Feasibility, Safety, and Efficacy of Accurate Uterine Fibroid Ablation Using Magnetic Resonance Imaging–Guided High-Intensity Focused Ultrasound With Shot Sonication

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The aim of this study was to investigate the feasibility, safety, and efficacy of uterine fibroid treatment using magnetic resonance imaging (MRI)-guided high-intensity focused ultrasound (US) with shot sonication for accurate ablation. Forty-three patients with 51 symptomatic uterine fibroids were treated with MRI-guided high-intensity focused US with shot sonication, which was a small acoustic focus of higher intensity with a shorter time (2 seconds) of US exposure and a shorter cooling time (2–3 seconds). The treatment efficacy and adverse events were analyzed, and the changes in the severity of symptoms and the reduction in fibroid volume were assessed 3 and 6 months after the procedure. All patients were successfully treated in a single session, without major complications, and the mean nonperfused volume ratio ± SD was 84.3% ± 15.7% (range, 33.8%–100%). Complete ablation was achieved in 13 T2-hypointense fibroids from 10 patients, and partial ablation was achieved in 38 fibroids from 33 patients. The overall mean treatment time was 135.0 ± 50.9 minutes (2.2 ± 0.8 hours). The transformed symptom severity scores and mean fibroid volumes decreased significantly after treatment (P < .05). In conclusion, MRI-guided high-intensity focused US with shot sonication is a feasible, safe, and effective technique for ablation of uterine fibroids and complete ablation of T2-hypointense fibroids.

Key Words—ablation; magnetic resonance imaging, magnetic resonance imaging–guided high-intensity focused ultrasound; nonperfused volume; uterine fibroid
who have already undergone a myomectomy for complete removal of uterine tumors. As it is unreasonable for these patients to undergo another additional surgical procedure, regardless of laparoscopic or hysteroscopic myomectomy, both of which are also restricted in terms of fibroid location and size, there is a need for the development of a new, noninvasive technique for removing uterine fibroids.

Recently, magnetic resonance imaging (MRI)-guided high-intensity focused US has become a noninvasive therapeutic procedure for patients with symptomatic uterine fibroids. It had been reported that many patients who underwent MRI-guided high-intensity focused US treatment presented with a decrease in uterine fibroid size and relief of the associated symptoms that lasted for greater than 2 years; however, a relatively high percentage (28%) of patients required alternative therapies 12 months later due to partial ablation of fibroids by MRI-guided high-intensity focused US. Prior studies showed that the efficacy for both volume reduction and symptom relief could be improved with an increase in the nonperfused volume ratio. As complete devascularization of uterine artery embolization has been recommended for long-term success, complete treatment of the total fibroid volume using sonication would be desirable because partial ablation was associated with high risks of recurrence. Therefore, it has been proposed that a high ratio or complete ablation of fibroids achieved with high-intensity focused US could maximize the long-term efficacy of uterine fibroid ablation.

A novel MRI-guided high-intensity focused US system developed by Chongqing Haifu Tech Co, Ltd (Chongqing, China) integrated into a 1.5-T MRI scanner uses a small acoustic focus of higher intensity with a shorter time (2–3 seconds) for the “shot sonication,” which can enable the biological focal region to reach the peripheral margin of the tumor without damage to the surrounding healthy tissue and avoid skin injury from thermal diffusion resulting from a long sonication. Compared with the 20- to 30-second sonication followed by a 60- to 90-second cooling time and the larger treatment areas of previously used MRI-guided high-intensity focused US, it was expected to be more possible to achieve complete thermoablination of fibroids and more efficient treatment and to improve therapeutic efficacy and safety. The aim of this study was to investigate the feasibility, safety, treatment efficiency, and efficacy of MRI-guided high-intensity focused US with shot sonication for accurate ablation of uterine fibroids.

Materials and Methods

Patients
We conducted a prospective study approved by the Institutional Ethics Committee (clinical trial registration number NCT01239641). Written informed consent for the MRI-guided high-intensity focused US procedure was obtained from all patients.

