For uterine-sparing fibroid treatment, consider laparoscopic ultrasound-guided radiofrequency ablation

Profile of a new minimally invasive treatment option

James A. Macer, MD

IN THIS ARTICLE

CASE Woman with heavy bleeding hopes to avoid hysterectomy

L.W. is a 44-year-old woman (G2P2) with a 2-year history of menorrhagia and severe dysmenorrhea but no intermenstrual spotting or bleeding. She reports that she has tried to control her symptoms using hormonal methods, without success.

Examination reveals that she has an irregular, nontender uterus 8 weeks in size. Transvaginal ultrasonography shows two deep, prominent, intramural fibroids. The first is 2 cm by 3 cm in size in the left lateral uterus, adjacent to the endometrial stripe. The second fibroid is 3 cm by 4 cm in the fundal region. Sonohysterography reveals no intracavitary fibroids, although the left lateral myoma has distorted the endometrial cavity.

The patient is seeking removal of her fibroids but would like to preserve her uterus, if at all possible.

What options would you offer her?

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Uterine fibroids are common in premenopausal women, affecting 70% to 80% of the population, especially women of African descent.[1] Although the majority of women with fibroids are asymptomatic, approximately 30% report pelvic pressure, dyspareunia, dysmenorrhea, or abnormal uterine bleeding.[2]

Our patients are increasingly aware of uterine-sparing treatments for symptomatic fibroids.[3,4] Women seek conservative procedures to avoid the risks and extended recovery times commonly associated with major surgery. Current laparoscopic techniques for removal of uterine fibroids can be complex and require advanced surgical skills. Deep intramural fibroids may not always be visible or readily accessible, making laparoscopic removal a more invasive and challenging approach for many gynecologic surgeons.

A significant recent advancement in minimally invasive gynecologic treatment of fibroids is the Acessa System (Halt Medical, Brentwood, California). This laparoscopic system involves the outpatient use of ultrasound-guided radiofrequency volumetric thermal ablation, or RFVTA.

In this article, I outline the development of this option and step you through its technique. I also review the outcomes data that have been published to date.

How the procedure evolved

In the 1980s, Donnez and Nisolle developed a method of laparoscopic Nd:YAG laser treatment of uterine fibroids, commonly referred to as myolysis.[5] Later, Goldfarb developed a laparoscopic bipolar needle technique that coagulated and occluded blood vessels at the periphery of the fibroid.[6] However, myolysis led to the formation of significant adhesions to the small bowel or omentum, or both, and was abandoned by the surgical community.

Other fibroid treatments have been developed, such as laparoscopic myomectomy, uterine artery ligation, uterine artery embolization (alone or as adjuvant treatment), and high-intensity focused ultrasound. Although these procedures have made a significant contribution to the minimally invasive treatment of fibroids, the need for reintervention can be substantial, as high as 29% at 1 to 10 years of follow-up in some reports.[7–17]

Radiofrequency needle ablation has been used successfully in the treatment and destruction of liver and kidney tumors for years. Lee envisioned use of the technology to treat uterine fibroids. He developed a technique using a retractable multiarray radiofrequency needle (Starburst XL, RITA Medical Systems, Fremont, California) that is inserted directly into the fibroid. In 2002, he reported the first use of intraperitoneal ultrasound for needle guidance in the laparoscopic ablation of 197 myomas in 52 symptomatic women who had declined hysterectomy and myomectomy.[18] He found that a significant proportion of women experienced resolution of their symptoms, including heavy menstrual bleeding, dysmenorrhea, dyspareunia, and pelvic pressure, by 3 months, with continued improvement at 12 months.

Because he was unhappy with aspects of the RITA needle that prevented accurate and consistent ablation of fibroids, he developed other devices that would lead to RFVTA and the Acessa System. This system allows the gynecologic surgeon to target and treat deep intramural fibroids that may not be readily visible via conventional laparoscopy.

Between the time of Lee's first report and his subsequent refinement of the device and procedure, several international fibroid radiofrequency ablation procedures emerged, including those of Bergamini, Milic, Ghezzi, and Carrafiello.[19–22] These investigators published results in small cohorts and described significant improvement in patient-reported Uterine Fibroid Symptom and Quality-of-Life (UFS-QOL) scores as well as a reduction in myoma volume.[23] Their studies provided evidence that RFA is a safe and effective uterine-sparing treatment of symptomatic uterine fibroids for selected patients.

