



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

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### KEY WORDS

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**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 cm<sup>3</sup> (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-

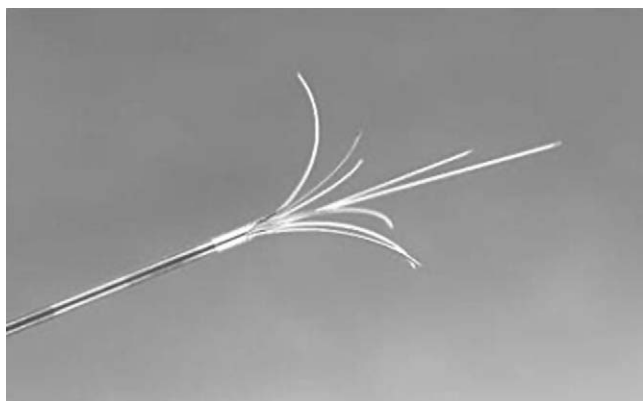
term outcomes of the currently used treatments for myomas.<sup>1</sup>

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.

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

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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.<sup>4</sup> However, intraoperative complications, mainly related to difficulty in achieving hemostasis, are far from avoided with laparoscopy.<sup>5</sup> 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,<sup>6</sup> cryomyolysis,<sup>7-9</sup> and laser photocoagulation.<sup>10-14</sup> 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.<sup>15,16</sup> 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 menorrhagia 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.

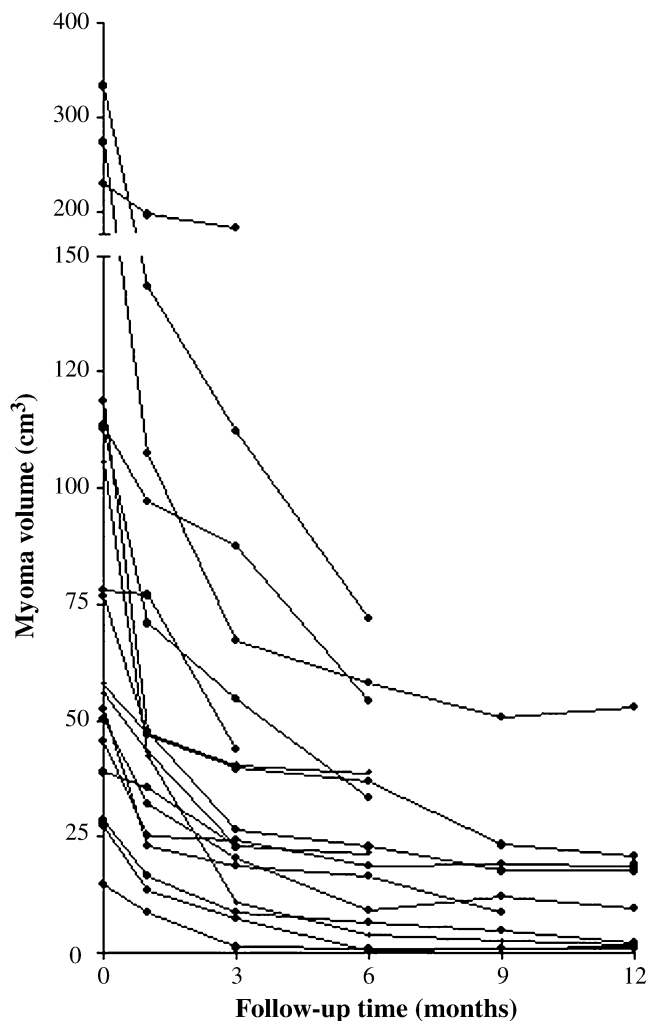
All patients were extensively counselled on the potential risks and benefits of the procedure, and on the possible alternative surgical treatments. The local Institutional Review Board of the University of Verona approved the study, and all participants provided written informed consent before study 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:  $\text{volume} = 4/3 \pi r^3$ , 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.<sup>17</sup> 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 disturbances-psychologic 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



**Figure 2** Changes in the volume of the myoma during the follow-up period after radiofrequency ablation.

monitoring of the temperatures of the surrounding tissue. The RF generator produces a voltage between the active RF electrode and the dispersive electrode, a large area grounding pad in contact with the patient's skin.

### Procedure

The RF ablation of uterine myomas was performed under general anesthesia. Prophylactic antibiotics were not used. A 10 mm trocar was inserted through an umbilical incision, and the RF needle was inserted percutaneously and placed within the target fibroid under laparoscopic video guidance. The depth of needle insertion was determined on the basis of preoperative ultrasound. When the deployable tines of the needle are fully extended, the device mimics the configuration of a "Christmas tree." Therefore, the tip of the central prong was placed about 1 cm beyond the center of the fibroid, so that the peripheral electrodes were localized

where the cross-sectional area of the myoma is largest. A scale on the needle surface makes the placement easier.

