital stay [days]	3 (1–8)	3 (2–7)	0.83ª
Early post-operative complications (\leq 30 days > G2) (N)	1 (%)	0	> 0.99 ^b
Late post-operative complications (> 30 days > G2) (N)	0	0	> 0.99 ^b

Table 3. Comparison of myomectomy population according to approach after propensity score matching 1:1

^a – Mann-Whitney U test, ^b – Fisher's exact test

Data are expressed as median (range), percentage (%) or absolute number (N).

ly significant variables in predicting blood loss that is equivalent to a hemoglobin drop of more than 3 points in the post-operative setting, confirming a much more complicated approach in the case of large myomas.

Although laparoscopic myomectomy has the advantages of minimally invasive technologies, some related problems have been raised recently, particularly regarding the removal of these masses from the abdominal cavity [18, 19]. After its approval in 1995 and for many years, power or electromechanical morcellation was the primary method of uterine fibroid fragmentation used at the time of laparoscopic myomectomy [20]. However, this method has been recently debated: the main issues were the risk of unintended morcellation of leiomyosarcomas and formation of endometriosis after adenomyoma morcellation. Moreover, another concern is the risk of developing "parasitic myomas" because of abdominopelvic dissemination of morcellated fibroid fragments [21-25]. Therefore, after Food and Drug Administration safety communications about this issue [26], the surgical community was pushed to utilize safer methods of performing morcellation, and nowadays the strategy adopted most often is morcellation performed in a laparoscopic bag. Evidence suggests that in-bag tumor morcellation may prevent parasitic fibroids, reduce the risk of upstaging premalignant lesions, and offer protection from direct morcellation trauma [27–31]. Thus, as recently suggested by the Food and Drug Administration's guidance, minimally invasive myomectomy is still feasible using hand morcellation, containment systems, and judicious use of the power morcellator [32]. As previously described, all laparoscopic myomectomies in the study were performed following scrupulous regular morcellation carried out safely in an endo-bag.

However, our study has several limitations, as it was a retrospective study, and the analysis did not consider the depth or location of the myomas.

Our results suggest that, in expert hands, it is rare that the laparoscopic myomectomy is not feasible; indeed, there have been very few conversions. However, the data analysis shows that for two myomas, of which one is greater than 8 cm, the cost-benefit relation with laparotomy is reduced. In these cases, laparoscopies are more challenging, and we must consider that the data predict longer operating times (over two hours) and more significant blood loss (over 500 ml).

Parameters	Group A (A1) One myoma ≤ 7 cm n = 116	Group A (A2) At least 2 myomas and at least one \ge 8 cm n = 53	Group B <i>n</i> = 99	<i>p</i> -value
Age (years)	36.9 (23.6–46.5)	37.3 (25.3–47.7)	38.2 (22.5–48.7)	0.16ª
BMI [kg/m ²]	21.6 (16.5–46.8)	24.8 (19.0–37.9)	21.7 (17.3–58.1)	0.24ª
Obese (BMI \geq 30 kg/m ²)	4 (3.4%)	6 (11.3%)	10 (10.1%)	0.08 ^b
Previous vaginal delivery (N)	26 (22.4%)	6 (11.3%)	13 (13.1%)	0.09 ^b
Previous caesarean section (N)	11 (9.5%)	3 (5.7%)	11 (11.1%)	0.54 ^b
Previous myomectomy (N)	3 (2.6%)	1 (1.9%)	11 (11.1%)	0.01 ^b
History of other previous gynecological procedures (N)	23 (19.8%)	8 (15.1%)	27 (27.3%)	0.18 ^b
History of other previous abdominal procedures (N)	22 (19.0%)	16 (30.5%)	24 (24.2%)	0.26 ^b
Concomitant adnexal pathology (N)	24 (20.7%)	5 (9.4%)	7 (7.1%)	0.009 ^b
Operative time (min)	95 (42–177)	126 (40–236)	105 (30–280)	< 0.0001ª
Operative time \geq 2 hours (N)	22 (19.0%)	30 (56.6%)	38 (38.4%)	< 0.0001 ^b
Intraoperative blood loss [ml]	150 (10–600)	200 (10–1000)	300 (10–2000)	< 0.0001ª
Intraoperative blood loss \ge 500 ml (N)	4 (3.4%)	4 (7.5%)	19 (19.2%)	0.0005 ^b
Hemoglobin drop on 1 st post-operative day [g/dl]	1.7 (0.1–4.2)	1.8 (0.1–4.9)*	2.2 (0.3–4.8)	< 0.0001ª
Transfusions (N)	0 (%)	1 (1.9%)	4 (4.0%)	> 0.99 ^b
Opening of the endometrial cavity (N)	2 (1.7%)	0	3 (3.0%)	> 0.99 ^b
Number of removed myomas	1	3 (2–18)	1 (2–16)	< 0.0001ª
Diameter of the larger myoma removed [cm]	6 (1–7)	10 (8–15)	10 (1–30)	< 0.0001ª
Overall weight of the removed myomas [g]	60 (10–320)	216 (51–765)	325 (30–5460)	< 0.0001ª
Conversions to laparotomy (N)	3 (2.7%)	7 (13.2%)	-	NA
Intraoperative complications (N)	0	0	0	> 0.99 ^b
Hospital stay [days]	2 (1–8)	3 (1–8)	3 (2–7)	< 0.0001ª
Early post-operative complications $(\leq 30 \text{ days} > G2)$ (N)	0	0	0	> 0.99 ^b
Late post-operative complications	0	0	0	> 0.99 ^b