The inclusion criteria for MRI-guided high-intensity focused US treatment of uterine fibroids included the following: 1) premenopausal or perimenopausal woman between the ages of 18 and 55 years; 2) symptomatic uterine fibroids of 3 cm or greater and less than 12 cm in diameter and no more than 2 fibroids as determined by MRI; 3) patients who were not pregnant and who had no plans for future pregnancy; (4) no contraindications to MRI or MR contrast agents; and (5) no evidence of calcification or substantial degeneration in the uterine fibroids, as determined by plain radiography or MRI. A total of 43 patients with 51 symptomatic uterine fibroids were consequently recruited. The choice of MRI-guided high-intensity focused US rather than surgery was based on patient preference.

Pretreatment Imaging
All patients underwent diagnostic pelvic MRI using a standardized protocol on a 1.5-T MRI system (Magnetom Avanto; Siemens Medical Systems, Berlin, Germany). T2-weighted images were acquired in axial, coronal, and sagittal planes, and T1-weighted images we acquired before and after administration of a gadolinium-diethylenetriaminepentaacetic acid-bis-methylamide contrast agent (Omniscan, 1.0 mmol/mL; GE Healthcare, Shanghai, China; 0.1 mmol/kg of body weight). The MR images were analyzed to determine the number, location, size, signal intensity, and contrast enhancement patterns of all fibroids. The T2-weighted signal intensity of fibroids was classified as hyperintense or hypointense compared with the skeletal muscle signal intensity.

Magnetic Resonance Imaging–Guided High-Intensity Focused US System
Uterine fibroid ablations were performed with the JM S100 clinical extracorporeal MRI-guided high-intensity focused US system (Chongqing Haifu’ Tech Co, Ltd; Figure 1), which was fully integrated into a 1.5-T Magnetom Avanto MRI system, which provided a real-time temperature mapping system for treatment control. Therapeutic US energy was produced by a single focused piezoelectric ceramic composite transducer with a diameter of 18 cm, a focal length of 15 cm, and an operating frequency of 1.0 MHz. The table, on
which the patient was placed in the prone position, contained the large-diameter transducer array in a water tank. The location of the acoustic focus could be electronically controlled, and its dimensions were 6 mm along the beam axis and 2 mm in the transverse direction. With use of computer control, the integrated transducer could be moved smoothly in 6 directions (Figure 2).

**Patient Preparation for the Procedure**

Before US treatment, a complete bowel preparation was performed after 12 hours of fasting, and an enema was performed in the early morning of the day of treatment. Each patient was shaved from the anterior abdominal wall down to the pubic crest. A Foley catheter was inserted into the patient’s urinary bladder at the beginning of the procedure. If bowel lay between the transducer and the targeted fibroid during the procedure, it could often be pushed away from the acoustic pathway by filling the bladder or using a degassed water balloon of appropriate size.15

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**Figure 1**. JM 5100 MRI-guided high intensity focused US apparatus used in this study.

**Figure 2**. The patient was placed in the prone position on the table (A). The location of the acoustic focus could be electronically controlled, and the integrated transducer could be moved smoothly in 6 directions (B–D, x-axis: right and left; y-axis: head [H] and feet [F]; z-axis: anterior and posterior [P]). Movement is shown on the y-axis (D).
Magnetic Resonance Imaging–Guided High-Intensity Focused US Procedure

All of the MRI-guided high-intensity focused US procedures were performed by a single interventional radiologist (Y.X.) with greater than 10 years of experience in image-guided tumor ablation therapy. The patients received 50 to 400 μg of intravenous fentanyl and 1 to 4 mg of intravenous midazolam hydrochloride for conscious sedation and were monitored to track the respiration rate, heart rate, blood pressure, and oxygen saturation level. The sedation nurse accompanied the patient in the same room, and the patient held up a balloon to stop sonication if she could not endure discomfort during the procedure.

Before treatment, coronal, sagittal, and transverse T2-weighted turbo spin echo images (repetition time/echo time, 4800/120 milliseconds; slice thickness, 4.0 mm; matrix, 256 × 100; and field of view, 36 × 36 cm) were obtained for treatment planning. The treatment area was outlined by the interventional radiologist and an MRI technologist, and “seeds” from the treatment area, which spared the surrounding tissue and organs, were generated automatically by the treatment-planning system software on the basis of the size and location of the fibroid (Figure 3).

To test the accuracy of targeting, initial lower-power sonications (50 w/cm²; sonication duration, 1 second) were performed to generate temperatures lower than 50°C, while the effect of temperature elevation was monitored by sagittal images (5 slices). The acoustic focus was adjusted to match the temperature-elevated focal spot shown by proton resonance frequency–shifted temperature-mapping imaging.

