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Sang-Wook Yoon
Chan Lee
Sun Hee Cha
Jeong-Sik Yu
Young-Jeong Na
Kyoung Ah Kim
Sang-Geun Jung
Seung-Jo Kim

Patient selection guidelines in MR-guided focused ultrasound surgery of uterine fibroids: a pictorial guide to relevant findings in screening pelvic MRI

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S.-W. Yoon (✉) · K. A. Kim
Department of Diagnostic Radiology,
College of Medicine,
Pochon CHA University
Bundang CHA General Hospital,
351, Yatap-dong, Bundang-gu,
Sungnam-si,
Gyunggi-do, Republic of Korea,
463–712
e-mail: jansons@cha.ac.kr
Tel.: +82-31-7805998
Fax: +82-31-7805381

C. Lee · Y.-J. Na · S.-G. Jung ·
S.-J. Kim
Comprehensive Gynecologic Cancer
Center, College of Medicine,
Pochon CHA University
Bundang CHA General Hospital,
351, Yatap-dong, Bundang-gu,
Sungnam-si,
Gyunggi-do, Republic of Korea,
463–712

S. H. Cha
Department of Obstetrics &
Gynecology, College of Medicine,
Pochon CHA University Bundang
CHA General Hospital,
351, Yatap-dong,
Bundang-gu, Sungnam-si,
Gyunggi-do, Republic of Korea,
463–712

J.-S. Yu
Department of Diagnostic Radiology,
Yonsei University College of Medicine,
YongDong Severance Hospital,
Seoul, Republic of Korea

Abstract Uterine leiomyomas (fibroids), the most common benign tumor in women of childbearing age, can cause symptoms including dysmenorrhea, menorrhagia, urinary symptoms, pain and infertility. Hysterectomy is a common approach to treating uterine fibroids, and less invasive surgical approaches such as myomectomy and uterine artery embolization also have been shown to alleviate symptoms. Magnetic resonance-guided focused ultrasound surgery (MRgFUS) is the only totally non-invasive surgical approved method for treating uterine fibroids. In clinical trials, MRgFUS resulted in significant relief of uterine fibroid symptoms. The safe and effective use of MRgFUS is affected by fibroid type and location, position relative to adjacent anatomical structures and the presence of co-existent pelvic disease. Additionally, successful outcomes with MRgFUS have been correlated with the volume of fibroids ablated during the procedure. Thus, selection of patients in whom sufficient fibroid volumes can be treated safely using the MRgFUS system is critical for successful outcomes. The MR images in this pictorial essay provide examples of uterine fibroids for which MRgFUS should be considered and is designed to facilitate the selection of patients for whom MRgFUS is most likely to provide sustained symptom relief.

Keywords Uterine fibroids · Focused ultrasound surgery · MRgFUS · Patient selection

Introduction

Uterine leiomyomas (fibroids) are the most common benign neoplasm in women of childbearing age. Fibroids have been identified clinically in at least 25% of women [1], and pathological analysis suggests that the prevalence of fibroids may be as high as 77% [2]. Although most fibroids are asymptomatic, approximately 25% are associated with symptoms that can have a significant impact on patient quality of life, including pelvic pain or fullness, dyspareunia, prolonged or excessive menstrual bleeding, increased urinary frequency and infertility [3].

Until recently, hysterectomy has been the primary treatment for symptomatic uterine fibroids, accounting for approximately 30% of hysterectomies [4]. The benefit of hysterectomy is that removal of the uterus eliminates resident fibroids and eliminates the potential for recurrence [5]. However, the procedure is invasive, requires general anesthesia and typically involves several weeks of postoperative recovery time during which patients may be limited from engaging in daily activities, including work.

Magnetic resonance-guided focused ultrasound (MRgFUS) is a totally non-invasive surgical approach for the treatment of symptomatic uterine fibroids. It utilizes precisely focused ultrasound waves to generate and maintain temperatures in excess of 56°C within the target tissue, resulting in protein denaturation, cell death and coagulative necrosis [3]. MRgFUS integrates the powerful ablative capabilities of focused ultrasound with magnetic resonance visualization to plan and guide treatment and to monitor treatment outcome in real time. This allows precise thermal ablation of the treated fibroid while preserving tissues that lay outside of the beam path.

