Chapter 9

Radiofrequency Volumetric Thermal Ablation of Symptomatic Uterine Fibroids: The Acessa™Procedure

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Abstract

Radiofrequency volumetric thermal ablation (RFVTA, the Acessa™Procedure) is a new, promising laparoscopic, ultrasound-guided fibroid treatment modality that gained FDA clearance in November 2012. It has been studied in multiple clinical trials. Each trial demonstrated clinically and statistically significant bleeding reduction in patients with heavy menstrual bleeding; significant and durable symptom reduction and quality-of-life improvement regardless bulk, pain, or bleeding symptoms, early return to normal and work activities; and low rates of surgical re-intervention in an outpatient procedure. Ninety-eight percent of Acessa patients would recommend the treatment to a friend who had the same health problem. Surgeons in the various RFVTA studies learned the technique and elements of laparoscopic ultrasound and RFVTA before being proctored during initial cases; generally three proctored procedures were necessary before surgeons felt proficient with basic cases. We present a discussion of the development, features of

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and clinical outcomes following radiofrequency volumetric thermal ablation (RFVTA) of fibroids.

Introduction

The ideal surgical approach to the treatment of uterine fibroids would: enable preservation of both the uterus and uterine function while effectively treating all fibroids regardless their number, size, or location; preserve myometrial integrity;be safe with few complications (minimal blood loss and adhesion formation);be economically viable (outpatient, rapid recovery with minimal postoperative discomfort). Hysterectomy is a procedure that provides the definitive treatment of fibroids following excision of the uterus and termination of reproductive function. Uterine artery embolization (UAE) combines the expertise of a gynecologist and an interventional radiologist to target fibroids by blocking their arterial blood supply with microspheres to produce ischemic necrosis. The procedure is associated with conservation of the uterus, no uterine incisions, and sedation rather than general anesthesia. Complications due to particle migration and delayed myoma passage have been reported [1–6]. Post-procedure pain is typically managed with intravenous narcotics during an overnight hospital stay. Some studies suggest that women with submucous fibroids may not be appropriate for UAE as embolic treatment of these myomas puts the patient at higher risks of expulsion and chronic discharge [1–7]. Magnetic resonance-guided focused ultrasound (MRgFUS) is a radiologic procedure that has shown clinical efficacy in a noninvasive, outpatient, ablative treatment. Multiple conditions may exclude eligibility for the procedure[8], and limitations in the number and size of treatable fibroids as well as cost and equipment availability may restrict applicability [9]. Perhaps the most traditional, uterine-conserving approach is hysteroscopic, abdominal, or laparoscopic myomectomy. Myomectomy has been and is still the standard care for women desiring uterine preservation and/or future fertility. Today, myomectomy often is an inpatient procedure and can involve significant operative blood loss, and adhesions also are a known complication [10–14]. A high skill level is required for suturing during laparoscopic myomectomy. Also, small deep intramural myomas and those fibroids abutting the endometrium may on occasion not be excised as they are inherently difficult to detect.

Radiofrequency volumetric thermal ablation is a promising new fibroid treatment modality. We present a discussion of the development, features of and clinical outcomes following radiofrequency volumetric thermal ablation (RFVTA) of fibroids.

History of Radiofrequency Ablation in Medicine and Gynecology

Radiofrequency (RF) ablation has had broad use in various surgical subspecialties. It has been shown to be safe and effective in the local destruction of soft tissue by coagulative

necrosis caused by heat from intracellular ionic agitation. The application of RF energy in medicine was first described in 1891 by D'Arsonval when he passed RF waves through tissue and observed increased tissue temperature [15]. Applied for both its palliative and life-extending effects, RF ablation has been used to treat cardiac arrhythmias, neurological abnormalities, and primary or metastatic cancer of the bone, liver, kidney, prostate, lung, skin, and breast [16–27]. In general, the size and shape of the ablation depends on the type, size, andshape of the needle electrode, whether the device comprises a single or multiple electrode needles, the temperature achieved, and the amount of time allowed for heat conduction.

In 2002, Bruce B. Lee was the first to publish laparoscopic ultrasound-guided, multi-needle RF ablation of uterine fibroids as an outpatient, uterine-conserving procedure with the RITA Medical Model 30 ablation system [28]. The Model 30 had 4 curved prongs that allowed for a roughly spherical ablation diameter of up to 3 cm [29]. In order to increase ablation size and efficiency, Lee subsequently used the RITA Starburst® ablation system with 7 deployable curved stainless steel electrodes. Initial clinical results from a pilot study of 58 patients and subsequently a prospective trial of 137 patients were promising, achieving not only a decrease in uterine volume but also a decrease in heavy menstrual bleeding, pelvic pain (dyspareunia and dysmenorrhea), and bulk symptoms. The Starburst allowed for a larger ablation volume but the electrodes were difficult to visualize under laparoscopic ultrasound and deployment of the array into fibroids was often problematic. Lee considered other forms of fibroid destruction including cryosurgery, microwave and laser probes but elected to develop a system specifically to treat uterine fibroids using radiofrequency energy. It was not until Lee's development of the Halt 2000 ablation system (Halt Medical, Inc., Brentwood, CA) initiated in 2004 that he felt confident that RFVTA of fibroids could safely and reliably be performed and produce ablations of up to 7 cm in diameter [30].

