

UTERINE FIBROIDS

Laparoscopy versus minilaparotomy in women with symptomatic uterine myomas: short-term and fertility results

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Objective: To retrospectively compare the feasibility, safety, morbidity, and pregnancy outcome of laparoscopy (LPS) and minilaparotomy (LPT) in the treatment of symptomatic uterine myomas.

Design: Retrospective, nonrandomized study.

Setting: Advanced Gynecological Endoscopy Center, Malzoni Medical Center, Avellino, Italy.

Patient(s): 680 nonconsecutive patients with symptomatic uterine myomas.

Intervention(s): 350 women underwent LPS, and 330 underwent LPT myomectomy.

Main Outcome Measure(s): Operative time, blood loss, hospital stay, pregnancy rate, and spontaneous abortion rate.

Result(s): The mean operative time was 63 ± 21 minutes (95% CI, 48–143) in the LPS group and 57 ± 23 minutes (95% CI, 38–121) in the LPT group. The mean length of hospital stay was statistically significantly greater in the LPT group (3.1 ± 0.5 ; 95% CI, 1–5) than the LPS group (2.1 ± 0.8 ; 95% CI, 1–4). The overall spontaneous pregnancy rate after myomectomy was 53%; the pregnancy rate after LPS myomectomy (56%) was not statistically significantly higher than the rate for LPT (50%).

Conclusion(s): Laparoscopy showed a lower morbidity than reported for the open approach and was characterized by less blood loss and a shorter postoperative hospitalization with an higher pregnancy rate. The operating time was not much longer in the laparoscopic group, and the intraoperative and postoperative complications appeared acceptable and not more than what is traditionally expected with the open approach. (Fertil Steril® 2010;93:2368–73. ©2010 by American Society for Reproductive Medicine.)

Key Words: Fertility, laparoscopy, minilaparotomy, myomectomy

The introduction of minimally invasive surgical techniques and laparoscopy (LPS) for the treatment of numerous gynecologic diseases has resulted in remarkable advantages for the patient in both social and economic terms (shorter hospitalization and earlier resumption of normal activities) (1, 2). Laparoscopy has been shown to be a valid alternative to the standard open technique, with comparable long-term outcomes, shorter hospital stay, earlier recovery, and a better quality of life. However, LPS myomectomy can be a difficult procedure, especially for large myomas (3, 4).

In 1996, a study proposed minilaparotomy (LPT) as a valid, cost-effective alternative to LPS in the treatment of benign gynecologic disease, and the use of LPT in the treatment of uterine myomas has already been investigated (5). A recent study

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reported that minilaparotomy represents a true minimally invasive surgical approach that can be used safely in the management of benign and neoplastic gynecologic disease (6–9).

Although several studies have compared myomectomy by laparoscopy and laparotomy (10–13), few long-term data on the effectiveness and the morbidity of laparoscopic and minilaparotomic approaches in the treatment of uterine myomas are available. Our study in a series of 680 women retrospectively compared the feasibility, safety, morbidity, and pregnancy outcomes of laparoscopy (LPS) and minilaparotomy (LPT) in the treatment of symptomatic uterine myomas.

MATERIALS AND METHODS

Between January 2002 and January 2007, 680 women underwent surgery with either LPS myomectomy or LPT myomectomy (Table 1) at the Advanced Gynecological Endoscopy Center of the Malzoni Medical Center, Avellino, Italy. All of the patients who underwent LPS were informed that LPT would be performed if difficulties were encountered with the LPS approach, and all of the women gave their informed consent.

TABLE 1

Patient characteristics.			
Characteristic	Laparoscopy (n = 350)	Minilaparotomy (n = 330)	P value
Median age, y (range)	34.3 (21.7–43.1)	36.1 (19.6–44.1)	
Median weight, kg (range)	58 (45–87)	61 (49–95)	
Median BMI, kg/m ² (range)	26 (19–34)	28 (21–37)	
Hospital stay (d), mean ± SD (95% CI)	2.1 ± 0.8 (1–4)	3.1 ± 0.5 (1–5)	< .01
Number of myomas removed, median (range)	2.5 (1–5)	2.7 (1–5)	NS
Type of myomas, n (%)			NS
Intramural	570 (65.2)	602 (67.6)	
Subserosal	305 (34.8)	289 (32.4)	
Position of leiomyomas, n (%)			NS
Anterior	258 (29.5)	245 (27.6)	
Posterior	346 (39.6)	339 (38.1)	
Fundal	141 (16.2)	152 (17.1)	
Infraligamentary	51 (5.8)	61 (6.9)	
Lateral	79 (8.9)	93 (10.3)	
Diameter of the largest myoma (cm), median (range)	6.3 (4.1–9.1)	6.5 (4.3–9.5)	NS

Note: BMI = body mass index; NS, not statistically significant.