While clinical studies demonstrate that MRgFUS is a safe and effective treatment for symptomatic uterine fibroids [6–8], not all patients are candidates for the procedure. Potential candidates are screened with pelvic MRI to determine if they meet patient selection guidelines. Factors to consider when selecting patients for MRgFUS include characteristics of the fibroids, location of the fibroid within the pelvis, obstacles to the energy beam pathway, position of the fibroid relative to nearby anatomical structures and the presence of other disease.

In a recent analysis of MRgFUS treatments for uterine fibroids, symptom improvement correlated with a decrease in the rate of subsequent alternative treatments and with more complete ablation of fibroids as measured by the non-perfused volume (NPV) [7]. The results demonstrate that successful and durable treatment of uterine fibroids with MRgFUS necessitates selecting those patients for whom higher non-perfused volumes can be attained using the MRgFUS system.

The purpose of this pictorial essay is to provide a visual guide describing the patient selection criteria for MRgFUS treatment in our hospital, which, according to our experience, enables optimal treatment results. This essay provides examples of uterine fibroids that should be considered for treatment with MRgFUS and depicts other diseases or fibroids for which, in our experience, MRgFUS is not optimal.

Methods

Images contained in this report were obtained from patients diagnosed as having uterine fibroids. These patients were sent for pelvic MRI screening in order to determine if they were candidates for MRgFUS. All patients undergoing screening were at least 18 years of age, with no massive abdominal scarring in the treatment area, no contraindications to MRI, and no serious health complications [9].

The purpose of the MRI screening procedure prior to selecting MRgFUS as a treatment modality is to check the accessibility, viability and texture of the fibroids. The images are used to check the size and number of fibroids, and to reveal existence of other uterine disorders. Suitable patients were then treated using the ExAblate 2000 system (InSightec, Tirat Hacarmel, Israel).

In the screening procedure, patients were positioned prone, feet first, on the MR table inside the MRI (Signa HDx, GE Healthcare, Milwaukee, WI), using a phased array torso coil. To simulate the position in which patients undergo MRgFUS and to flatten the abdomen, MRI screening was conducted with patients lying on a 4-cm-thick screening pad. Once positioned, the patient's pelvis was imaged using several sequences. To identify anatomical structures within the pelvis, T2-weighted turbo spin echo images in axial, sagittal and coronal orientations were acquired. TR was 4,830 ms, TE 120 ms, matrix size 256× 144, slice thickness 5 mm, spacing 1 mm and FOV 30 cm. To evaluate the presence of hemorrhagic or fatty tissues, T1-weighted fast spin echo images were acquired in the axial orientation (with TR of 460 ms, TE 11 ms, matrix size 256×144, slice thickness 5 mm, spacing 1 mm and FOV 30 cm). A gadolinium-based contrast agent (Optimark, Covidien imaging solutions) was injected in order to evaluate the hemodynamic characteristics of the fibroids and to assess their potential viability. T1 fat saturation contrast-enhanced image was acquired in axial orientation: TR of 594 ms, TE 11 ms, matrix size 256×144, slice thickness 5 mm, spacing 1 mm and FOV 30 cm.

Although not essential for suitability evaluation, we performed in our hospital additional dynamic contrast-enhanced imaging as part of additional data evaluation. T1-weighted 3D gradient echo fat saturation dynamic contrast-enhanced images were acquired in sagittal orientation, to evaluate the fibroid vascularity (with TR of 4.81 ms, TE 2.3 ms, matrix size 256×115, slice thickness 3 mm, spacing 0.6 mm and FOV 30 cm).

Observations

Factors to consider when selecting uterine fibroids for treatment with MRgFUS

Relevance to symptoms

The first criterion for selecting MRgFUS as a treatment is the existence of uterine fibroid(s) and the relevance of that fibroid(s) to the patient's symptoms. The location and size of the fibroids have clinical significance [10], for example, submucosal fibroids that project into the endometrial canal are a common cause of uterine bleeding, while subserosal leiomyomas that are beneath the serosa may compress adjacent organs and cause specific symptoms in the bladder and intestines [10]. If a patient's symptoms do not correlate with the size and location of the leiomyomas, MRgFUS may not be the appropriate treatment.