During the nascent development of the Halt 2000 ablation system and radiofrequency volumetric thermal ablation (RFVTA), Lee and others refined the system in bench studies with porcine liver, kidney, and muscle ablations to determine the extent of the ablation zones and how they might be distorted due to proximity to skin, fascial plane, muscle, and fat. Tissue necrosis was confirmed at histopathology (Figures 1A and 1B).
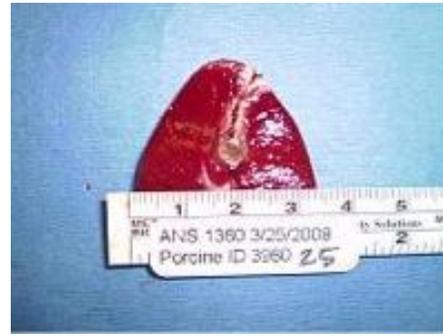

1A   1B
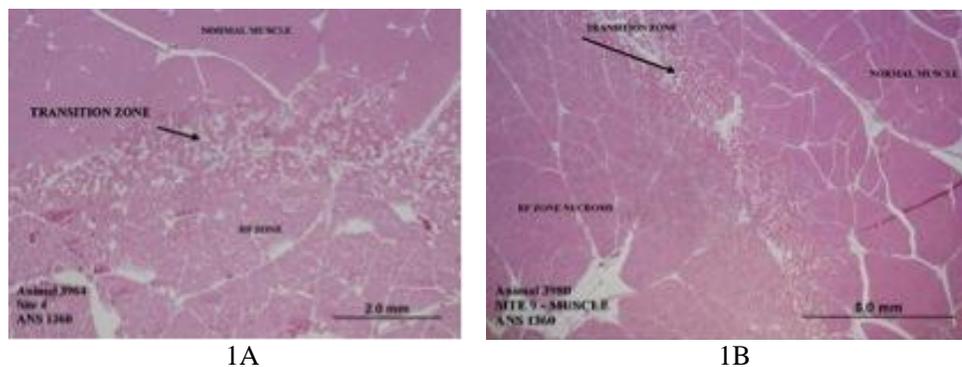
Figures 1A and 1B. Histopathology demonstrating areas of RF zone necrosis with transition zone into adjacent normal skeletal muscle.

Studies of the coagulation tract, which forms upon withdrawal of the ablation hand-piece, were also performed in porcine liver and kidney tissue samples (Figures 2A and 2B).

2A   2B

Figures 2A and 2B. Coagulation tracts in porcine liver and kidney ablations.

The animal studies were followed by a perihysterectomy fibroid ablation study, which correlated histological results using vital staining in fibroids treated at hysterectomy with previous findings from *in vitro* testing (Figure 3).

Figure 3. Gross pathologic uterine specimen from perihysterectomy study demonstrating well defined zone of coagulative necrosis within the fibroid capsule. Nitro blue tetrazolium viability staining.

RFVTA Features

The components of the RFVTA system (now called Acessa™) include a dual-mode, monopolar RF generator; two dispersive electrode pads; a sterile 3.4-mm diameter, disposable, handheld electrosurgical handpiece with deployable needle electrode array and a tip that enables coagulation of the needle track; a foot pedal for activation; and connecting

cables (Figure 4). The RFVTA system is used in conjunction with a standard 5- or 10-mm laparoscope and a side-firing, laparoscopic transducer (either Aloka, Hitachi, Tokyo, Japan orBK Medical, Peabody, Massachusetts, USA). Principle features of RFVTA of uterine fibroids are:

1. Laparoscopic imaging using standard laparoscopic equipment and laparoscopic (contact) ultrasound-guided mapping and needle guidance.
2. An RF algorithm incorporated in the generator, which defines the ramp and treatment process at the selected target temperature.
3. The obviation of sutures—either serosal or myometrial.
4. Restriction of the ablation zone within the confines of the myoma, thus preserving myometrial integrity.
5. The ability to treat myomas of every type and location (including submucosal, cervical, broad ligament, and intraligamentous myomas).


Figure 4. Components of the RFVTA (Acessa™) System.

Laparoscopic (contact) ultrasound provides sensitive imaging, detecting more fibroids than either pre-operative transvaginal ultrasound or contrast-enhanced MRI [31–34]. Specially designed electrode dispersive pads, which are placed symmetrically on each leg just above the patella, virtually eliminate skin burns at the pad sites. Burns had been a consistent—if infrequent—complication of radiofrequency ablation procedures.

Administration of prophylactic antibiotics prior to the procedure is recommended. After induction of general anesthesia, insertion of a Foley catheter, and placement of a tenaculum on the cervix for uterine retraction and manipulation, the patient is placed in the supine position, and the dispersive electrode pads are placed as described. Standard sterile techniques are used throughout. Two laparoscopic ports are placed to accommodate the laparoscope and

the laparoscopic ultrasound transducer. The port locations are usually infra-umbilical or more superior for larger uteri and one in the midline at the top of the uterine fundus.

