

Original Article

Laparoscopy vs Minilaparotomy in Women with Symptomatic Uterine Myomas: A Prospective Randomized Study

Ettore Cicinelli, MD, Raffaele Tinelli, MD*, Giuseppe Colafoglio, MD, and Nicola Saliari, MD

From the Department of Obstetrics and Gynecology, University of Bari Medical School, Bari, Italy (all authors).

ABSTRACT Objective: To compare outcomes in patients with symptomatic uterine myomas who underwent laparoscopic (LPS) or minilaparotomic (MLPT) myomectomy.

Design: Prospective randomized study (Canadian Task Force classification II-2).

Setting: University hospital.

Patients: Eighty patients with no more than 3 uterine myomas of maximal diameter of 7 cm.

Intervention: Either LPS or MLPT myomectomy.

Measurements and Main Results: Mean blood loss, mean duration of postoperative ileus, and mean decrease in hemoglobin were significantly lower in the LPS compared with the MLPT group ($p < .001$). Mean operative time was not significantly longer in the LPS group compared with the MLPT group. Duration of hospitalization was significantly shorter in the LPS compared with the MLPT group ($p < .001$). No intraoperative complications were observed during MLPT. In 1 patient, conversion from LPS to MLPT was necessary because of difficulty in reconstructing the uterine wall.

Conclusion: Laparoscopic myomectomy is a suitable alternative to MLPT in women with 1 to 3 myomas. However, preoperative careful evaluation of the size and sites of the myomas is necessary to avert conversion and prevent complications. Journal of Minimally Invasive Gynecology (2009) 16, 422–426 © 2009 AAGL. All rights reserved.

Keywords: Complications; Laparoscopy; Minilaparotomy; Myomectomy; Uterine myomas

Uterine myomas are the most common uterine neoplasm and are diagnosed in 25% to 30% of women [1,2]. Myomas are often the cause of abnormal uterine bleeding, pelvic pain, infertility and miscarriage. Traditionally, abdominal myomectomy is considered the surgical technique of choice. However, in recent years, several studies have demonstrated the feasibility of laparoscopic (LPS) myomectomy approach [3,4]. Compared with the laparotomic approach, LPS myomectomy has some advantages including less pain and faster recovery [5–7], reduced blood loss, less morbidity [6], fewer complications [7], better cosmetic results, patient compliance, and lower adhesion rate [8]. However, LPS myomectomy is perceived as challenging by most gynecologic surgeons. Major concerns include wall reconstruction and skill in suturing

[9–11], reproductive outcome [12–15], risk of recurrence [16–19], cost [20,21], operative time [6,7], and risk of conversion to an open procedure [14,19]. To optimize the surgical outcome and to improve the feasibility of LPS myomectomy and to enable this approach to become the standard technique, limits in terms of number (≤ 5) and size (8–10 cm) of myomas have been suggested [5,8,12,14].

In recent years, a laparotomic approach via a small abdominal incision (minilaparotomic myomectomy [MLPT]) has been proposed as an alternative to LPS. Skin incisions no larger than 5 to 6 cm enable reduction of the clinical effect and complications of traditional laparotomy without requiring extraordinary skill in laparoscopic suturing [22–25].

To our knowledge, the literature contains few studies that compared LPS and MLPT myomectomy, and the results are conflicting [5,15,26,27]. Whereas Fanfani et al [24] concluded that there is no difference between the 2 techniques, both Alessandri et al [6] and Palomba et al [7] reported that LPS myomectomy is characterized by less blood loss and shorter hospital stay but also by longer operative time.

To contribute to defining the best surgical approach for uterine myomectomy, in a randomized study, we compared the results of LPS and MLPT myomectomy in women with

The authors have no commercial, proprietary, or financial interest in the products or companies described in this article.

Corresponding Author: Raffaele Tinelli, MD, Department of Obstetrics and Gynecology, University of Bari Medical School, Piazza Giulio Cesare, 70124 Bari, Italy.

E-mail: raffaeletinelli@tiscali.it

Submitted December 21, 2008. Accepted for publication March 13, 2009.

Available at www.sciencedirect.com and www.jmig.org

symptomatic uterine myomas within the above-described surgical limits for the LPS technique.

Materials and Methods

Between January 2007 and December 2007, we enrolled 80 women with symptomatic uterine myomas who were referred to our department of obstetrics and gynecology for surgical treatment. Indications for myomectomy were abnormal uterine bleeding, infertility, repeated miscarriage, and pain. The study was approved by the institutional review board, and all women gave informed consent. The procedures used in this study were in accord with the guidelines of the Helsinki Declaration on human experimentation.