Table 4. Comparison of laparoscopy with one myoma \leq 7 cm and laparoscopy with at least 2 myomas and at least one \geq 8 cm vs. open technique

^a – Mann-Whitney *U* test, ^b – Fisher's exact test, NA – not available

Data are expressed as median (range), percentage (%) or absolute number (N).

Table 5. Univariate and multivariate analysis of factors potentially related to the risk of laparotomy conversion during laparoscopic myomectomy

Parameters	Laparotomic conversion						
		Univariate analys	is	N	Multivariate analysis		
	OR	95% CI	<i>p</i> -value	OR	95% CI	<i>p</i> -value	
Age (≥ 40 years)	1.3	0.56–1.2	0.48				
BMI (≥ 30 kg/m²)	0.49	0.06-3.8	0.45				
Previous caesarean section	0.96	0.2–4.3	0.96				
Previous myomectomy	1.8	0.4–8.7	0.45				
Concomitant adnexal pathology	0.8	0.2–2.7	0.66				
Myoma size \geq 8 cm	14.5	2.0–107.8	0.02	15.8	2.1–120.9	0.008	
More than 2 myomas	1.8	0.8–4.2	0.20				
At least 2 myomas and one \ge 8 cm	4.4	1.3–14.5	0.03	4.3	1.2–13.6	0.03	

OR – odds ratio, CI – confidence interval

Parameters	Operative time > 2 hours					
_		Univariate analys	sis	N	sis	
—	OR	95% CI	<i>p</i> -value	OR	95% CI	<i>p</i> -value
Age (≥ 40 years)	1.9	1.2–2.8	0.006	1.9	1.2–2.9	0.009
BMI (≥ 30 kg/m²)	1.7	0.8–3.7	0.20			
Previous caesarean section	1.2	0.5–2.6	0.60			
Previous myomectomy	2.8	1.04-8.0	0.036	2.2	0.8–6.5	0.13
Concomitant adnexal pathology	1.2	0.6–2.1	0.61			
Myoma size \geq 8 cm	4.5	0.5-44.1	0.15			
More than 2 myomas	2.6	1.6–4.3	< 0.0001	2.0	1.2–3.5	0.01
At least 2 myomas and one \ge 8 cm	5.6	1.8–17.6	0.0008	3.2	0.9–11.0	0.06

Table 6. Univariate and multivariate analysis of factors potentially related to an operative time \geq 2 hours

OR – odds ratio, CI – confidence interval

Table 7. Univariate and multivariate analysis of factors potentially related to intraoperative blood loss ≥ 500 ml

Intraoperative blood loss \geq 500 ml					
ι	Jnivariate analys	sis	Μ	vsis	
OR	95% CI	<i>p</i> -value	OR	95% CI	<i>p</i> -value
1.7	0.9–3.4	0.12			
0.7	0.2–3.1	0.59			
0.6	0.2–2.8	0.51			
0.5	0.06–4.2	0.49			
0.3	0.07–1.3	0.06			
3.5	0.5–34.1	0.35			
0.7	0.3–1.6	0.35			
0.5	0.06–3.8	0.46			
	OR 1.7 0.7 0.6 0.5 0.3 3.5 0.7 0.5	In Univariate analys OR 95% Cl 1.7 0.9–3.4 0.7 0.2–3.1 0.6 0.2–2.8 0.5 0.06–4.2 0.3 0.07–1.3 3.5 0.5–34.1 0.7 0.3–1.6 0.5 0.06–3.8	Intraoperative blo Univariate analysis OR 95% Cl p-value 1.7 0.9–3.4 0.12 0.7 0.2–3.1 0.59 0.6 0.2–2.8 0.51 0.5 0.06–4.2 0.49 0.3 0.07–1.3 0.06 3.5 0.5–34.1 0.35 0.7 0.3–1.6 0.35 0.5 0.06–3.8 0.46	Intraoperative blood loss ≥ 500 Univariate analysis N OR 95% Cl p -value OR 1.7 0.9–3.4 0.12 0.7 0.7 0.2–3.1 0.59 0.6 0.6 0.2–2.8 0.51 0.5 0.3 0.07–1.3 0.06 0.3 3.5 0.5–34.1 0.35 0.35 0.7 0.3–1.6 0.35 0.46	Intraoperative blood loss ≥ 500 ml Multivariate analysis OR 95% Cl p -value OR 95% Cl 1.7 0.9–3.4 0.12 0.12 0.7 0.2–3.1 0.59 0.6 0.6 0.2–2.8 0.51 0.5 0.3 0.07–1.3 0.06 0.3 3.5 0.5–34.1 0.35 0.35 0.7 0.3–1.6 0.35 0.46