After pelvic inspection, fibroid mapping is performed in a systematic fashion using laparoscopic and ultrasound visualization to document the position (left, right, anterior, posterior; fundal, mid-uterus, lower segment, or cervical), fibroid type (submucosal types 1, 2, or 3; intramural; or subserosal), and fibroid size in three dimensions (Figures5A and 5B).
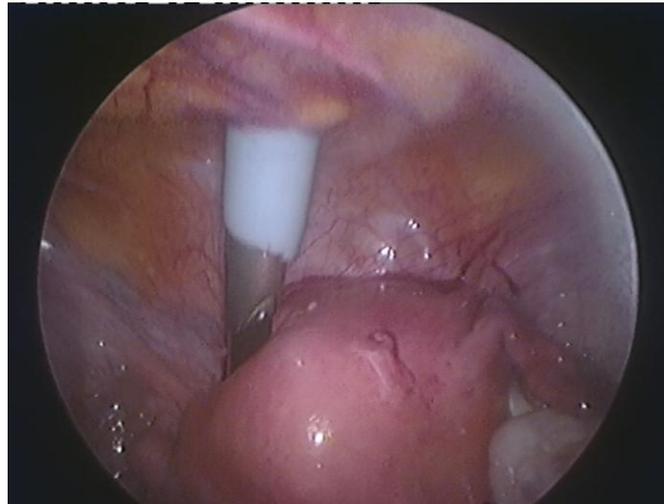
5A

5B

Figures 5A and 5B. (5A) Laparoscopic view of stabilization and ultrasound mapping of a myomatous uterus using a laparoscopic transducer; (5B) laparoscopic ultrasound view of multiple myomas.

The RF handpiece tip is inserted percutaneously under laparoscopic guidance through a 2-mm skin incision and, under laparoscopic and ultrasound guidance, the tip is introduced 1 cm into the midline of each fibroid. Ultrasonography is used to confirm correct tip placement.

The transducer also functions as a uterine manipulator and stabilizer during tip placement and ablation.

The dual-function generator is placed in manual ablation mode via control buttons on the RF handpiece. For fibroids less than 2 cm in diameter, the handpiece array is not deployed. Both generator activation and deactivation is by depression of the foot pedal. For fibroids 2 cm in diameter or larger, the surgeon deploys the array by pushing downward on the deployment ring of the handpiece, so that the most distal point of the array is 1 cm proximal to the distal margin of the fibroid. The individual straight electrodes are easily visualized by laparoscopic ultrasonography (Figure 6).
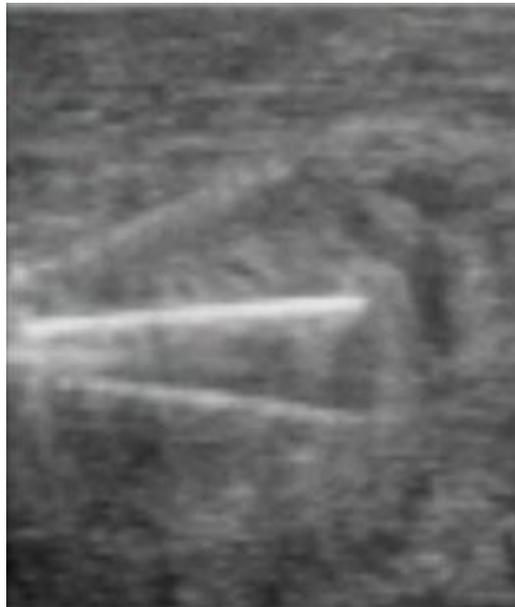

Figure 6. Laparoscopic ultrasound view of straight electrode array within myoma.

If the array position is unsatisfactory due to irregular fibroid shape or is less than or greater than 1 cm from the fibroid margin in the transverse, sagittal, or anteroposterior planes, the surgeon may reposition the handpiece and, if necessary, perform two or more complimentary and overlapping ablations, keeping the distal portion of the array 1 cm from the capsule to prevent damage to normal myometrium.

The target temperature defaults to the preferred temperature of 95°C. Depression of the foot pedal activates the generator initiating the ablation sequence. During the ramp phase, the generator functions at high power until the average temperature measured by all thermocouples at the tips of the array reaches the target temperature. Once the target temperature is reached, the timing of the ablation begins and the generator adjusts output to automatically maintain that temperature. The generator continuously displays the temperature measured by each thermocouple and the temperature at the leading edge of each electrode dispersive pad in real time. When the length of time at target temperature is reached as indicated by the treatment algorithm, depression of the foot pedal stops the ablation. The array is withdrawn into the handpiece shaft and use of the control buttons on the handpiece directs the generator to switch to coagulation mode. The handpiece is then withdrawn while

the foot pedal is depressed, achieving coagulation and hemostasis of the tract. Hemostasis is confirmed by laparoscopic visualization (Figure 7).
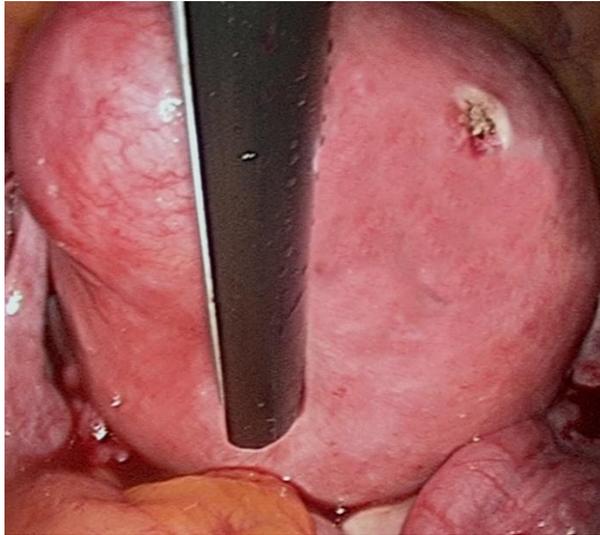

Figure 7. Laparoscopic view of coagulated electrode tract (right) after tip withdrawal and confirmation of hemostasis.