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The main indications for myomectomy were abnormal uterine bleeding, unexplained infertility, abortion, and pain. The diagnosis of unexplained infertility was made after exclusion of endocrine abnormalities, and tubal and male infertility factors with a complete hormonal assay, a hysterosalpingogram, and a semen analysis; we excluded the patients whose partners presented with severe oligoasthenospermia.

Inclusion criteria were symptomatic subserous or intramural myomas with sizes ranging from 3 to 10 cm and the number of myomas ranging from one to five. Of the enrolled participants, 350 women underwent LPS myomectomy at our institution, and none of the surgeries required conversion to laparotomy; 330 patients underwent LPT myomectomy. All the surgeons involved in the current protocol were skilled in both procedures, and the decision between the two minimally invasive approaches was made preoperatively according to surgeon preference and was based on patient and myoma characteristics.

Patients were not considered candidates for the LPS approach and underwent LPT when any of the following criteria was present: a documented significant cardiopulmonary disease defined as a history of cardiac failure, myocardial infarction, unstable angina, or pulmonary obstructive disease poorly controlled or contraindicating prolonged Trendelenburg position; prior pelvic or abdominal radiation therapy; severe hip disease precluding the use of the dorsolithotomy position; or inadequate bone marrow, renal, and hepatic function. Previous abdominal surgery was not considered a contraindication for the LPS approach.

Exclusion criteria for the two groups were submucosal myomas, contraindications for general anesthesia, systemic

infections, presence of more than five uterine leiomyomas or of leiomyomas with a main diameter more than 10 cm, adnexal abnormalities at ultrasound, an abnormal Papanicolaou smear, or a positive plasma pregnancy test.

The patient characteristics reported were age, height, weight, body mass index (BMI), operative time, estimated blood loss, perioperative blood transfusions, length of hospital stay, intraoperative and postoperative complications, fertility, and pregnancy outcome.

All of the patients underwent a pelvic examination and preoperative transvaginal ultrasonography with color Doppler evaluation to determine the number, location, and size of the myomas and the presence/absence of associated pelvic diseases, and underwent diagnostic hysteroscopy to exclude the presence of submucous myomas.

All of the patients had antibiotic prophylaxis (cefodoxitin, 2 g intravenously) and perioperative low-molecular-weight enoxaparin (40 mg/24 hours, subcutaneously). The vaginal cavity was cleansed with povidone-iodine solution, and a Foley catheter was placed in the bladder.

In addition, before the LPS procedure, an intraoperative lower extremity sequential compression device for venous thrombosis prophylaxis was used. The patient was usually placed in the dorsolithotomy position with the legs in universal Allen stirrups.

All procedures were performed under general endotracheal anesthesia. After induction of general anesthesia, an orogastric tube was inserted by the anesthesiologist to decompress the stomach, which was removed at the end of the operation.

The length of postoperative ileus was evaluated by asking the patients when they recovered the ability to pass gas. The median hemoglobin decline was determined 24 hours after surgery.

All patients underwent gynecologic and ultrasonographic examinations to assess leiomyoma recurrence at 6 months after surgical intervention. Of the 680 patients who underwent myomectomy, 164 wished to conceive after the surgery and had been considered for this study: of these patients 91 underwent LPS and 73 LPT. Information regarding the patients was obtained from the hospital records, physicians, and direct report from the patients. We confirmed by direct telephone interviews the information and status of patients who had wished to conceive. The median length of follow-up observation was 35 months (range: 4 to 63 months).

Surgical Technique

A 10-mm trocar (Wolf; Richard Wolf, Knittlingen, Germany) that incorporated the zero-degree laparoscope (Karl Storz, Tuttlingen, Germany) was inserted through an umbilical vertical incision, and entrance into the abdominal cavity was made under direct visualization after pneumoperitoneum by Veress needle (Auto-Suture, Norwalk, CT) was induced at the level of umbilicus; the laparoscope was connected to a video monitor.

Once the trocar was safely introduced into the abdominal cavity, the cavity was insufflated. The intra-abdominal pressure was maintained at 15 mm hg. A uterine manipulator was placed in the cervix to permit anteversion, lateral uterine movements, and organ exposure.

In patients with a prior midline incision, the initial entry into the abdominal cavity was made approximately 2 cm below the left costal margin at the level of the midclavicular line to avoid injury to bowel adherent to the anterior abdominal wall.