OR - odds ratio, CI - confidence interval

Table 8. Univariate and multivariate analysis of factors potentially related to the risk of loss of more than three points of hemoglobin [g/dl] in the first post-operative day

Parameters	Loss of \geq 3 points of hemoglobin [g/dl]						
-	l	Univariate analys	sis	Ν	/sis		
-	OR	95% CI	<i>p</i> -value	OR	95% CI	p-value	
Age (≥ 40 years)	0.9	0.4–1.8	0.70				
BMI (≥ 30 kg/m²)	0.3	0.04–2.3	0.17				
Previous caesarean section	0.6	0.1–2.7	0.48				
Previous myomectomy	2.8	0.9–9.1	0.10	2.9	0.9–9.6	0.07	
Concomitant adnexal pathology	0.7	0.2–1.9	0.42				
Myoma size ≥ 8 cm	8.9	1.2–65.2	0.04	9.6	1.3–70.7	0.02	
More than 2 myomas	0.9	0.4–2.0	0.85				
At least 2 myomas and one \ge 8 cm	1.1	0.2–4.8	0.93				

OR – odds ratio, CI – confidence interval

Conclusions

The choice of surgical technique for myomectomy must be made considering the age of the patient, BMI, and number and size of fibroids. The surgeon's skills and experience in mini-invasive surgery could influence our choice, and this study suggested that presence of two myomas, of which one is greater than 8 cm, represents a reasonable limit where laparoscopic choice does not reach the standards of clinical utility.

Disclosure

The authors report no conflict of interest.