After completion of all ablations, the pelvis is irrigated and inspected and port sites are closed according to standard protocol. Patients are discharged the same day, with celecoxib and/or acetaminophen to manage postoperative pain. Pelvic rest is recommended for 3 weeks post procedure as a precautionary measure against infection.

Feasibility Studies

First Cases with Dedicated RFVTA System

Garza et al., reported the first series of cases in which RFVTA of symptomatic uterine fibroids were performed with the Halt Fibroid Ablation System [30]. Thirty-one women with a mean age of 40.2 ± 5.9 years and whose primary complaints were heavy menstrual bleeding, dysmenorrhea, dyspareunia, and pelvic pressure were followed postoperatively at 3 (n = 31), 6 (n = 29), and 12 months (n = 19). A total of 76 fibroids (range, 1–7 per patient) were treated. Patients realized improvementof their transformed Uterine Fibroid Symptom and Quality of Life (UFS-QOL) scores over 12 months: symptom severity decreased from a baseline value of 43.6 to 5.5 and health-related quality of life increased from 60.2 at baseline to 97.8. The greatest change in scores was achieved in the first 3 months posttreatment. Use of more than 15 catamenial pads on the heaviest day decreased from 66.7% of the participants (n = 20) at baseline to 5.3% (n = 1) at 12 months. The UFS-QOL questionnaire was selected as a tool to measure qualitative patient endpoints, as the questionnaire is a validated and reliable assessment instrument [35,36].

Mean uterine volume steadily decreased from 194.4 ± 105.9 cm^3 at baseline to 113.2 ± 53.5 cm^3 at 12 months. One patient experienced an abdominal wall vascular injury at a trocar site, which was reported as possibly related to the RF handpiece. The mean number of days to return to normal activities, whether at work or at home, was 3.4 ± 1.9 days. There were no known repeat hospitalizations, repeat treatments, or fibroid-related procedures of any kind during the observation period.

Confirmation of Earlier Results

Robles et al., set out to confirm Garza's report in terms of safety, change in patient UFS-QOL scores, and change in mean uterine volume [37]. Unlike the former study, Robles was able to follow most of his patients through to 12 months (35 patients at 12 months out of 36 at baseline [mean age, 43.6 ± 4.7 years]). The most prevalent symptoms at baseline were similar: heavy menstrual bleeding, dysmenorrhea, pelvic pressure, and urinary frequency or retention. UFS-QOL symptom-severity scores improved (decreased) most readily from baseline (63.3) to 3 months (23.1) and continued improving to 9.6 at 12 months. Likewise, quality-of-life scores improved (increased) the most during the first 3 months from 36.3 to 79.9 and gradually continued improvement to 87.7 at 12 months. Heavy menstrual bleeding was reported by 100% of the study participants at baseline and by only 6.1% of participants at 12 months. In addition, at 12 months 70.6% of women reported being symptom free.

As in the Garza study, mean uterine volume decreased over time: from 215.2 ± 117.9 cm^3 at baseline to 167.0 ± 120.8 cm^3 at 12 months. There were no procedure or device-related adverse events and of the 36 women reporting, all returned to normal activities within 5.3 days (range, 2–11 days). None of the patients sought additional treatment of potential fibroid-related symptoms after RFVTA during the observation period.

Pivotal clinical Trial

The pivotal study was a prospective, multicenter (11 clinical sites), single-arm international study where reproductive-aged study participants (n = 135), who desired uterine conservation but who did not desire future childbearing, served as their own controls [38,39]. Pre-treatment transvaginal ultrasound and MRI confirmed the presence of fibroids. Subjects with the diagnosis of adenomyosis by MRI and those with pedunculated subserosal myomas and type 0 intracavitary myomas were excluded. All enrolled subjects had moderate-to-severe heavy menstrual bleeding (≥ 160 mL to ≤ 500 mL) confirmed by a central laboratory's alkaline hematin testing of all catamenial products (pads, tampons, liners). Assessment of enrollees' alkaline hematin levels occurred at baseline and at 3, 6, and 12 months post treatment. This trial was primarily designed and approved by the U.S. Food and Drug Administration (US FDA) as a bleeding and surgical re-intervention study of women with heavy menstrual bleeding and fibroids. At the time of this writing, UFS-QOL and Euro-QOL 5-D Health State Index assessments were available at baseline and at 3, 6, 12, and 24 months post RFVTA.