How it works

RFVTA uses laparoscopy and laparoscopic ultrasound to guide placement of a needle electrode with a deployable array. Earlier international studies of radiofrequency ablation[18–22] and ongoing studies of RFVTA[23–26] have demonstrated the procedure's therapeutic potential. Acessa was recently cleared (November 2012) by the US Food and Drug Administration (FDA).

RFVTA technique, step by step

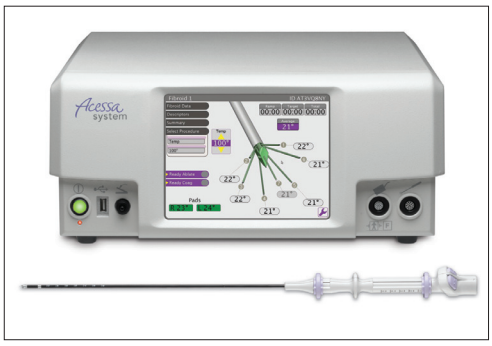
1. Begin with a standard 5-mm laparoscopic infraumbilical port for the camera and video laparoscope (see the **VIDEO** at obgmanagement.com).
2. Place a 12-mm port in the midline, suprapubically at the level of the uterus, for insertion of the laparoscopic ultrasound probe. Now it is possible to map the uterus and plan an approach to destroy the fibroids.
3. Once you have determined your approach, insert the handpiece containing the radiofrequency needle through the abdominal wall under laparoscopic visualization.
4. Place the needle into the targeted fibroid using both laparoscopic and ultrasound guidance. Depending on the size of the fibroid, the needle array can be deployed to the maximum diameter necessary to effect destruction.
5. Engage the radiofrequency generator (**FIGURE 1**, page 52), utilizing the timing function for optimal destruction of the fibroid, based on the appropriate

WATCH THE VIDEO!
RFVTA technique

Use this QR code to download the video to your Smartphone,* or go to obgmanagement.com

*Free QR readers are available at the iPhone App Store, Android Market, and BlackBerry App World.

FIGURE 1 The Acessa System



This view of the generator and monitor shows the display of temperature at each needle tip, as well as the average temperature of the needle array (in this case, at ambient temperature). It also displays the return-pad temperatures on the anterior thighs of the patient. The handheld probe is shown below the generator. (Courtesy Halt Medical, Inc., Brentwood, California)

algorithm. The fibroid then will be ablated and destroyed without damage to the surrounding healthy myometrium.

The Acessa radiofrequency generator and accessories are designed to deliver monopolar radiofrequency energy to tissue through the handheld electrical probe. The procedure is monitored by real-time feedback to and from the generator via each of the thermocouples at the tips of the seven-needle array (**FIGURE 1**). In addition, laparoscopic ultrasound-guided visualization permits monitoring of needle placement within the fibroid capsule (**FIGURES 2A AND 2B**) and confirmation of hemostasis upon removal of the probe tip (**FIGURE 2C**).

FAST TRACK

The Acessa System is currently not recommended for women seeking future childbearing

RFVTA treats a wide range of fibroids

The Acessa System is used to treat fibroids of any location and type, with the exception of pedunculated or Type 0 myomas, in which case laparoscopic or hysteroscopic myomectomy is recommended. Calcified fibroids pose no challenges. A single radiofrequency needle generally is used to treat multiple fibroids, with ablation zones ranging in diameter from 1.0 to 6.7 cm. Large, irregularly shaped fibroids may require multiple ablation zones during the same procedure.

Final steps

6. Once the treatment is complete, as confirmed by informatics transmitted by the generator, retract the needle array, set the generator to coagulation mode to coagulate the needle track during withdrawal of the probe, and confirm hemostasis (**FIGURE 2C**).
7. After completion of all fibroid destruction, remove the disposable radiofrequency probe and close the laparoscopic and ultrasound port sites using standard procedures.

The patient can be discharged the same day and generally is able to return to normal activities within 3 to 5 days.

Postoperative analgesia usually consists solely of nonsteroidal anti-inflammatory agents.

A look at outcomes data

Garza and colleagues published the first feasibility report in 2011.[24] They described the results of laparoscopic, ultrasound-guided RFVTA for the treatment of symptomatic uterine fibroids in Mexico using an Acessa predecessor. The 31 women enrolled in the study desired uterine preservation. Of these participants, 19 had completed 12 months of follow-up by the time the report was submitted for publication. Their responses to the UFS-QOL questionnaire indicated that their symptoms had decreased significantly in severity from baseline to 12 months, and their quality-of-life scores also improved significantly (P <.001). Mean uterine volume also declined significantly.