After the accuracy of the target spot was confirmed, the sufficient thermal dose was delivered by increasing the power (up to 400 W) to achieve temperatures of 60°C or higher at the focal region. The duration of each shot sonication was 2 seconds, followed by a 2- or 3-second cooling period for high-intensity focused US treatment, while proton resonance frequency–shifted MRI was performed to monitor the temperature elevation in real time. The acoustic power and energy were determined according to the real-time temperature monitoring for the optimum sonication parameters of the treatment. When the focal temperature was higher than 70°C, the acoustic power was decreased. However, if the acoustic power was raised up to 400 W and did not reach 60°C, the therapeutic run (2-second sonication followed by a 2- to 3-second cooling interval) would be repeated until it reached 60°C to 65°C, which could result in tissue ablation.9,16 Generally, 2 or 3 US pulses.
(range, 1–16 pulses) could ablate each target volume (Video 1). The focal region of targeted ablation that represented the area of 60°C and higher on temperature mapping could be increased to approximately 4 mm in width (transverse axis) and 10 to 12 mm in length (beam axis), which was a basic treatment area measuring approximately 30 to 35 mm², with a less than 1-mm rimlike area of 55°C to 60°C surrounding it (Figure 4). After a targeted focus ablation was completed, the focus was moved to the next neighboring target based on the treatment plan. When the targeted area was near the margin of the fibroid, a lower acoustic power was used for a smaller focal lesion, measuring 2 mm (transverse axis) × 6 mm (beam axis) at temperatures higher than 60°C on the temperature mapping (Figure 5). The size of all sonicationals visualized per MR thermometry was recorded to match the previously planned focal region.

Depending on the volume of the targeted fibroid and treatment zone, a variable number of sonicationals were performed to cover the entire volumes of all fibroids, except in cases in which the patient felt extreme severe pain, were intolerant of extreme pain, had nerve numbness, or felt pain spreading to the lower legs. The tolerability of the treatment was determined by the patients’ responses concerning their status during the procedure. In most cases, a degassed water balloon of the proper size was placed between the patient’s abdominal wall and the transducer to avoid the presence of a bowel loop on the US beam path. All patients received only a single treatment session.

**Posttreatment Imaging and Follow-up**

Immediately after treatment, axial, sagittal, and coronal T1-weighted MRI images were acquired for assessment before and after administration of the contrast agent, and the fraction of ablation, defined as the nonperfused volume divided by the fibroid volume was calculated. The fibroid and ablation volumes were measured by the parallel planimetric area method as described previously. All patients had follow-up at 3 and 6 months, and the MRI protocol and parameters were the same as those before treatment.

Patients’ symptoms associated with fibroids were prospectively collected and quantitatively analyzed according to the Uterine Fibroid Symptom and Quality of Life symptom severity scores. Eight questions particularly for myoma were administered, and the responses were rated on a scale of 1 to 5 (1, none; 2, mild; 3, moderate; 4, severe; and 5, very severe). Raw scores were converted to a score on a scale of 100 by the following formula: transformed score = (raw score – 8)/32 × 100. Lower scores indicated better symptom relief on the symptom severity scale. The questionnaire was given before treatment and at 3- and 6-month follow-ups.

![Figure 4](image-url) Sagittal T2-weighted imaging showed the targeted acoustic focus in the fibroid based on the treatment plan (A). Real-time proton resonance frequency–shifted temperature mapping showed the temperature elevating to 65.3°C (maximum) at the target region of the slice position (B). Red and yellow represent temperatures of 60°C or higher and 55°C to 60°C, respectively. Acoustic power of 300 W produced the red region of 35.44 mm² (transverse axis, 4 mm; beam axis, 11–12 mm).
**Data Analysis and Statistics**
All data were presented as mean ± standard deviation. Statistical analyses of the data were performed by analysis of variance and the Student t test. \( P < .05 \) was considered statistically significant.