Three suprapubic ancillary trocars were used: one 5-mm trocar was inserted in the midline 3 cm under the umbilicus, and one was inserted in each iliac fossa (5 mm on the left side and 10 mm on the right side) laterally to inferior epigastric vessels, respectively.

Before the operative procedure, all the pelvic structures were inspected, and the abdomen was explored through the laparoscope in a clockwise fashion. The patient was placed approximately in a 30 degree Trendelenburg position to facilitate the retroperitoneal exposure by retaining the small intestine in the middle and upper abdomen using gravity and gentle instrumentation. The number, size, and location of myomas were noted; the course of the ureter, especially in the case of broad ligament myomas, was traced.

Using a monopolar needle, the serosa overlying the myoma was then incised until the pseudocapsule of the myoma was reached. After the identification of the cleavage plane, the myoma was then fixed with a myoma drill (Karl Storz)

for adequate traction, and the excision of the fibroid was performed by introducing Endoshears (Tyco U.S. Surgical, Norwalk, CT) and bipolar forceps (BiClamp, ERBE VIO System, Tübingen, Germany) between the uterine wall and the myoma for coagulating and cutting connective tissue bridges.

Hemostasis was performed with bipolar forceps, and the suture of the uterine wall was performed in one or two layers with Polysorb 0 GS-21 (Polysorb, USSC, Norwalk, CT) interrupted sutures, made with extracorporeal knots.

The myomas were removed and extracted from the pelvic cavity using a single-patient-use electromechanical tissue morcellator (Gynecare Morceller, Ethicon Women's Health and Urology, Johnson & Johnson Gateway, Somerville, NJ) through laparoscopic port sites of 15 mm.

The LPS control of the hemostasis was performed. At the conclusion of the surgical procedure, we deflated the abdomen before removing the trocars. The 5- and 10-mm incisions were closed with mattress sutures of 4-0 Prolene.

Minilaparotomy was performed with a suprapubic transverse incision 4 to 6 cm in length, approximately 3 cm above the pubic symphysis. The incision was performed slightly higher for patients with a posterior myoma. The skin and subcutaneous tissue were opened horizontally to the level of the fascia, and the rectus muscle was separated longitudinally in the midline. The parietal peritoneum was opened longitudinally until the pelvic cavity.

A 3- to 6-cm linear incision was performed, making a small opening on the uterine wall on the most prominent part of the myoma that was enucleated after identification of the pseudocapsule. Careful dissection around the capsule of the myoma with coagulation of blood vessels as they were encountered was performed with significantly reduced blood loss. The large blood vessels at the base were easily identified and desiccated when the remains of the myoma were brought through the incision.

Hemostasis was performed with bipolar forceps, and the suture of the uterine wall was performed in one or two layers with Polysorb 0 GS-21 (Polysorb; USSC) interrupted sutures.

In the case of large myomas, morcellation by a cold knife was performed to avoid enlarging the incision, and a scar measurement was made at the end of the minilaparotomy.

Statistical Analysis

The chi-square test, Fisher's exact test, Mann-Whitney *U* test, and Student's *t*-test were used for statistical analysis. Variables with normal distribution were expressed as mean (\pm standard deviation) and 95% confidence interval (CI). Nonparametric variables were expressed as median and range. Statistical analysis was performed by use of the Statistical Package for Social Science for Windows (SPSS, Inc., Chicago, IL). $P < .05$ was considered statistically significant.

RESULTS

Median age, median BMI, median number, median diameter, type, and localization of myomas removed were similar in the two groups. Various patient characteristics are shown in [Tables 1 and 2](#) (variables with normal distribution are expressed as mean and 95% CI).

The median diameter of the largest myoma was 6.3 cm (range: 4.1 to 9.1) in the LPS group and 6.5 cm (range: 4.3 to 9.5) in the LPT group ($P=.053$). The mean operative time was 63 ± 21 minutes (95% CI, 48–143) in the LPS group and 57 ± 23 minutes (95% CI, 38–121) in the LPT group ($P=.059$). In our experience, no patient required an intraoperative or postoperative blood transfusion in either of the two groups, and no patient underwent a second surgery in the LPT group for early postoperative complications.

We routinely removed the catheter immediately after the surgical procedure, and all patients could void spontaneously without any difficulty. Postoperative fever was reported in 17 patients (5.4%) who underwent LPS and in 21 patients (6.3%) who underwent LPT ($P=.45$). In one patient of the LPS group we observed a postoperative hematoma that was diagnosed within the first 24 hours after surgery as a net hemoglobin decline that was resolved with hemostasis performed by LPS with bipolar forceps and interrupted sutures of the uterine wall after the cavity was adequately drained and without conversion to laparotomy. No wound dehiscences were registered in the 30 days after surgery in the two groups.