There were no cases of intraoperative exclusion and surgeons treated a total of 640 fibroids measuring 0.7 to 9.7 cm in largest diameter, including calcified fibroids, which were not problematic. Although all study subjects had heavy menstrual bleeding, fewer than half (48.4%) were found to have one or more submucosal myomas. The median number of fibroids treated per subject was 4, with a range of 1–29. The mean procedure time from incision to skin closure was 2.1 ± 1.0 h. Median intraoperative blood loss was 32.5 mL (range, 5–150 mL), and 96.0% of patients were treated on an outpatient basis. In the first year of the study, 8 women were excluded from the final analysis as 4 did not provide catamenial products at the 12-month follow-up visit, 3 became pregnant, and 1 was diagnosed with Hashimoto's disease. Most participants (81.9%, 104/127) experienced a decrease in menstrual blood loss from baseline to 12 months, and 40.2% (95% CI: 31.6%–48.7%) achieved at least a 50% reduction in blood loss during the same period. Total mean uterine volume decreased by 15.7% at 3 months and by 24.3% at 12 months. Mean fibroid volume also decreased significantly during the same time periods: by 39.8% at 3 months and by 45.1% at 12 months.

Mean symptom severity scores decreased/improved significantly ($p < .001$) in the first 3 months from 61.1 to 29.1 and continued to improve gradually to 25.4 at 24 months (Figure 8). The same significance also was seen in an increase/improvement of mean health-related quality-of-life (HRQL) scores in the first 3 months (37.3 to 75.1); improvement continued to 79.3 at 24 months. Mean Health State scores improved from a baseline of 71.1 to 84.0 at 24 months. Ninety-eight percent of those women reporting responded that they would recommend Acessa to a friend with the same health problem.
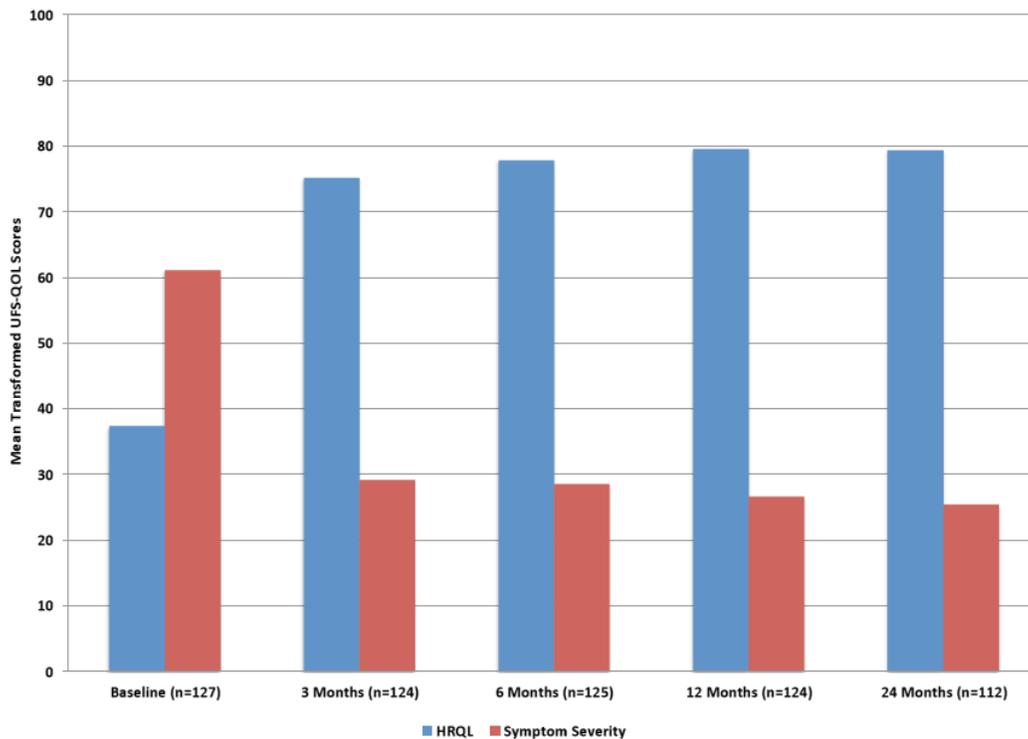

Figure 8. Improvement in mean transformed UFS-QOL scores over time.

Device-related adverse events were reported for 5 women (5/135, 3.7%) in the first 12 months of follow up: a 2-cm laceration of the serosa of the sigmoid colon caused by the ultrasound probe; an instance of postprocedural mild vaginal bleeding which resolved spontaneously; an instance of severe lower abdominal pain successfully treated with ibuprofen; a small superficial uterine serosal burn not requiring treatment; and a postprocedural pelvic abscess discovered 33 days after treatment and reportedly following unprotected intercourse. One serious adverse event classified as possibly related to the procedure, occurred between 12 and 24 months. A subject conceived and delivered a full-term healthy infant by C-section, at which time a partial myomectomy was performed. Forty-eight hours later, she experienced pain, heavy vaginal bleeding, and expulsion of the partially excised fibroid. Although she required transfusion, the balance of her recovery was uneventful.