The target temperature for the RF ablation was 100°C. The RF generator automatically adjusts the power to maintain the selected temperature. The time required to obtain a given volume of coagulation is a function of both temperature and tissue impedance. The duration of ablative sessions was decided according to the manufacturer's recommendations: the complete ablation of a 3 cm large myoma takes approximately 5 minutes. Multiple overlapping ablation cycles have been performed for fibroids with a mean diameter larger than 5 cm. The RF device may also be used to coagulate the needle track after the procedure is completed.

### Statistical analysis

Statistical analysis was performed with GraphPad Prism version 3.00 for Windows (GraphPad Software, San Diego, Calif). The Wilcoxon matched pairs test was used to compare the volumes and the percentage of volume reduction of the treated myomas, as well as the UFS-QOL scores. The statistical significance was considered to be achieved when  $P < 0.05$ .

### Results

During the study period, 18 patients underwent laparoscopic RF ablation of uterine fibroids. The median (range) age of the patients was 44.3 years (40-50). The median number of fibroids treated per patient was 1 (1-3). The median baseline diameter and volume of the dominant myoma were 5 cm (3-8.6) and 67.2 cm<sup>3</sup> (14.8-332.8), respectively. The mean diameter of the dominant fibroid was less than 4 cm in 4 cases, 4 to 6 cm in 11 cases, and larger than 6 cm in 3 cases. The location of the dominant myoma was posterior in 9 (50%) cases, anterior in 4 (22%), and fundal in 5 (28%). The median (range) baseline volume of the dominant myoma was 67.2 cm<sup>3</sup> (14.8-332.8). The primary presenting symptom was menorrhagia in 15 (83.3%) cases, and pelvic pressure or pain in 3 cases (16.7%). The median preoperative symptom score was 43.7 (12.5-90.6), while the median health-related quality-of-life score was 66.7 (35-93.9).

The operative time ranged from 20 to 40 minutes (median 25). Seven (38.9%) of the dominant fibroids were treated with a single pass. No intraoperative or postoperative complications occurred during or after the RF procedure. The RF needle track ablation program completely avoided the occurrence of blood loss in all cases. Only 2 patients complained of mild abdominal pain, not requiring analgesic drugs. All patients were observed overnight and discharged from hospital on the first postoperative day.

**Table I** Myoma volume and volume reduction at 1, 3, 6, 9, and 12-months, follow-up

	Baseline (n = 18)	1 mo (n = 18)	3 mo (n = 18)	6 mo (n = 10)	9 mo (n = 9)	12 mo (n = 9)
Myomas volume (cm <sup>3</sup> )	67.2 (14.8-332.8)	45.1 (3.2-196)*	25.4 (1.2-181.3)*	21.4 (0.7-72.1)*	10.5 (1-50.6)	9.7 (1.1-52.8)
Volume reduction	0	41.5% (1-94)*	59% (21-92)*	77% (33-97)*	83% (58-98)	85% (59-98)

\*  $P < .01$  vs the previous sonographic examination.

**Table II** Symptom scores and health-related quality-of-life scores at baseline and at 3, 6, 9, and 12-months, follow-up

	Baseline (n = 18)	3 mo (n = 18)	6 mo (n = 10)	9 mo (n = 9)	12 mo (n = 9)
Symptom score	43.7 (12.5-90.6)	20.3 (3.1-40.6)*	4.7 (0-28.1)*	0 (0-9.4)*	0 (0-4.1)
QOL score	66.7 (35.0-93.9)	82.7 (25.9-100)*	100 (98.2-100)*	100 (99.1-100)	100 (99.3-100)

\*  $P < .05$  vs the previous assessment.

The median follow-up time was 10 months (3-12). The median fibroid volume and the median reduction of the volume during the follow-up period are shown in Table I. When analysis was restricted only to women who completed the 1-year follow-up period ( $n = 9$ ), at 9 and 12 months neither a significant further decrease in size, nor a regrowth of myomas, was observed compared with the 6-month postoperative evaluation. Figure 2 displays the volume changes of the dominant myomas after the RF ablation.

The changes in symptoms score and in health-related quality-of-life score are shown in Table II. Seven out of 9 (77.8%) women who completed the 1-year follow-up period were totally symptom-free.

## Comment

The results of this pilot study suggest that RF ablation may represent a safe, well-tolerated, and effective alternative to conventional surgery for the treatment of symptomatic uterine myomas in selected groups of patients.