At admission, women were randomly assigned to either the MLPT or the LPS group. Randomization order was obtained by using a computer-generated randomization list. All women underwent transvaginal ultrasonography to confirm eligibility for the protocol. Inclusion criteria were the presence of no more than 3 symptomatic subserous or intramural myomas no larger than 7 cm. Exclusion criteria were the presence of more than 3 myomas, at least 1 myoma larger than 7 cm, cardiopulmonary disease contraindicating the LPS approach, and preoperative hemoglobin level less than 9 g/dL.

One week before surgery, all women underwent transvaginal ultrasonography to assess for the presence or absence of associated pelvic diseases and to determine the number, dimension, and location of myomas. Surgeons were informed of the type of intervention planned (LPS or MLPT) just before performing the operation. All interventions, both LPS or MLPT myomectomy, were performed by the same surgical team (E.C., R.T., and G.C.).

Bowel preparation and antithrombotic prophylaxis were performed, and short-term intraoperative prophylactic antibiotic therapy with a second-generation cephalosporin was administered to all patients. Age, body mass index, intraoperative blood loss, 24-hour postoperative decrease in hemoglobin level, need for blood transfusion, duration of postoperative ileus, length of hospital stay, and intraoperative or postoperative complications were recorded. Fever was defined as body temperature of 38°C or higher at 2 consecutive measurements at 6-hour intervals excluding the first day after surgery.

Six months after surgery, all patients underwent gynecologic and ultrasonographic examinations to assess for recurrence of myomas.

Laparoscopic Myomectomy

Technically, pneumoperitoneum was induced using a Veress needle. One infraumbilical entry for the laparoscope and 3 suprapubic ancillary trocars were used. Specifically, one 5-mm trocar was inserted in the midline 3 cm under the umbilicus, and a 5-mm trocar was placed on each side of the pelvis. In addition, a uterine manipulator was placed in the cervix to position the uterus optimally during enucleation and suturing. The patient was placed in the Trendelenburg position at approximately

30 degrees, and the number, size, and location of the myomas were noted. The uterine serosa overlying the myoma was incised with a monopolar needle without using any vasoconstricting solution, and the myoma was fixed for adequate traction with a Manhes grasping forceps (Karl Storz GmbH, Tuttlingen, Germany) and was pulled out using a drill. Bipolar coagulation and cutting of connective tissue bridges facilitated myoma extrusion. The uterine wall was sutured in 2 layers using Monocryl-1 synthetic monofilament (Ethicon SpA, Rome, Italy) using an extracorporeal technique. Myomas were extracted by morcellation using an electromechanical morcellator (Karl Storz GmbH). The 5- and 10-mm incisions were sutured with interrupted polyglactin 910 sutures (Vicryl 2-0; Ethicon SpA).

Minilaparotomic Myomectomy

A 5-cm transverse suprapubic incision was made. The height with respect to the pubic symphysis varied from 1 to 3 cm depending on the location of the myomas in the anterior or posterior uterine wall, respectively. The skin and subcutaneous tissues were opened horizontally, and the fascia was opened longitudinally. After separating the rectus muscles, the parietal peritoneum was exposed and incised vertically. The most prominent part of the uterine serosa overlying each myoma was cut using a monopolar knife. Care was paid to make the cut as small as possible. Enucleation was performed following the cleavage plane between the myoma and the pseudocapsule. The myoma beds were sutured with interrupted polyglactin 910 sutures.

Statistical Analysis

Results in the 2 groups were compared using the Mann-Whitney U test, the Fisher exact test, and the χ^2 test, as appropriate. Confidence intervals were calculated for categorical data. All calculations were performed using commercially available software (SPSS release 10.0.5; SPSS, Inc, Chicago, Illinois). A p value of <.05 was considered statistically significant.

Results

Patient characteristics are given in the Table 1. Continuous parametric variables were expressed as mean (SD) and 95% confidence interval.

No difference was observed between the 2 groups insofar as mean age, mean body mass index, uterine size, number and position of myomas, and dimension of the largest myoma (Table 1).

Peritoneal adhesions were observed in 7 patients in the LPS group (17.5 %) and 11 patients in the MLPT group (27.5 %), and endometriotic lesions in 4 patients in the LPS group (10 %) and 6 patients in the MLPT group (15 %) ($p = .45$). The mean (SD) number of myomas removed was similar in the LPS and MLPT groups: 2.1 (0.3) vs 2.0 (0.4) ($p = .43$). Similarly, mean size of the biggest myoma was similar in the 2 groups: 5.2 (1.0) vs 4.8 (1.1) cm ($p = .41$).