**Results**

**Patient Characteristics**
The mean age of the 43 patients included in the study was 41.6 ± 5.5 years (range, 28–52 years), and the mean size of the 51 symptomatic uterine fibroids was 6.4 ± 1.7 cm (range, 3.0–10.1 cm). The 51 treated fibroids were located in intramural (n = 38), submucosal (n = 1), and subserosal (n = 12) areas, and all patients had fibroid-associated symptoms of pelvic pain, menorrhagia, dysmenorrhagia, dyspareunia, and pressure-related symptoms, such as pelvic fullness and urinary frequency.

**Immediate Treatment Outcomes**
The mean nonperfused volume ratio was 84.3% ± 15.7% (range, 33.8%–100%) based on immediate contrast-enhanced MRI after sonication. Complete ablation was achieved in 13 fibroids (26%) from 10 patients (23%), and the mean fibroid volume and nonperfused volume of each case were 109.6 ± 90.7 cm\(^3\) (range, 13.2–405.1 cm\(^3\)) and 92.4 ± 82.7 cm\(^3\) (range, 7.9–380.4 cm\(^3\)), respectively \( (P < .05 \) compared with complete ablation). Among them, the nonperfused volume ratios ranged from 90.0% to 99.1% in 12 fibroids from 10 patients and were less than 90% in 26 fibroids from 23 patients. Of the 38 partially ablated fibroids in the 33 patients, 8, 13, and 17 were hypervascular, moderately vascular, and hypovascular, respectively (2, 4, and 6 with 90.0%–99.1% nonperfused volume ratios and 6, 13, and 7 with <90% nonperfused volume ratios), and 31 and 7 were hypointense and hyperintense on T2-weighted imaging, respectively (11 and 1 with 90.0–99.1% nonperfused volume ratios and 20 and 6 with <90% nonperfused volume ratios).

**Procedure Time and Treatment Efficiency**
The overall mean treatment time was 135.0 ± 50.9 minutes (2.2 ± 0.8 hours; range, 1.0–4.3 hours). The mean treatment time was 174.5 ± 42.2 minutes (range, 110–250 minutes), and the mean sonication time was 24.7 ± 9.1 minutes (range, 12.9–46.0 minutes, or 387–1380 US pulses) in the 10 patients with completely ablated fibroids. In contrast, the mean treatment time was 129.0 ± 53.1 minutes (range,
and the mean sonication time was 17.6 ± 6.7 minutes (range, 8.2–39.2 minutes, or 246–1176 US pulses) in the 33 patients with partially ablated fibroids (P < .05). The treatment speeds based on the immediate non-perfused volume results and treatment time (from first sonication to last sonication) were 42.2 ± 25.6 cm³/h (range,

Figure 6. A uterine fibroid in a 28-year-old woman was hypointense on pretreatment T2-weighted imaging (A). Sagittal contrast-enhanced T1-weighted imaging showed inhomogeneous enhancement before MRI-guided high-intensity focused US treatment (B). Sagittal contrast-enhanced T2-weighted imaging showed a 100% nonperfused volume in the fibroid immediately after sonication (C) and volume shrinkage (59% of baseline) with a sustained nonperfused area at the 6-month follow-up (D).
13.8–95.0 cm³/h) in the complete ablation group and 45.3 ± 32.5 cm³/h (range, 3.9–117.1 cm³/h) in the partial ablation group (P > .05). The mean energy efficiency factor was 5.1 ± 3.0 J/mm³ (range, 0.8–9.8 J/mm³) in the complete ablation group, which was a little lower than the 6.0 ± 4.9 J/mm³ (range, 1.2–20.6 J/mm³) in the partial ablation group; however, this difference was not statistically significant (P > .05).

**Patient Tolerance and Complications**

No patient had any extreme or intolerable pain during the high-intensity focused US treatment. One patient with a partially ablated fibroid near the sacrum felt mild lower back pain, which lasted to the second day after the treatment. Three patients with complete ablation of fibroids and 4 patients with partial ablation had mild pain in the lower abdomen for 1 to 3 hours after the procedure. No abdominal skin burns or nerve injury occurred in any patient, except for 1 patient with a 93% nonperfused volume in the treated fibroid, who had a small skin blister (second-degree skin burn). The incidence of complications was 4.7% (2 of 43).