At 6 months after surgery no myoma recurrence was observed at transvaginal ultrasonography.

Fifty-one of the 91 patients (56%) who underwent LPS myomectomy and 37 of the 73 patients (50%) who underwent LPT myomectomy had a total of 97 spontaneous pregnancies (not statistically significant): 59 in the LPS group and 38 in the LPT group. Moreover, there were eight spontaneous abortions in the LPS group and 13 in the LPT group ([Table 3](#)).

The overall pregnancy rate after myomectomy was 53% (88 out of 164 patients), and the delivery rate was 90% (88 deliveries). Forty-two deliveries (26 in the LPS group and 16 in the LPT group) were vaginal (43%), and 55 (33 in the

LPS group and 22 in the LPT group) were by caesarean section (57%). Five preterm deliveries (5%) occurred (three in the LPS group and two in the LPT group) and three cases of twin pregnancy (one in the LPS group and two in the LPT group), two of which ended at 35 weeks and one at 34 by caesarean section. At the end of the study, the cumulative pregnancy rate and the cumulative live birth rate were similar between the two groups (not statistically significant).

DISCUSSION

In the past, some randomized trials demonstrated the benefits of LPS versus abdominal myomectomy (11) and of minilaparotomic versus abdominal myomectomy (14). A recent study (12) demonstrated that, in women with a mean number of 2.7 myomas and a mean large myoma size of 7 cm, LPS reduced postoperative pain, time of discharge, and time of recovery when compared with abdominal myomectomy. However, not all surgeons are comfortable with LPS myomectomy and uterine repair. Minilaparotomy has been proposed to maintain the efficacy of uterine repair and to reduce the clinical impact of myomectomy by laparotomy (15).

Laparoscopic myomectomy is perceived by most gynecologic surgeons as technically challenging, and the ability to perform a quick and safe laparoscopic suture is probably the major technical limit (16–18).

In our experience, LPS has been associated with a statistically significantly lower decline of hemoglobin concentration, a shorter time of postoperative ileus, and a reduced time of discharge when compared with LPT; the mean blood loss was significantly higher in the LPT group compared with the LPS group, but no patient required an intraoperative or postoperative blood transfusion, and only one patient in the LPS group underwent a second surgery for an early postoperative complication. The data from the 6-month follow-up period suggested that LPS and LPT myomectomy have the same therapeutic effectiveness.

The extremely low conversion rate we experienced showed that LPS myomectomy is feasible even with multiple large myomas, although the prolonged operating time could be a result of anesthetic problems during the surgical procedures. Several investigators (16, 19–20) have noted that the rate of

TABLE 2

Intraoperative characteristics.

Intraoperative data	Laparoscopy (n = 350)	Minilaparotomy (n = 330)	P value
Blood loss (mL), mean \pm SD (95% CI)	145 \pm 39 (45–260)	195 \pm 52 (50–290)	< .01
Hemoglobin decline (g/dL), median (range)	0.9 (0.2–2.4)	1.7 (0.3–2.9)	< .01
Operative time (min), mean \pm SD (95% CI)	63 \pm 21 (48–143)	57 \pm 23 (38–121)	.059
Postoperative fever, n (%)	17 (5.4)	21 (6.3)	.45
Time of postoperative ileus (h), mean \pm SD (95% CI)	22 \pm 6 (8–39)	29 \pm 6 (11–41)	< .01

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TABLE 3**Fertility outcomes in the laparoscopic and minilaparotomic groups.**

Fertility outcomes	Laparoscopy (n = 91)	Minilaparotomy (n = 73)	P value
Spontaneous pregnancies	59	38	
Spontaneous abortion	8	13	.086
Pregnancy rate, no. of pregnant patients/no. of patients (%)	51/91 (56)	37/73 (50)	.49
Vaginal deliveries, no. of vaginal deliveries/no. of pregnancies (%)	26 (44)	16 (42)	
Caesarean section, no. of cesarean deliveries/no. of pregnancies (%)	33 (56)	22 (58)	
Preterm delivery, no. of preterm deliveries/no. of pregnancies (%)	3 (5)	2 (5)	

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complications, even if very low, correlates positively with the number and larger diameter of the myoma. Also, intraligamentous myomas have been confirmed to be at higher risk of complications, and most of them are hemorrhagic.

Laparoscopy is a technically challenging procedure that requires training, specialized instrumentation, advanced extracorporeal suturing capability, and skilled use of the morcellator; also, potentially catastrophic vascular or visceral injuries can occur (21).