Robles and colleagues set out to confirm these findings using the investigational Halt Ablation System. They conducted a prospective, single-center, open-label clinical trial in Guatemala.[25] They found dramatic improvement in symptom severity and health-related quality of life from baseline to 12 months. Mean uterine volume also decreased by 23.6% during this period. In addition, the severity and duration of menses declined.

Acessa is currently not approved for women seeking future childbearing. However, several successful pregnancies have

been reported following the procedure.[24,26–28] Theoretically, because it causes less damage to and disruption of healthy myometrium, Acessa may prove to be preferable to myomectomy. Head-to-head studies to evaluate this premise are ongoing.

Latest findings confirm widespread improvement of symptoms

The most recent and detailed reports of safety and efficacy of laparoscopic, ultrasound-guided RFVTA at 12 and 24 months were published by teams led by Chudnoff[26] and Guido[27] earlier this year. These investigations involved 135 women who reported moderate to severe heavy menstrual bleeding (160 mL–500 mL by alkaline hematin analysis). Clinically significant reduction in menstrual blood loss was achieved in 67.7% of participants at 12 months of follow-up.[29]

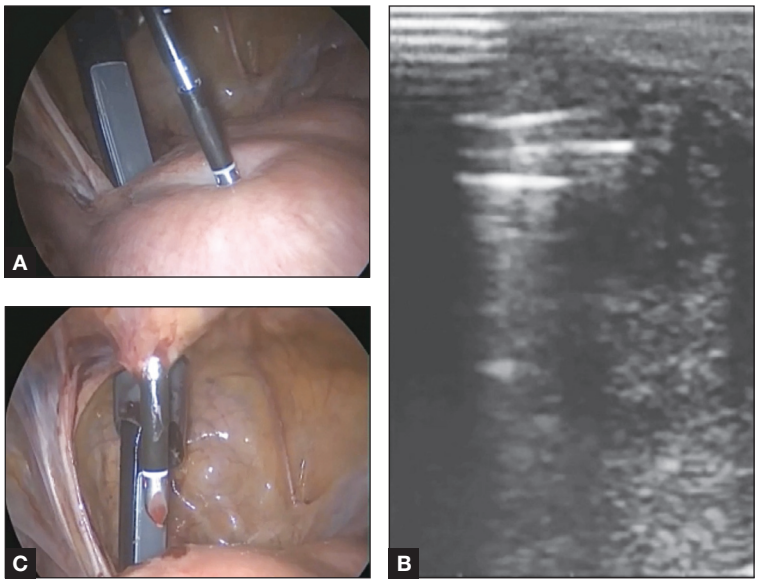
Galen and colleagues performed a retrospective analysis of these same patients, demonstrating that RFVTA of intramural fibroids without submucosal components leads to a clinically and statistically significant reduction in menstrual blood loss.[30]

Patients generally began these trials with high symptom-severity scores and low health-related quality of life, yet all achieved significant improvement over time, as their UFS-QOL scores indicate (**TABLE**, page 54). The majority of patients (96%) were treated on an outpatient basis. As measured by contrast-enhanced magnetic resonance imaging, total mean uterine volume decreased by 24.3% at 12 months, and total mean fibroid volume decreased by 45.1% during the same interval. Ninety-four percent of the women reported that the treatment was effective in eliminating their symptoms at 12 months, and 98% said they would recommend the procedure to a friend having the same health problems.

Complication rates were low

Complications included a postoperative pelvic abscess and four other minor events. The latter were treated at the time of RFVTA or resolved without additional procedures. The reintervention rate was 0.7% (1/135 patients).[26]

FIGURE 2 Intraoperative views



A. Laparoscopic view of the radiofrequency needle (right and front) at the beginning of insertion into the uterus for treatment of a large intramural fibroid. The 12-mm laparoscopic ultrasound transducer to the left of and behind the needle is used for both intrauterine imaging and uterine stabilization. **B.** Ultrasound image of the open needle array within the capsule of the targeted fibroid prior to RFVTA treatment. **C.** Laparoscopic view of the uterus upon withdrawal of the probe after track coagulation (front) and achievement of hemostasis.