Figure 1 shows MR images of a patient with a single submucosal fibroid (1a) and a patient with a single intramural fibroid (1b); both have no other pathologies. In the clinical examination, patient 1a described her symptoms of dysmenorrhea and menorrhagia; these probably related to her submucosal fibroid. Patient 1b suffers from frequent urination, which probably relates to her large intramural fibroid. Both cases are appropriate for treatment with MRgFUS.

In case the patient is asymptomatic, we sometimes consider treating this patient as a preventative treatment, keeping in mind the risks and benefits of the treatment. For example, the minimum length of a single sonication (a focal ablation) is about 2.5 cm in the A-P direction. Therefore, in case the fibroid is subserosal and smaller than 3 cm, there is a high risk of undesired heating outside the uterus due to the fibroid's small dimensions. If the patient is not symptomatic, she should not be treated and should remain under close observation with conservative management.

Fibroid type

Application of MRgFUS to the treatment of submucosal, intramural and subserosal fibroids leads to thermal damage within the fibroid tissue, resulting in ablation of the tumor [11]. These treated fibroids remain inside the uterus and are absorbed by the body in the postoperative period, translated to volume reduction [12]. This eliminates or decreases the size of the treated fibroid, which is associated with a decrease in symptoms. Figure 2 shows a pedunculated subserosal fibroid that caused the patient to experience pressure-related symptoms. The fibroid is connected to the uterus with a small and narrow stalk, and there is a theoretical risk that ablation could break the stalk between the fibroid and the uterus, potentially resulting in the release of the fibroid into the abdominal cavity. While no such cases have been reported, in cases of extremely narrow stalks, we suggest considering benefits and risks before making a decision.

Fibroid size

The ExAblate system can create different sizes of focal ablation (sonication), varying in size, energy and transmission regimen. Increasing the energy to create multi foci parallel to the beam direction results in an elongated spot, while multi foci perpendicular to the beam result in a thick spot. In this way, the operator can optimize the treatment plan for a specific fibroid size.

As multiple sonications are needed to destroy the entire fibroid, the total treatment volume is limited by treatment time. From our experience, treating and ablating an 8-cm fibroid takes approximately 3 h of sonications, depending on energy absorption and location of the fibroid. Fibroids that are larger than 10 cm are less suitable for the treatment, as they may require a long treatment time. If the physician decides to treat such a fibroid, we suggest two optional solutions: (1) perform two sessions of treatment, taking into account that each session targets a different portion of the fibroid. This will require planning ahead of both treatments, and preferably the fibroid should be split into a superior and an inferior region for each of the treatments. In this way, we avoid that the ultrasound beam in the second treatment passes through already treated regions, which