References

- Cicinelli E, Tinelli R, Colafiglio G, Saliani N. Laparoscopy vs. minilaparotomy in women with symptomatic uterine myomas: a prospective randomized study. J Minim Invasive Gynecol 2009; 16: 422-426.
- Cramer SF, Patel A. The frequency of uterine leiomyomas. Am J Clin Pathol 1990; 94: 435-438.
- Parker WH. Etiology, symptomatology, and diagnosis of uterine myomas. Fertil Steril 2007; 87: 725-736.
- Sabre A, Serventi L, Nuritdinova D, Schiattarella A, Sisti G. Abnormal uterine bleeding types according to the PALM-COEIN FIGO classification in a medically underserved American community. J Turkish-German Gynecol Assoc 2021; 22: 91-96.
- De Franciscis P, Schiattarella A, Riemma G, et al. Hysteroscopic and ultrasonographic evaluation of ulipristal acetate treatment for symptomatic myomas in premenopausal women: a prospective study. Minim Invasive Ther Allied Technol 2022; 31: 435-440.
- 6. Parker WH. Uterine myomas: management. Fertil Steril 2007; 88: 255-271.
- Semm K. New methods of pelviscopy (gynecologic laparoscopy) for myomectomy, ovariectomy, tubectomy and adnectomy. Endoscopy 1979; 11: 85-93.
- Mais V, Ajossa S, Guerriero S, Mascia M, Solla E, Melis GB. Laparoscopic versus abdominal myomectomy: a prospective, randomized trial to evaluate benefits in early outcome. Am J Obstet Gynecol 1996; 174: 654-658.
- Buckley VA, Nesbitt-Hawes EM, Atkinson, et al. Laparoscopic myomectomy: clinical outcomes and comparative evidence. J Minim Invasive Gynecol 2015; 22: 11-25.
- Saccardi C, Gizzo S, Noventa M, Ancona E, Borghero A, Litta PS. Limits and complications of laparoscopic myomectomy: which are the best predictors? A large cohort single-center experience. Arch Gynecol Obstet 2014; 290: 951-956.
- 11. Shen Q, Chen M, Wang Y, et al. Effects of laparoscopic versus minilaparotomic myomectomy on uterine leiomyoma: a meta-analysis. J Minim Invasive Gynecol 2015: 22: 177-184.
- Sizzi O, Rossetti A, Malzoni M, et al. Italian multicenter study on complications of laparoscopic myomectomy. J Minim Invasive Gynecol 2007: 14: 453-462.
- Vargas M V, Moawad GN, Sievers C, et al. Feasibility, safety, and prediction of complications for minimally invasive myomectomy in women with large and numerous myomata. J Minim Invasive Gynecol 2017: 24: 315-322.
- Sinha R, Hegde A, Mahajan C, Dubey N, Sundaram M. Laparoscopic myomectomy: do size, number, and location of the myomas form limiting factors for laparoscopic myomectomy? J Minim Invasive Gynecol 2008: 15: 292-300.
- Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet 2007; 370: 1453-1457.
- 16. AAGL Practice Report: morcellation during uterine tissue extraction. J Minim Invasive Gynecol 2014; 21: 517-530.
- Borah BJ, Moriarty JP, Crown WH, Doshi JA. Applications of propensity score methods in observational comparative effectiveness and safety research: where have we come and where should we go? J Comp Eff Res 2014; 3: 63-78.
- Tanos V, Berry KE, Frist M, Campo R, de Wilde RL. Prevention and management of complications in laparoscopic myomectomy. Biomed Res Int 2018; 2018: 8250952.
- Glaser LM, Friedman J, Tsai S, Chaudhari A, Milad M. Laparoscopic myomectomy and morcellation: a review of techniques, outcomes, and practice guidelines. Best Pract Res Clin Obstet Gynaecol 2018; 46: 99-112.
- 20. Adelman MR. The morcellation debate: the history and the science. Clin Obstet Gynecol 2015; 58: 710-717.
- 21. The American College of Obstetricians and Gynecologists. Power morcellation and occult malignancy in gynecologic surgery. Available from: https://www.sgo.org/wp-content/uploads/2014/04/ACOG_Statement.pdf.
- 22. Theben JU, Schellong ARM, Altgassen C, Kelling K, Schneider S, Große-Drieling D. Unexpected malignancies after laparoscopic-assisted supracervical hysterectomies (LASH): an analysis of 1,584 LASH cases. Arch Gynecol Obstet 2012; 287: 455-462.

- Tanos V, Brölmann H, de Wilde RL, O'Donovan P, Symeonidou E, Campo R. ESGE survey on tissue power morcellation complications other than leiomyosarcoma. Gynecol Surg 2016; 13: 281-288.
- Donnez O, Squifflet J, Leconte I, Jadoul P, Donnez J. Posthysterectomy pelvic adenomyotic masses observed in 8 cases out of a series of 1405 laparoscopic subtotal hysterectomies. J Minim Invasive Gynecol 2007; 14: 156-160.
- Cucinella G, Granese R, Calagna G, Somigliana E, Perino A. Parasitic myomas after laparoscopic surgery: an emerging complication in the use of morcellator? Description of four cases. Fertil Steril 2011; 96: e90-e96.
- 26. U.S. Food and Drug Administration. UPDATED. Laparoscopic uterine power morcellation in hysterectomy and myomectomy: FDA safety communication. Available from: https://www.wilsonlaw.com/wp-content/ uploads/2014/12/UPDATED-Safety-Communication_Laparoscopic-Power-Morcellation.pdf.
- 27. Cohen SL, Einarsson JI, Wang KC, et al. Contained power morcellation within an insufflated isolation bag. Obstet Gynecol 2014; 124: 491-497.
- Leal MA, Piñera A, de Santiago J, Zapardiel I. Novel technique for contained power morcellation through umbilicus with insufflated bag. Gynecol Obstet Invest 2016; 82: 205-207.
- Steller C, Cholkeri-Singh A, Sasaki K, Miller CE. Power morcellation using a contained bag system. JSLS J Soc Laparoendosc Surg 2017: 21: e2016.00095.
- Paul PG, Thomas M, Das T, Patil S, Garg R. Contained morcellation for laparoscopic myomectomy within a specially designed bag. J Minim Invasive Gynecol 2016: 23: 257-260.
- Cohen SL, Morris SN, Brown DN, et al. Contained tissue extraction using power morcellation: prospective evaluation of leakage parameters. J Minim Invasive Gynecol 2015; 22: S83-S84.
- Parker WH, Kaunitz AM, Pritts EA, et al. U.S. Food and Drug Administration's guidance regarding morcellation of leiomyomas. Obstet Gynecol 2016; 127: 18-22.