There were 7 surgical re-interventions in the first two years: one uterine artery embolization at 10 months followed by two hysteroscopic myomectomies and 4 hysterectomies between 12 and 24 months. Adenomyosis was found on pathology in 3 of the hysterectomies. Subjects with adenomyosis had a smaller reduction in menstrual blood loss (18%, 16%, and 34%, respectively, at 3, 6, and 12 months) than did those without. However, the presence or absence of adenomyosis did not seem to have a quantifiable effect upon mean UFS-QOL symptom severity and HRQL scores and changes in those scores over time. Despite the exclusion of subjects with adenomyosis diagnosed by MRI at baseline, adenomyosis was diagnosed through pathology specimens from surgical re-intervention procedures and through MRI review by a central radiologist. Given the small number of women with fibroids and adenomyosis in this trial, additional data are needed to characterize the outcomes of RFVTA in this subset of patients.

Overall, the clinical outcomes from this pivotal trial demonstrated reproducibility and durability through the first two years of analysis. Both patient-reported outcomes (quality of life and symptom reduction) and objective measures (menstrual bleeding and fibroid volumes) showed benefits that were continuous and statistically significant.

Rfvta and Myomectomy:
A Postmarket Randomized Controlled Trial

A randomized, controlled trial (RCT) in Germany compared outcomes of RFVTA and laparoscopic myomectomy (LM) in reproductive-aged patients with symptomatic fibroids who desired future childbearing [40]. The study was designed to compare intraoperative and immediate postoperative outcomes and—longer term—to study UFS-QOL and pregnancy outcomes. The surgeons involved in the study had extensive experience in laparoscopic myomectomy but no experience with RFVTA prior to training for the RCT.

As described earlier in this chapter, laparoscopic ultrasound (LUS) mapping of a myomatous uterus is a standard and fundamental step prior to RFVTA of uterine fibroids; however, there is currently limited experience with LUS at the time of laparoscopic myomectomy [33,34]. This RCT incorporated LUS prior to randomization and treatment (both ablation and excision) to permit the surgeon equal access to precise imaging. Subsequent to each subject's fibroid mapping and classification, an envelope containing her

treatment assignment was drawn, and only then was the surgeon made aware of the treatment approach, i.e., RFVTA or laparoscopic myomectomy. In each of the randomized groups, two women reported subfertility.

At LUS, 72 fibroids were imaged in the RFVTA group (n = 25) and 61 were imaged in the LM group (n = 25). The numbers of fibroids treated/excised as percentages of those imaged on LUS were 98.6% (71/72) for the RFVTA group and 80.3% (49/61) for the LM group. At LM, surgeons sometimes elected not to treat smaller fibroids to minimize operative time and myometrial dissection. Four to five trocars were utilized to perform LM; two trocars were used in the RFVTA group.

Brucker et al., reported mean hospitalization times of 9.98 ± 5.47 h for the RFVTA patients and 29.94 ± 14.18 h for the LM patients. In the RFVTA group, 20 of 25 patients were discharged the same day. Five RFVTA patients stayed overnight, four of whom underwent adhesiolysis in addition to fibroid ablation and were hospitalized overnight as a standard of care.

Mean times between first incision and closure of port sites were 1.15 ± 0.36 h for the RFVTA group and 1.34 ± 0.59 h for the LM group. Mean operative blood loss was 16 ± 9 mL for the RFVTA procedures and 51 ± 57 mL for the LM procedures. One RFVTA patient developed vertigo and had an unplanned hospitalization; this was the only complication reported in the group. The only complication reported in the LM group was a port-site hematoma.

The women in both groups will be followed for 5 years and long-term results have not yet been collected and reported. However, in this small study and compared to LM, patients who underwent RFVTA had less intraoperative blood loss, a similar operative time, treatment of more fibroids, and a significantly shorter postoperative stay.

Pregnancy Post RFVTA

There are few data on pregnancy outcomes post RFVTA. Six study subjects (mean age, 37.1 years) from the feasibility and pivotal studies conceived at 3.5 to 15 months post procedure [41,42]. One woman had a normal spontaneous vaginal delivery at term of a 3487 infant with Apgar Scores of 9/9. Four other women delivered healthy infants at 37 to 38.3 weeks by C-section: two were delivered via repeat Cesarean section, with the remaining two delivered by Cesarean section out of concern for the unknown risk of uterine rupture post ablation. The sixth pregnancy ended in a spontaneous abortion at 10 weeks; the spontaneous abortion rate (16.75%, 1/6) was within the range of 11% to 22% reported in the literature [43]. No adverse pregnancy outcomes—such as, preterm delivery, abruption placentae, placenta accreta, or intrauterine growth restriction—occurred, and in no case were uterine wall defects, scarring or adhesions observed.

The pregnancy outcomes are encouraging, and future pregnancy and potential vaginal delivery post RFVTA are being explored in three trials, respectively, in Canada [ClinicalTrials.gov Identifier: NCT01563783], California [NCT0180124], and Germany [NCT01750008].

