

# Directed laparoscopic cryomyolysis for symptomatic leiomyomata: One-year follow up

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## KEYWORDS:

Cryomyolysis;  
Myoma;  
Follow-up

## Abstract

**STUDY OBJECTIVE:** To evaluate the long-term effectiveness of laparoscopic cryomyolysis as a minimally invasive technique for the treatment of symptomatic uterine myomas in menstruating women.

**DESIGN:** Open, one-arm pilot study (Canadian Task Force classification II).

**SETTING:** University-affiliated public hospital.

**PATIENTS:** Twenty patients with symptomatic uterine myomas were treated with directed cryomyolysis. All had reported abnormal bleeding and/or pelvic pain/pressure and/or urinary frequency. Myoma diameters varied from 4 to 10 cm.

**INTERVENTION:** One-year follow-up after laparoscopic-directed cryomyolysis.

**MEASUREMENTS AND MAIN RESULTS:** Laparoscopic cryomyolysis was performed using the Her Option Cryoablation Unit (American Medical Systems, Minneapolis, MN). Patients were evaluated 1, 3, 6, 9, and 12 months after surgery. Power color Doppler ultrasound was performed preoperatively and postoperatively to demonstrate the effectiveness of the technique in reducing or eliminating the primary blood supply to the myomas, as well documenting regression of the myomas. All patients reported a high rate of satisfaction with the treatment including absence of symptoms 12 months after surgery, with no bleeding and no myoma-related symptoms, comparable with patients who underwent hysterectomy. Mean shrinkage of myoma volume increased until 9 months after surgery ( $59.5\% \pm 13.2\%$ ), reaching a steady mean-volume reduction of approximately 60% ( $61.9\% \pm 11.9\%$ ) 12 months after surgery.

**CONCLUSIONS:** Directed laparoscopic cryomyolysis appears to be an effective and safe technique for providing rapid symptom relief and at least 12 months' effectiveness in the treatment of symptomatic uterine leiomyomas.

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Uterine myoma is one of the most common gynecologic conditions, and it has been estimated that the incidence each

year of diagnosed myomas in women aged 25 to 44 years in the United States is 12.8 per 1000 women.<sup>1</sup> These benign lesions may cause uterovaginal bleeding, menorrhagia with severe anemia, urinary disturbances, and abdominal pressure and pelvic pain.<sup>2</sup>

Many therapeutic approaches are available for the treatment of uterine myomas, such as hysterectomy, myomec-

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tomy, uterine artery embolization, laparoscopic uterine artery occlusion, and medical treatment. Myomectomy and medical treatment are subject to a high rate of relapse and recurrence, estimated at up to 50%.<sup>3</sup>

Uterine myoma is the first benign indication for hysterectomy, the second most common gynecologic surgical procedure after dilatation and curettage. Several alternative procedures have been suggested to reduce the number and invasiveness of hysterectomies, such as minilaparotomy,<sup>4</sup> laparoscopic hysterectomy or myomectomy,<sup>5</sup> hysteroscopic myomectomy,<sup>6</sup> and endometrial ablation.<sup>7</sup> In addition, several medical treatments have been used to reduce the dimension of myomas by means of anti-estrogen drugs such as gonadotropin-releasing hormone (GnRH) analogs.<sup>8</sup> However, after the discontinuation of treatment, myomas start to grow again.<sup>3</sup> Early in 1996, Olive et al<sup>9</sup> published their experience on cryomyolysis as a conservative alternative in treating uterine myomas.

Recently we published our experience with laparoscopic cryomyolysis as an alternative and minimally invasive treatment for symptomatic uterine myomas.<sup>10</sup> In our previous paper, we reported that laparoscopic cryomyolysis was effective in reducing symptoms, especially abnormal uterine bleeding (AUB), and myoma dimensions 6 months after treatment. In this paper, we report on the results of the 1-year follow-up after direct cryomyolysis for the management of symptomatic myomas in order to evaluate 12-month effectiveness of this treatment.

## Materials and methods

The patients considered in this study were screened and underwent laparoscopic cryomyolysis as described in our previous paper.<sup>10</sup> This is a follow-up extension of a previous pilot study with institutional review board approval and patient informed consent. Briefly, the patients with symptomatic uterine myomas seen in the Department of Gynecology, S. Giuseppe Hospital of the Tor Vergata University of Rome from April 2002 through September 2002 were considered for study participation.

Candidates for the study were premenopausal women of at least 40 years of age who exhibited one or more of the following symptoms: AUB, urinary frequency, or pelvic pain/pressure. Symptoms had to be attributable to no more than three nonpedunculated subserosal and/or intramural myomas with maximum diameters of 4 to 8 cm as measured by ultrasonography. Patients who desired future pregnancy or had conditions such as suspected adenomyosis, salpingitis, endometriosis, or malignancies were excluded.

A total of 20 women who met all inclusion criteria were selected to undergo laparoscopic cryomyolysis. Baseline evaluations included: Papanicolaou smears, diagnostic hysteroscopy with endometrial biopsy, and hematology. All study participants were tested for pregnancy. No GnRH analogs or oral contraceptives were administered to patients

**Table 1** Demographic characteristics of women treated with laparoscopic cryomyolysis or hysterectomy

Characteristic (mean)	LCM (N = 20)	Hysterectomy (N = 35)
Age (yrs)	48.2 ± 9.0	47.9 ± 10
BMI	22.2 ± 2.4	22.5 ± 3.1
Uterine dimension (cm)	252 ± 124	261 ± 132
Number of myomas	2.7 ± 0.8	2.5 ± 1.0
Parity	1.5 ± 1.0	1.8 ± 1.0

BMI = body mass index; LCM = laparoscopic cryomyolysis.

in the study 6 months before treatment and for 12 months after the procedure during the follow-up period.

All patients underwent transvaginal and transabdominal sonographic examination within 1 week before the procedure to evaluate the size and echotexture of the uterus, adnexa, and myomas. Position and localization of the myomas were described, and longitudinal, transverse, and anteroposterior dimensions were measured. Myoma volume and uterine volume were then estimated using the formula for a prolated ellipse: length × width × height × 0.523. In addition, power color Doppler ultrasound images of every myoma were obtained to determine the location of the primary blood supply of each myoma. The vascularity was described as marked, moderate, mild, or not evaluable and noted as central or peripheral. All sonography was performed by a single examiner using an ESAOTE Technos MP machine (ESAOTE, Genova, Italy) with color and power Doppler capability, a convex transabdominal 2- to 5-MHz transducer, and a microconvex 5- to 9-MHz transvaginal probe.

Follow-up sonographic studies for all patients were carried out 1, 3, 6, 9, and 12 months' postoperatively. Follow-up examinations were performed in the same manner as the presurgical imaging evaluation. Differences in size and vascularity of each myoma were noted.

Twelve months after the procedure, all the women answered a questionnaire about satisfaction with the treatment (very good, good, moderate, poor), persistence of AUB and pain (complete remission, rarely present, often recurring, persistent). The same questionnaire was administered to a group of 35 women who underwent laparoscopic supracervical hysterectomy for uterine myomas performed by the same surgeon in the same period of time as the study, matched for age, symptoms, and number and dimension of myomas (Table 1). Their responses were compared with those of the patients who underwent laparoscopic cryomyolysis. None of the women in either treatment group had any further treatment after surgery for AUB.

## Statistical analysis

Descriptive statistics for mean, SD, median, and range are provided. Analyses were performed using the SPSS 4

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