**Treated Fibroid Volume and Symptom Changes After MRI-Guided High-Intensity Focused US**

The mean fibroid volume reductions in the 10 patients with complete ablation were 39.5% ± 10.2% (range, 26%–60%) and 59.1% ± 9.0% (range, 47%–79%) at the 3- and 6-month follow-ups, respectively (P < .01). The mean transformed symptom severity score decreased from 52.0 ± 8.3 (range, 36–68) at baseline to 36.6 ± 7.9 (range, 22–50) after 3 months (P < .05) and 29.0 ± 3.2 (range 26–36) after 6 months (P < .05).

The mean fibroid volume reductions in the 33 patients with partial ablation were 31.7% ± 15.2% (range, 13%–54%) and 40.1% ± 18.4% (range, 17%–59%) at the 3- and 6-month follow-ups, respectively (P < .05). The mean transformed symptom severity score fell from 53.9 ± 9.1 (range, 38–70) at baseline to 35.8 ± 4.8 (range, 28–46) after 3 months (P < .05) and 29.4 ± 4.2 (range, 22–42) after 6 months (P < .05).

**Discussion**

This new MRI-guided high-intensity focused US system had a minimum treatment area of 2 × 2 × 6 mm (equivalent to a volume of 0.01 cm³) based on its acoustic focal region and a range of acoustic powers (50–400 W) with a 1.0-MHz high-intensity focused US field for tumor ablation; furthermore, a less than 1-mm rimlike zone with a temperature of 55°C to 60°C surrounding the focus indicated that shot sonication made heat diffusion less possible. Consequently, such precise thermal lesions can be used for accurate ablation of the peripheral areas of treated tumors. Through the increase in the acoustic power delivered, the targeted focal volume increased to approximately 0.1 cm³ (axial diameter of 4 mm and longitudinal diameter of 11–12 mm) as a single ellipsoidal treatment area for ablating the main portion of the fibroid generally, and the duration of shot sonication was only 2 seconds, followed by a 2- to 3-second cooling time. This system was different from the previous MRI-guided high-intensity focused US systems using a 20- to 30-second sonication duration with a 60- to 90-second cooling time for a relatively larger treatment area (0.5-cm³ bean-shaped region, 8-mm axial diameter, and 20-mm longitudinal diameter). Magnetic resonance imaging–guided high-intensity focused US with shot sonication has the following advantages: (1) ensuring energy efficiency to avoid spread of the thermal dose resulting from respiratory motion due to longer exposure time; (2) increasing the energy efficiency due to application of higher acoustic power (200–400 W) to the targeted focus; (3) ensuring accurate ablation with a small focal region for completely covering the total volume of the fibroid and avoiding the risk of unintended lesions; and (4) increasing the treatment efficiency due to the short duration of each sonication with a short cooling interval. Thus, the anatomically and thermally precise ablation by high-intensity focused US with overlying shot sonication would, in theory, be expected to cover the entire tumor volume without injuring the surrounding healthy tissues.

Given that the entire fibroid volume was completely treated according to the high-intensity focused US treatment plan, the characteristics of the tumors influenced the nonperfused volume from sonication-produced ablation. Hypervascular blood perfusion of tumors during thermal therapy could prevent temperature elevation due to the heat sink effect. In this study, 2 hypervascular fibroids in 2 patients and 4 moderately vascular fibroids in 3 patients were completely ablated by MRI-guided high-intensity focused US with shot sonication. These fibroids were considered the suitable candidates for high-intensity focused US therapy due to their hypointense signal on pretreatment T2-weighted imaging. It was postulated that shot sonication with higher acoustic power could occlude or damage blood vessels of less than 0.2 mm in diameter and change the fibroid vascular flow pattern because its interior is supplied by small centripetal arteries. Our results showed that 13 T2-hypointense fibroids (26%) in 10 patients (23%) were completely ablated; however, 38 fibroids (75%) in 33 patients (77%) were partially ablated, and
among them, almost complete ablation (nonperfused volume ratio, 90.0%–99.1%) was achieved in 12 fibroids from 10 of these patients. In this study, although patients with both completely and partially ablated fibroids had significant reductions in treated fibroid volumes and symptom relief and 6 months after MRI-guided high-intensity focused US treatment, rapid growth of residual viable tissue in 5 partially ablated fibroids from 5 patients was observed, even though only a small portion of nonablated tumor tissue was left in the fibroids (Figure 7).