Treatment Algorithms

Where does RFVTA with Acessa fit among the treatments for symptomatic fibroids? We feel that Acessa is appropriate for many of those women who either refused or failed medical or surgical therapy or for whom medical therapy would be inappropriate, depending on patient personal goals for uterine conservation, hormonal status, and concern for future fertility. Acessa may be considered for the treatment of bulk, pain and bleeding symptoms as presented in treatment algorithms (Figures 9A and 9B). Patients who would not be considered candidates for Acessa include those for whom laparoscopy would be contraindicated, those having a uterine malignancy, and patients desiring hysterectomy or those who would benefit from hysterectomy for other reasons.
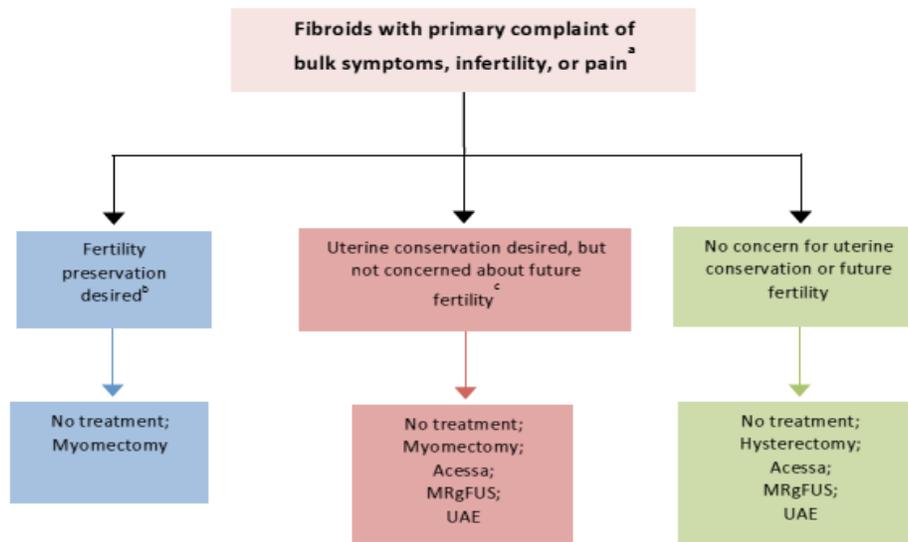
[a] Patient failed medical therapy, was on medical therapy for > 6 months, refused medical therapy, or medical therapy was deemed inappropriate.
[b] At the time of this writing, insufficient data exist on which to evaluate the safety and effectiveness of the Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy.
[c] Some treatment options may not be appropriate for patients with large, pedunculated fibroids.
Abbreviations: MRgFUS = magnetic resonance guided focused ultrasound; UAE = uterine artery embolization.
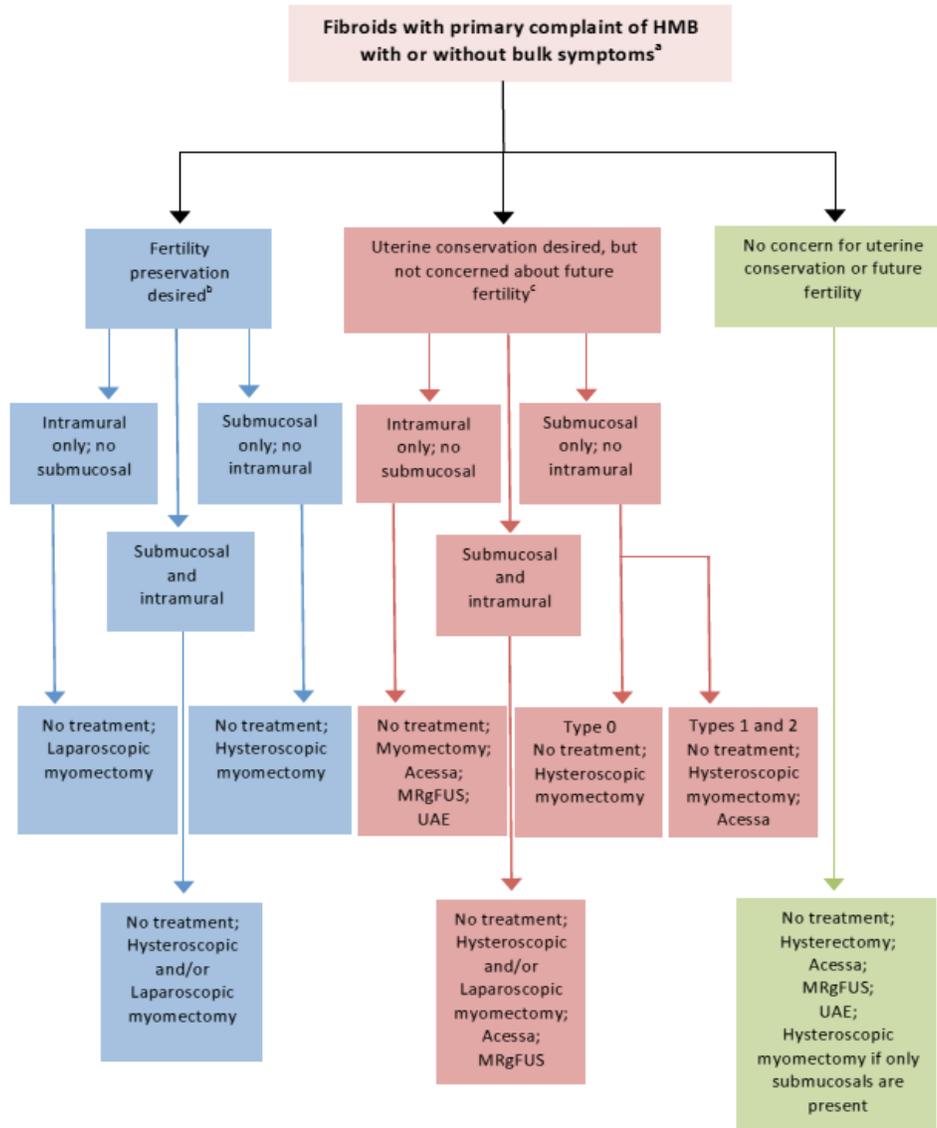
Figure 9A. Non-medical treatment algorithm for patients with fibroids and primary complaint of bulk symptoms, infertility or pain.

