



Laparoscopic radiofrequency thermal ablation: A new approach to symptomatic uterine myomas

Valentino Bergamini, MD,^a Fabio Ghezzi, MD,^{b,*} Antonella Cromi, MD,^b Gaia Bellini, MD,^a Giovanni Zanconato, MD,^a Stefano Scarperi, MD,^a Massimo Franchi, MD^a

Department of Obstetrics and Gynecology, University of Verona, Italy, and Department of Obstetrics and Gynecology, University of Insubria, Varese, Italy

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KEY WORDS

Myoma Myolysis Radiofrequency Laparoscopy **Objective:** The purpose of this study was to evaluate the feasibility and efficacy of laparoscopic radiofrequency ablation of uterine fibroids.

Study design: Eighteen women with symptomatic intramural uterine myomas underwent radiofrequency ablation under laparoscopic guidance. Postoperative sonographic evaluations of the fibroids size were scheduled at 1, 3, 6, 9, and 12 months. The impact of myoma-related symptoms on quality of life (QOL) was assessed using a validated questionnaire.

Results: The median number of myomas treated per patient was 1 (1-3). The median baseline volume of the dominant myoma was 67.2 cm³ (14.8-332.8). No intraoperative or postoperative complications occurred. The median reductions in myomas volume were 41.5%, 59%, and 77% at 1, 3, and 6-months, follow-up evaluation, respectively. No further change in fibroid size was observed at 9 months and 1 year. A significant improvement in the symptoms score and QOL score was observed at 3 and 6 months, follow-up.

Conclusion: In this pilot study, laparoscopic radiofrequency ablation successfully reduced fibroid symptoms and fibroid volume in short-term follow-up. Additional studies are needed before its efficacy and safety can be confirmed.

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Uterine myomas are the most common tumors of the female genital tract, with a prevalence that is up to 50% in women of reproductive age. Despite the frequency with which uterine fibroids are diagnosed and treated, the available literature does not provide high-quality evidence on effectiveness, risk-benefit ratio, and long-

Myomectomy performed by laparotomy is associated with a substantial morbidity, comparable with that of major gynecologic surgery, such as abdominal or vaginal hysterectomy.^{2,3} The laparoscopic approach

E-mail: fabio.ghezzi@uninsubria.it

term outcomes of the currently used treatments for myomas.¹
In women who desire future pregnancies, or who wish

In women who desire future pregnancies, or who wish to retain their uterus for other reasons, the traditional surgical treatment of choice for intramural or subserous symptomatic fibroids is myomectomy, either abdominal or laparoscopic.

^{*} Reprint requests: Fabio Ghezzi, MD, Dept Obstetrics and Gynecology, University of Insubria, Piazza Biroldi 1, 21100 Varese, Italy.

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Figure 1 Disposable radiofrequency needle electrode with extendible prongs, used for uterine fibroids ablation.

offers advantages over conventional myomectomy, such as the reduction in postoperative recovery time, less postoperative pain, and shorter hospital stay. However, intraoperative complications, mainly related to difficulty in achieving hemostasis, are far from avoided with laparoscopy. Moreover, prolonged operating times and technical concerns may outweigh the potential benefits of a minimal access surgery.

In the last decade, alternative options for the conservative surgical treatment of uterine fibroids have been introduced, including uterine artery embolization, 6 cryomyolysis, 7-9 and laser photocoagulation. 10-14 Preliminary results of these minimally invasive procedures, aimed at reducing patient morbidity and further hastening postoperative recovery, seem encouraging.

Radiofrequency (RF) thermal ablation has become a widespread modality to achieve the local control of tumors, particularly in patients with primary or metastatic liver disease who are not candidates for resectional therapy. ^{15,16} RF heating has never been used as a therapeutic option for the shrinkage of uterine myomas.

In the present study, we report our early experience in a group of patients undergoing laparoscopic RF thermal ablation of symptomatic uterine myomas, with emphasis on the safety and efficacy of this new procedure.

Material and methods

Premenopausal women over 40 years presenting with symptomatic intramural uterine myomas were considered eligible for the study. All patients had completed child-bearing and declined hysterectomy. Presenting symptoms were menhorragia or pelvic pain/pressure not responsive to medical therapy including progestin, oral contraceptives, and anti-inflammatory drugs. Patients previously treated with gonadotrophin-releasing hormone agonists were excluded. The presence of more than 3 uterine fibroids, a history of gynecologic malignancy within the past 5 years, a recent pelvic inflammatory disease, an

abnormal coagulation screen, current pregnancy, or breastfeeding were considered as exclusion criteria.

All patients were extensively counselled on the potential risks and benefits of the procedure, and on the possible alternative surgical treatments. The local Institutional Review Board of the University of Verona approved the study, and all participants provided written informed consent before study entry.

Preoperative evaluation included an accurate transvaginal ultrasound assessment of the number, size, and location of the myomas. Fibroid volume was estimated according to the following formula: volume = $4/3~\pi~r^3$, where r is the mean radius of the fibroid calculated from the measurements of the longitudinal, transverse, and antero-posterior diameter of the lesion. Sonographic evaluations were repeated at 1, 3, 6, 9, and 12 months postoperatively. When more than 1 myoma was treated in a single patient, only the characteristics of the dominant myoma were considered for statistical analysis.

The impact of symptoms on health-related quality of life in the study population was assessed using the Uterine Fibroids Symptom and Quality of Life (UFS-QOL) questionnaire. 17 The questionnaire consists of 8 questions addressing both the frequency and the severity of symptoms, and 29 questions on health-related QOL. The following health related quality of life items are addressed: fatigue, self-image, mood disturbancespsychologic distress, fear of embarrassment, interference with daily activities, relationships with family and friends, and sexual function. Two distinct scores were calculated for symptom severity and quality of life. Higher symptoms scores are indicative of greater symptom severity, while higher quality of life scores mean a better health-related quality of life. Women were asked to complete the UFS-QOL questionnaire at baseline and at 3, 6, 9, and 12 months after treatment.

Equipment

The RF delivery system (Rita Medical System model 1500, Mountain View, Calif) consisted of a RF generator operating at 460 KHz, with maximum power of 250 watts, and a temperature range from 15 to 125 degrees centigrade. The generator displays the temperature of the needle tip, tissue impedance characteristics, and procedure time. The system is connected through a flexible cable to a 25 cm long, 14-gauge needle, with an exposed tip (primary electrode) and 7 extendible prongs (secondary electrodes) at the distal end (Figure 1). The prongs are designed to bracket the target tissue when they are deployed laterally with a manual movement, in order to produce a spherical area of coagulative necrosis, with a maximum diameter of 5 cm. The secondary electrodes can be extracted partially or completely, according to the maximum diameter of the lesion. Four of the 7 have a thermocouple on their tips, allowing a real-time

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