ELSEVIER

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Original Article

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

Ettore Cicinelli, MD, Raffaele Tinelli, MD*, Giuseppe Colafiglio, MD, and Nicola Saliani, 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

1553-4650/$ - see front matter © 2009 AAGL. All rights reserved.
doi:10.1016/j.jmig.2009.03.011

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 infraumbical 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 ($p = .41$).