In terms of partially ablated fibroids, the additional reasons, including the clinical status, patient motion during the procedure, and the acoustic environment, influenced the therapeutic outcome. When the targeted focus was adjacent to the vertebral bone and sacral nerves, the sonication had to be aborted when the patients felt severe pain or numbness, which may be a potential risk resulting from the far field of focused US. Some of the partially ablated fibroids with nonperfused volumes of greater than 90% would have been fully ablated, since a targeted fibroid may change position because of patient movement during the procedure, providing the possibility of untreated regions among the treatment areas due to the adapted treatment plan; in addition, a lesion-lesion interference effect can also disrupt full coverage of biological focal regions.22 Therefore, the clinical strategy of MRI-guided high-intensity focused US with shot sonication can be further optimized to increase the efficacy of fibroid ablation, although a mean nonperfused volume ratio of 84.3% ± 15.7% was achieved in this initial study.

The results of previous clinical trials on fibroid treatment have shown that the sonication procedures were time-consuming, and only partial ablation of the tumor volume was achieved, which remains a limiting factor for the adoption of MRI-guided high-intensity focused US ablation of fibroids as a popular therapeutic option. Volumetric sonication was developed to allow ablation of larger volumes instead of the “point-by-point” ablation technique, thus resulting in increased treatment efficiency. However, the whole procedure lasted 3 to 4 hours or longer, and the ablation fraction was only around 50% or less of the fibroid volume in recent volumetric ablation studies9,17; obviously, volumetric sonication has not substantially decreased treatment time compared with the other prior studies. Trumm et al23 reported the highest mean nonperfused volume ratio of 88% ± 15% (range, 38%–100%) in the first study with the second-generation ExAblate 2100 MRI-guided focused US system (Insightec, Tirat Carmel, Israel) thus far, and the mean treatment time was 3.3 ± 1.2 hours (range, 1.1–6.6 h), which was greater than 1 hour longer than the 2.2 ± 0.8 hours (range, 1.0–4.3 hours) for the mean nonperfused volume ratio of 84.3% ± 15.7% (range, 33.8%–100%) in our study. This difference was primarily because the long duration of sonication (20–30 seconds) required a long cooling duration (60–90 seconds) for the treated tissue to return to the baseline temperature.24,25 Although the MRI-guided high-intensity focused US system with shot sonication used the point-by-point treatment strategy, the sonication time and

Figure 7. Sagittal contrast-enhanced T1-weighted imaging before treatment showed an inhomogeneous contrast-enhanced uterine fibroid in a 43-year-old woman (A), almost complete ablation (98% nonperfused volume) of the treated fibroid but a small portion of residual tissue immediately after MRI-guided high-intensity focused US (B), and substantial shrinkage of nonperfused area and regrowth of the residual tissue at the 6-month follow-up (C).
cooking time were 1/10 to 1/15 and 1/20 to 1/30 of those in the previous reports, respectively. The mean treatment speeds of 42.2 ± 25.6 cm³/h in the complete ablation group and 45.3 ± 32.5 cm³/h in the partial ablation group reached or exceeded the upper limit of 19.8 to 42.4 cm³/h reported in the previous studies.²⁶⁻²⁸

A previous study showed that uterine fibroid treatment by US-guided high-intensity focused US had 10.2% complications, including nerve injury, hematoma, skin burns, severe abdominal pain, and vertebral burns.²⁹ In this study, none of 43 patients had a severe adverse event or major complications, except minor adverse events. One patient with a completely ablated fibroid had mild lower back pain for 2 days and occasionally felt mild back pain subsequently. It was possible that the sacral vertebral injury was due to fibroid treatment adjacent to the sacrum. The other patient with a partially ablated fibroid had a second-degree skin burn (blister) that recovered within 1 week. The incidence (2 of 43 [4.7%]) of complications in MRI-guided high-intensity focused US with shot sonication was relatively low in comparison with previously reported rates.²⁹

This work was an initial study at a single medical center to evaluate the midterm outcome of symptomatic uterine fibroids treated with MRI-guided high-intensity focused US with shot sonication. Further investigation, particularly long-term follow-up, is required to assess treatment efficacy. In conclusion, MRI-guided high-intensity focused US with shot sonication is feasible, safe, and effective for treatment of uterine fibroids, and complete ablation of entire tumor volumes could be achieved in T2-hypointense fibroids.

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