The widespread use of thermoablative procedures in gynecology has been limited by concerns of the ability to create coagulative necrosis in a controlled fashion, with minimum damage to normal surrounding tissues. Myolysis as a treatment option for uterine fibroids was first introduced in the late 1980s as an hysteroscopic technique<sup>18</sup> and, subsequently, as a variation on the technique of laparoscopic myomectomy, in which fibroid tissue was coagulated rather than removed. The first series, where myomas ablation was performed with Nd:YAG laser, have clearly shown the efficacy of this technique in achieving fibroids shrinkage.<sup>10,11</sup> However, concerns have arisen because of the extremely high incidence of adhesion formation detected at second-look laparoscopy. Since then, several new techniques for

fibroids myolysis have been sought in an attempt to find minimally invasive approaches to uterine myomas, less technically demanding, and less time consuming than laparoscopic myomectomy, while minimizing adhesion formation. A number of case series have been published supporting the feasibility of myomas ablation either by thermotherapy (bipolar or monopolar coagulation, diode laser),<sup>19-20</sup> or by cryotherapy.<sup>7-9</sup> Although each method has been proven to be effective, most of them have some limitations related to high costs, difficult application and monitoring, and inability to consistently avoid nontarget tissue.

RF energy is an alternating current with a frequency between 10 and 900 kHz. At these frequencies, the heat generated by the electrical current is dissipated into the area that is close to the electrode-tissue interface. Tissues are heated not by conduction of heat directly, but by agitation of tissue ions at a high frequency. Although several potential mechanisms for cellular injury caused by RF energy have been postulated, the predominant mechanism is thermal damage caused by frictional heating.<sup>21</sup> Once temperature is above 50°C, cell membranes melt and fuse, proteins denature, and irreversible cell death occurs.<sup>22</sup> Pathologic studies in patients with unresectable hepatic tumors have demonstrated that RF lesions behave like aseptic necrosis, with a clearly demarcated rim from surrounding tissue.<sup>23</sup>

Current multiprong RF devices are designed to produce a large spherical volume of necrosis at every insertion, decreasing the total number of needle passes. Conversely, when laser fibers or monopolar/bipolar needles are employed for fibroids myolysis, because of the narrow area of tissue destruction created by a single straight needle, multiple passes or simultaneous insertion of multiple needles are necessary to treat the entire lesion. It has been postulated that the presence of multiple holes on the myoma serosa could increase the risks of postoperative adhesion formation.<sup>20</sup> Further

investigations, including second-look data, are needed to assess whether RF ablation might reduce post-myolysis adhesions.

The ability of RF electrodes used in the present study to create a large spherical area (up to a diameter of 5 cm) of tissue ablation resembles the ice ball around the probe in the cryoablation systems. Radiofrequency energy seems at least as effective as cryomyolysis in achieving myoma shrinkage. Our results are in keeping with the findings of Zupi et al,<sup>8</sup> who recently reported a series of 20 women undergoing laparoscopic cryomyolysis for symptomatic uterine myomas. These authors reported a mean fibroid volume reduction of  $56.9 \pm 12.3\%$  at 6 months' follow-up, with resolution or significant improvement of myoma-related symptoms in 95% of cases. Because the choice of the optimal treatment for fibroids should take into account efficacy, complication rate, and cost-effectiveness ratio, RF thermoablation seems to offer some advantages. First, the electrical generators required for RF ablation are considerably cheaper compared with cryosurgery equipments. Second, the cryoprobe's diameter are usually larger (>2 mm) than the 14-gauge needle used for RF thermotherapy, increasing the risks of bleeding from the puncture site. Third, the needle track ablation system allows a quasi-bloodless procedure. Finally, the need of 1 or more freeze/thaw cycles per myoma during cryotherapy may result in a longer operative time.

Two case series described magnetic resonance-guided percutaneous ablation of uterine myomas with cryotherapy<sup>9</sup> and laser fibers.<sup>12</sup> Although a percutaneous approach is a minimally invasive procedure, performable under local anesthesia as an ambulatory surgery, preliminary results showed a high incidence of major perioperative complications, suggesting that a direct visual monitoring is advisable during ablative procedures.

A controversial issue about uterine fibroids myolysis is whether tissue local destruction without surgical repair might increase the risks of suboptimal healing and, ultimately, the chance of uterine rupture during pregnancy. Because the safety for women whose aim is future pregnancy has not been established, an appropriate selection of patient candidates for ablative procedures is mandatory. Currently, laparoscopic myolysis should be restricted to patients in the late reproductive years, when myoma-related symptoms are more frequently reported.<sup>24</sup> In this population of women, an increasing trend toward seeking alternatives to hysterectomy has been observed in the last years.<sup>25</sup>

In conclusion, our preliminary results suggest that laparoscopic RF ablation is a promising new approach for the conservative treatment of uterine fibroids. It is a low-cost and low-tech procedure, with an effectiveness and an impact on myoma-related symptoms comparable to those of other minimally invasive innovations. The

major limitation of this study is the short follow-up time, which does not allow to evaluate the mid- and long-term recurrence rate, and to draw definite conclusions about the effectiveness of RF myolysis. This pilot study can serve as a stimulus for further investigations aimed at comparing this technique with other surgical approaches, as well as with uterine artery embolization, which has been proven as a valid alternative to surgical therapy.

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