Conclusion

Clinical Take-Aways

RFVTA with Acessa provides a safe, effective, and durable outpatient procedure for the treatment of symptomatic fibroids. The method and device provide means for the treatment of

essentially all fibroids regardless their location, type, number or size. One woman in the pivotal phase III trial had 29 fibroids imaged by LUS, all of which were successfully ablated. RFVTA produces minimal myometrial damage (limited to the needle track); coagulation provides hemostasis upon probe tip withdrawal; and no instrumentation in the uterine cavity is required, leaving the endometrium intact.

Fibroids with primary complaint of HMB with or without bulk symptoms[a]

- Fertility preservation desired[b]
  - Intramural only; no submucosal
    - No treatment; Laparoscopic myomectomy
  - Submucosal only; no intramural
    - No treatment; Hysteroscopic myomectomy
  - Submucosal and intramural
    - No treatment; Hysteroscopic and/or Laparoscopic myomectomy

- Uterine conservation desired, but not concerned about future fertility[c]
  - Intramural only; no submucosal
    - No treatment; Myomectomy; Acessa; MRgFUS; UAE
  - Submucosal only; no intramural
    - Type 0 No treatment; Hysteroscopic myomectomy
    - Types 1 and 2 No treatment; Hysteroscopic myomectomy; Acessa
  - Submucosal and intramural
    - No treatment; Hysteroscopic and/or Laparoscopic myomectomy; Acessa; MRgFUS

- No concern for uterine conservation or future fertility
  - No treatment; Hysterectomy; Acessa; MRgFUS; UAE; Hysteroscopic myomectomy if only submucosals are present

[a] Patient failed medical therapy, was on medical therapy for > 6 months, refused medical therapy, or medical therapy was deemed inappropriate.
[b] At the time of this writing, insufficient data exist on which to evaluate the safety and effectiveness of the Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy.
[c] Some treatment options may not be appropriate for patients with large, pedunculated fibroids.
Abbreviations: HMB = heavy menstrual bleeding; MRgFUS = magnetic resonance guided focused ultrasound; UAE = uterine artery embolization.

Figure 9B. Non-medical treatment algorithm for patients with heavy menstrual bleeding with or without bulk symptoms.

Until recently, heavy menstrual bleeding had been attributed strictly to submucosal myomas. Cases where submucosal myomas were removed but heavy menstrual bleeding persisted were puzzling. Results reported from the pivotal trial provide compelling evidence that treatment of intramural fibroids by RFVTA—even in the absence of submucosal myomas—reduces heavy menstrual bleeding in both clinically and statistically significant amounts (Table 1) [44–47].

Table 1. Volume and percentage reduction in alkaline hematin (AH) 12 months post RFVTA. Classification of fibroids is according to the following FIGO types: type 3 (intramural abutting the endometrium with submucosal components), type 4 (intramural not contacting the endometrium) or type 5 (subserosal/intramural) and/or types 1 or 2 (submucosal) fibroids[a, b, c]

Types	n	Mean AH Reduction ± SD (mL)	Median (range)
Types 3, 4, or 5—but no types 1 or 2	63	-92.16 ± 116.76 (-31.8%)	-76.0 (-435–289)
Types 4 or 5—but no types 1, 2, or 3	27	-65.22 ± 79.30 (-25.0%)	-73.0 (-204–196)
Type 3—but no types 1, 2, 4, or 5	17	-123.18 ± 117.87 (-40.5%)	-114.0 (-324–35)
Type 3 and types 4 or 5—but no types 1 or 2	19	-102.68 ± 153.00 (-33.8%)	-72.0 (-435–289)
Types 1 or 2—but no types 3, 4, or 5	10	-138.20 ± 107.95 (-45.1%)	-161.0 (-287–124)
Types 3, 4, or 5 and types 1 or 2	49	-107.31 ± 110.73 (-39.7%)	-124.0 (-394–107)

[a] Visualized by laparoscopic ultrasound.
[b] AH = alkaline hematin; SD = standard deviation.
[c] Modified from Table 2, reference 44.

Data indicate that RFVTA patients experience enduring symptom reduction and quality-of-life improvement to at least two years post treatment. The vast majority of women are treated on an outpatient basis and return to work and to normal activities in a matter of a few days and have minimal or no pain. More than 94% of women treated with Acessa reported that the treatment had been effective in eliminating their symptoms; 98% of the women reported that they would recommend Acessa to a friend with the same health problem.

RFVTA with Acessa is an effective, minimally invasive gynecologic procedure with rapid recovery, minimal postoperative pain, and high patient satisfaction. Given the apparent benefits, safety, and widespread applicability of RFVTA to patients with various symptoms and types of myomas, RFVTA appears to be a valuable and reasonable option for many, if not the majority, of patients with symptomatic uterine fibroids.

Acknowledgment

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