A recent randomized study by Alessandri et al. (22) compared the postoperative recovery of 148 patients undergoing LPS or LPT myomectomy. Laparoscopy was associated with a significantly lower decline of hemoglobin concentration, a reduced length of postoperative ileus, and a shorter time to discharge. Pain intensity at 6 hours after surgery was significantly lower in the LPS group. There were two complications in the LPS group (one laparoconversion and one acute diffuse peritonitis caused by ileal perforation).

In a recent prospective multicenter study by Sizzi et al. (19) of 2050 myomectomies by LPS, the most serious events were hemorrhages (14 cases) with three cases that required blood transfusions, 10 postoperative hematomas, one bowel injury, one postoperative acute kidney failure, and two unexpected sarcomas. They found that the probability of complications significantly rises with an increase in the number of myomas and with the intramural or the intraligamentous location of myomas whereas the myoma size seemed to influence particularly the risk of major complications.

In a recent randomized, controlled trial by Palomba et al. (23) of 136 myomectomies by LPS or LPT, the intraoperative blood loss, variation in hemoglobin levels, quantity of pain control drugs used postoperatively, and hospitalization were significantly lower in the LPS group than in the LPT group, but LPT was associated with a shorter operating time. They concluded that a careful evaluation of the dimensions and localizations of fibroids is needed to make the right choice of approach.

Although the feasibility and safety of LPS myomectomy has been confirmed over the last two decades (17), the impact

of the route of myomectomy on fertility has yet to be adequately studied.

In our study, among the 164 patients who wished to conceive after myomectomy, the overall spontaneous pregnancy rate after myomectomy was 53%, but the pregnancy rate after LPS myomectomy (56%) was not statistically significantly higher than after LPT myomectomy (50%), in keeping with others studies of myomectomy by LPT or LPS in which pregnancy rates in infertile women varied between 36% and 65% (1, 24).

In our experience, the cumulative pregnancy rate and the cumulative live birth rate were similar between women treated by LPS or LPT, which is in agreement with several other studies (12, 13, 25) that found no difference in fertility and obstetric outcomes in infertile women affected by large myomas who received LPS or LPT myomectomy. This finding is in contrast with another study that found that patients who underwent LPS procedures had a higher probability of conceiving, possibly because of a reduced occurrence of postoperative adhesions (26). In fact, myomectomy is a surgical intervention with a higher rate of postoperative pelvic adhesions (27). Unfortunately, no clear data are available in the literature regarding the relationship between adhesions and infertility, or the real efficacy of adhesiolysis in infertile patients. In addition, no laparoscopic second-look was performed in our to evaluate the de novo formation of adhesions after either LPS or LPT myomectomy (28).

In a recent series by Campo et al. (13), 60% of deliveries after myomectomy were vaginal, and the percentage of vaginal deliveries after myomectomy by LPS (69%) was higher than with LPT (50%). In our study, more than half of women undergoing surgical treatment became pregnant, and the 43% of deliveries after myomectomy were vaginal (26 in the LPS group and 16 in the LPT group). Dubuisson et al. (17) reported a 72% spontaneous or induced labor rate and a 58% vaginal delivery rate after myomectomy by LPS, and Dessolet et al. (29) reported a vaginal delivery rate of 67.6% after LPS myomectomy. In a recent randomized controlled trial on 136 patients who underwent LPT or LPS myomectomy, Palomba et al. (25) concluded that LPT and LPS myomectomy

similarly improved the reproductive outcomes in patients with unexplained infertility but that the LPS approach provided the best benefits in fertile patients with symptomatic leiomyomas.

Our study confirms that LPT myomectomy is related to a lower global degree of surgical difficulty, and that it is a highly feasible and safe procedure even if the LPS approach remains, in expert hands, the procedure better related to the best short-term outcomes (23). Ultimately, the experience of the operating surgeon and the preference of the patient should be important points in the selection of a specific surgical approach in all patients with uterine myomas who are surgical candidates (30).

Laparoscopic myomectomy should be considered a safe and effective alternative therapeutic procedure to LPT for management of symptomatic uterine myomas. We found that LPS had a lower morbidity than reported for the open approach and that it was characterized by less blood loss, a shorter postoperative hospitalization, and a higher pregnancy rate. The operating time was not much longer in the LPS group, and the intraoperative and postoperative complications appeared acceptable and not more than what is traditionally expected with the open approach. However, multicenter randomized clinical trials with longer follow-up observations are necessary to evaluate the long-term clinical outcomes of this procedure.

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