Table 1
Patient characteristics

Characteristic	Laparoscopy (n = 40)	Minilaparotomy (n = 40)	p Value
Age, mean (SD); 95% CI, y	32.1 (8.5); 22.2–44.1	34.3 (9.3); 17.6–43.7	.71
Weight, mean (SD); 95% CI, kg	56 (13); 41–89	60 (16); 46–93	.63
BMI, ^a mean (SD); 95% CI	29 (7); 18–32	30 (8); 19–35	.54
Hospital stay, mean (SD); 95% CI, d	2.1 (0.6); 1–5	3.3 (0.5); 1–5	<.01
Complications, No. (%)			
Endometriosis	4 (10)	6 (15)	.45
Peritoneal adhesions	7 (17.5)	11 (27.5)	.49
Postoperative fever	5 (12.5)	10 (25)	<.01

Abbreviations: BMI, body mass index; CI, confidence interval.

^a Calculated as weight in kilograms divided by height in meters squared.

Mean blood loss and mean hemoglobin level decrease were significantly lower in the LPS compared with the MLPT group: 133 (29) vs 186 (44) mL ($p < .01$) and 1.5 (0.4) vs 2.5 (0.3) g/dL ($p < .01$). Mean operative time was longer by 9 minutes in the LPS group compared with the MLPT group (not significantly different) (Table 2). The mean (SD) duration of postoperative ileus was significantly shorter in the LPS group compared with the MLPT group: 18 (7) vs 31 (6) hours ($p < .01$). The mean hospital stay in the LPS group was significantly shorter than in the MLPT group: 2.1 (0.6) vs. 3.3 (0.5) days ($p < .001$). No patient required any intraoperative or postoperative blood transfusion. No intraoperative complications were observed during MLPT, whereas in 1 patient in the LPS group with a 7-cm intramural myoma, conversion to MLPT myomectomy was required because of difficulty in reconstructing the uterine wall. In 1 patient, moderate subcutaneous emphysema developed at pneumoperitoneum creation, which was managed by simply waiting approximately 10 minutes before continuing the operation. Postoperative fever was reported in 5 patients in the LPS group (12.5 %) and in 10 patients in the MLPT group (25%) ($p < .01$). At 6 months after surgery, no myoma recurrence was observed at transvaginal ultrasonography.

Discussion

The results of our study favor LPS myomectomy. The data demonstrate that the LPS approach is associated with a number of clinical advantages such as less blood loss and shorter hospital stay and that it does not cause substantial prolongation of surgical time. Several authors [17,28,29] have noted that the rate of complications, even if low, correlates positively with the number and size of the myomas. In addition, intraligamentous location of myomas is considered to pose a higher risk of complications, primarily hemorrhagic. A recent report confirmed that the probability of complications is significantly correlated with the number and the site (intramural or intraligamentous) of myomas, whereas their size seems to influence primarily the risk of major complications [28].

Fanfani et al [24] compared LPS and LMPT in the management of 213 women with at least 1 subserosal or intramural uterine myoma. One hundred twenty myomectomies were performed using the MLPT technique, and 93 using the LPS technique. No intraoperative or early postoperative complications were reported. The median (range) operating time was 62.3 (45–80) minutes and 61.6 (40–90) minutes in the LPS and MLPT groups, respectively ($p = \text{NS}$). Median length of hospital stay was 2.3 (2–3) days and 2.8 (2–3) days in the LPS and MLPT groups, respectively ($p = \text{NS}$). Those authors concluded that the MLPT technique can be considered a minimally invasive alternative to the LPS technique in the surgical management of intramural and subserosal myomas.

A recent randomized study [6] analyzed the surgical outcomes in 148 patients undergoing LPS or MLPT myomectomy. In that study, LPS was associated with a lower decrease in hemoglobin level, a shorter duration of postoperative ileus, less postoperative analgesic use, and a shorter time to discharge when compared with MLPT. The authors concluded that LPS myomectomy compared with MLPT myomectomy may offer the benefits of less postoperative analgesic use and faster postoperative recovery.

In our experience, mean blood loss, mean duration of postoperative ileus, and mean hemoglobin level decrease were significantly lower in the LPS compared with the MLPT group. Length of hospital stay was significantly shorter in the LPS compared with the MLPT group, and no patient required any intraoperative or postoperative blood transfusion. No intraoperative complications were observed in the MLPT group, whereas in 1 patient in the LPS group with a 7-cm intramural myoma, conversion was necessary because of difficulty in reconstructing the uterine wall.

In 1 patient, moderate subcutaneous emphysema occurred at pneumoperitoneum creation and was managed by waiting 10 minutes before continuing the operation. The low rate of complications may be related to the inclusion criterion that excluded myomas larger than 7 cm. Findings at 6-month follow-up suggested that LPS and MLPT myomectomy have the same therapeutic effectiveness.