Guido and colleagues reported 24-month outcomes for the 124 women entering the second year of the Halt study and affirmed the findings of Chudnoff's team.[27] The 112 patient-reported UFS-QOL scores at 24 months were virtually identical to those reported at 12 months. Six surgical reinterventions (6 of 124 patients, or 4.8%) for fibroid-related bleeding were reported between 12 and 24 months.

280 women have been treated so far

As of September 2013, 280 women have been treated under five international study protocols using the Halt Acessa System, and approximately two-thirds have been followed for more than 12 months, with excellent results. Two of the five clinical trials are under way in Germany and Canada:

- The Laparoscopic Uterine-Sparing Techniques Outcomes and Reinterventions (LUSTOR) trial in Germany is a prospective, randomized, single-center study

How laparoscopic, ultrasound-guided RFA/RFVTA improved symptoms and quality of life

Study	Symptom severity				Health-related quality of life			
	Baseline	3 months	6 months	12 months	Baseline	3 months	6 months	12 months
Bergamini et al[19]	43.7 (n = 18)	20.3 (n = 18)	4.7 (n = 10)	0.0 (n = 9)	66.7 (n = 18)	82.7 (n = 18)	100 (n = 10)	100 (n = 9)
Ghezzi et al[21]	43.7 (n = 25)	Not reported	4.7 (n = 25)	0.0 (n = 24)	63.1 (n = 25)	Not reported	99.1 (n = 25)	100 (n = 24)
Carafiello et al[22]	50.3 (n = 11)	Not reported	Not reported	13.4 (n = 5)	62 (n = 11)	Not reported	Not reported	90.4 (n = 5)
Garza et al[24]	43.6 (n = 31)	15.2 (n = 31)	12.2 (n = 29)	5.5 (n = 19)	60.2 (n = 31)	87.9 (n = 31)	90.7 (n = 29)	97.8 (n = 19)
Robles et al[25]	63.3 (n = 36)	23.1 (n = 35)	15.4 (n = 32)	9.6 (n = 33)	36.3 (n = 36)	79.9 (n = 35)	85.1 (n = 32)	87.7 (n = 33)
Chudnoff et al[26]	61.1 (n = 127)	29.1 (n = 124)	28.5 (n = 125)	26.6 (n =124)	37.3 (n = 127)	75.1 (n = 124)	77.8 (n = 125)	79.5 (n =124)

comparing outcomes of RFVTA and laparoscopic myomectomy. Fifty women were enrolled and treated and will be followed for as long as 60 months.

- The Treatment Results of Uterine-Sparing Technologies (TRUST) trial is a prospective, multicenter, randomized study in Canada that compares direct and indirect costs associated with RFVTA, laparoscopic and abdominal myomectomy, and uterine artery embolization. Some US sites also will participate. As many as 200 women will be treated and followed for as long as 60 months.

FAST TRACK

Data suggest that radiofrequency volumetric thermal ablation of uterine fibroids improves symptom severity and health-related quality of life and offers good cosmesis and quick recovery

RFVTA offers several benefits

Although hysterectomy provides a definitive "cure" to fibroid-related symptoms, it is not preferred by many patients and generally is more costly, with an increased risk of complications, a longer hospital stay, longer recovery (6–8 weeks), longer disability and more time off from work, and potential long-term sequelae.

The Acessa procedure not only is an outpatient, minimally invasive, uterine-sparing fibroid treatment option, it permits access to and ablation of almost all fibroids (with the exception of penduculated or Type 0 myomas). The data to date suggest that RFVTA provides many benefits, including a decline in symptom severity and improved health-related quality of life, as well as good cosmesis, quick recovery, and a rapid return to full activity.

There is a learning curve for RFVTA with Acessa—as with any new procedure. If physicians already perform ultrasound imaging, the learning process is shorter. Physicians interested in Acessa and furthering their education and training in laparoscopic RFVTA should consult the manufacturer's professional education division through the company Web site at http://www.haltmedical.com.

CASE Resolved

After she is counseled about the various uterine-sparing options for treatment, L.W. chooses to undergo laparoscopic, ultrasound-guided RFVTA using the Acessa System. The procedure is performed successfully, with the two fibroids destroyed using the appropriate algorithms, which took into account the size of the fibroids and the deployed needle array. Two additional 1-cm fibroids were found during the procedure and ablated. The patient was discharged home shortly after the procedure, with a nonsteroidal anti-inflammatory drug given for pain relief.

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