Our results are in disagreement with a recent study by Fanfani et al [25] of 213 myomectomies performed using the LPS or MLPT technique. The authors reported that no difference in mean operative time, median duration of ileus, and median length of hospital stay was detected between the 2 groups. Moreover, no significant difference in postoperative analgesic administration was recorded. No patients underwent a second surgery because of early postoperative complications, and no wound infections or dehiscences were reported in the 30 days after surgery in the 2 groups. The authors concluded that the MLPT technique can be considered a minimally invasive alternative to the LPS technique in the surgical management of intramural and subserosal myomas.

In a recent study, Somigliana et al [30] observed a causal relationship between fibroids and infertility, with particular emphasis on the benefits of myomectomy. This association was primarily supported by studies comparing pregnancy

Table 2
Intraoperative characteristics

Characteristic	Laparoscopy (n = 40)	Minilaparotomy (n = 40)	p Value
No. of myomas removed, mean (SD); 95% CI	2.1 (0.3); 1–3	2.0 (0.4); 1–3	.43
Maximal myoma size, mean (SD); 95% CI, cm	5.2 (1.0); 1.3–7.0	4.8 (1.1); 1.5–7	.41
Blood loss, mean (SD); 95% CI, mL	133 (29); 61–293	186 (44); 67–277	<.01
Hemoglobin level decrease, mean (SD); 95% CI, g/dL	1.5 (0.4); 0.2–2.1	2.5 (0.3); 0.3–3.6	<.01
Operative time, mean (SD); 95% CI, min	80 (23); 59–159	71 (18); 34–161	NS
Postoperative fever, No. (%)	5 (12.5)	10 (25)	<.01
Postoperative ileus, mean (SD); 95% CI, hr	18 (7); 10–36	31 (6); 11–39	<.01
Site of myomas, No. (%)			
Anterior	24 (36.5)	21 (32.3)	NS
Posterior	20 (31.3)	24 (36.9)	NS
Fundal	13 (19.3)	13 (20.5)	NS
Lateral	8 (12.9)	7 (10.3)	NS

Abbreviations: CI, confidence interval; NS, not significant; SD, standard deviation.

rate after in vitro fertilization in women with and without fibroids. The emerging view was that submucosal, intramural, and subserosal fibroids interfere with fertility in decreasing order of importance. The beneficial effects of surgery were further supported by findings from clinical series that showed that the pregnancy rate after myomectomy is satisfactory. The most important complication was rupture of the uterus during pregnancy or labor [31].

In an observational study, Dubuisson et al [32] analyzed the outcome of pregnancies and deliveries after LPS myomectomy and assessed the risk of uterine rupture. Ninety-eight patients became pregnant at least once after undergoing LPS, for a total of 145 pregnancies. Among the 100 patients who delivered, there were 3 cases of spontaneous uterine rupture. Because only 1 of these uterine ruptures occurred on the LPS myomectomy scar, the risk of uterine rupture was 1.0% (95% confidence interval, 0.0%–5.5%). Sixty-two patients (72.0%) experienced trials of labor. Of these, 58 (80.6%) were delivered vaginally, and four by cesarean section. There was no uterine rupture during the trials of labor. The authors concluded that spontaneous uterine rupture seems to be rare after LPS myomectomy and that particular care must be given to uterine closure when performing LPS myomectomy.

In a recent randomized controlled trial by Palomba et al [7] including 136 myomectomies performed using the LPS or MLPT technique, intraoperative blood loss, variation in hemoglobin levels, postoperative use of analgesics, and hospital stay were significantly lower in the LPS compared with the MLPT group, whereas the MLPT technique was associated with shorter operating time. The authors concluded that careful evaluation of the dimensions and locations of fibroids is needed to determine the best approach. The different results in terms of duration of operation between our

study and that of Palomba et al [7] may be explained by a few factors. First, we enrolled only women with no more than 3 myomas and no myomas larger than 7 cm, and this limited the operating time required to accomplish the intervention. Second, in our study, we used a new electromechanical disposable morcellator, which proved effective in rapid removal of the myomas.

Conclusions

Laparoscopic myomectomy is a safe and effective alternative to MLPT myomectomy in young women with no more than 3 symptomatic uterine myomas and with myomas no larger than 7 cm. In our patients, LPS did not substantially increase operating time and resulted in decreased intraoperative blood loss, less postoperative fever, and shorter hospital stay. Intraoperative complications were similar in the 2 groups. Multicenter, randomized, clinical trials with longer follow-up will be necessary to evaluate the long-term outcomes of LPS myomectomy. Careful evaluation of the number, size, and location of myomas is necessary in choosing the best surgical approach.

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