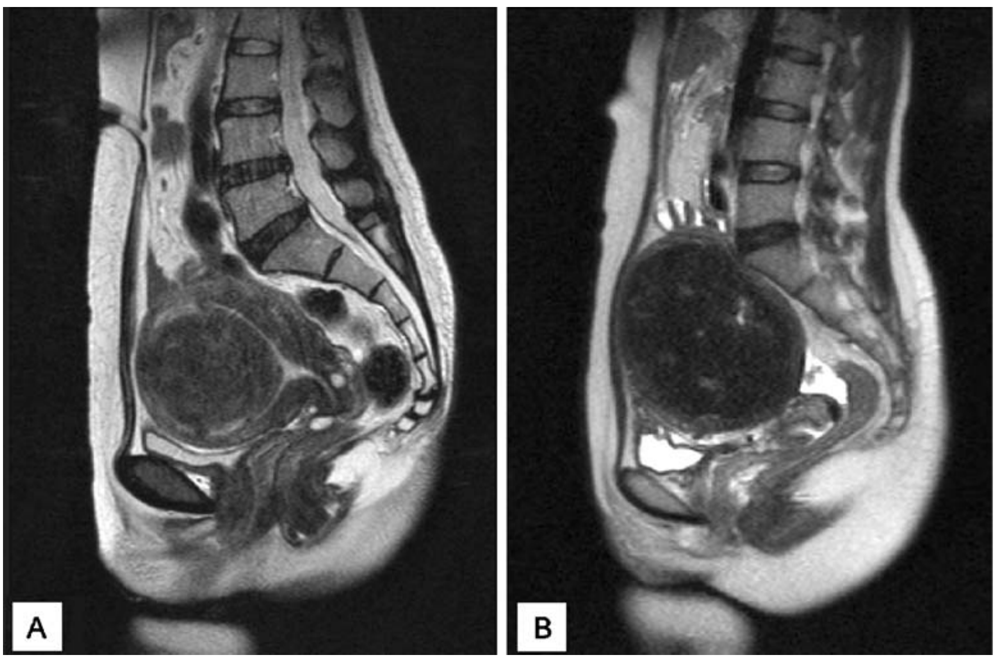


Fig. 1 Sagittal T2-weighted images of two patients suitable for the treatment. Patient 1A has a 7-cm submucosal uterine fibroid that relates to her dysmenorrhea and menorrhagia. Patient 1B has a transmural uterine fibroid that relates to her frequent urination symptoms

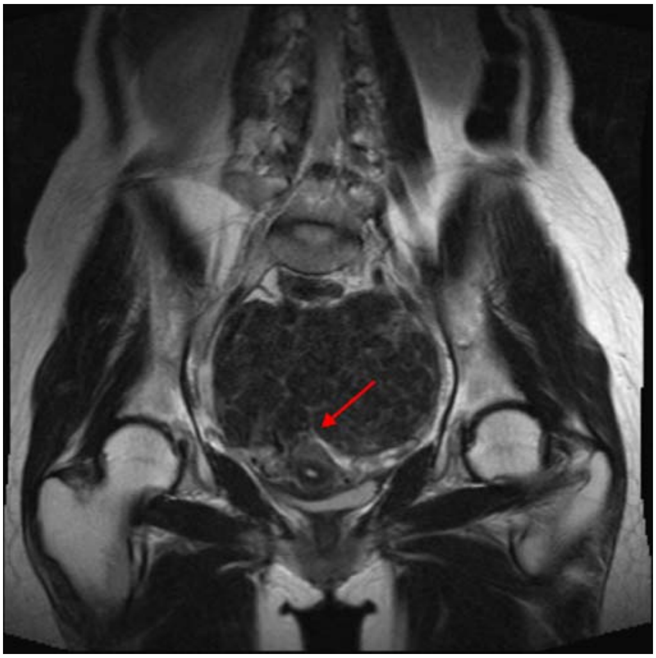


Fig. 2 Coronal T2-weighted image of a pedunculated subserosal uterine fibroid. Connection area to the uterus is marked with an arrow

might absorb the energy due to its dry tissue. (2) Consider pre-treatment with GnRH agonist prior to MRgFUS. Previous studies have shown that pre-treatment of fibroids with a GnRH agonist leads to fibroid shrinkage and improved treatment outcomes following MRgFUS [9, 10]. Figure 3a shows an initial screening MRI of a 14.2×9.9-cm fibroid. Following injections of GnRH agonist in three consecutive months, the dimensions of this fibroid were reduced to 10.8×9.1 cm (Fig. 3b). MRgFUS was performed subsequently.

Distance from the skin

During the treatment, the patient is lying prone over a water bath in which the transducer is immersed. The patient's abdomen is acoustically coupled to the water bath using a special gel pad. The ExAblate system allows a focal treatment area to be generated up to 12 cm vertical distance from the skin location. Figure 4a is a sagittal image of a patient with multiple fibroids, one of which was too posterior and outside the treatment boundary. Fibroids with more than 50% of their volume outside the treatment boundaries may be excluded or may require mitigation techniques to reduce the distance between the fibroid and the transducer. Such techniques include using a thinner acoustic coupling gel pad, which reduces the distance between the patient and the transducer, or filling the rectum with water in order to push the uterus and the fibroids anterior, closer to the transducer.

Fibroid number

As the number of fibroids increases, it becomes increasingly likely that at least one or more fibroids will not be accessible or appropriate for treatment with MRgFUS. Patients with more than six symptomatic uterine fibroids may not be good candidates for MRgFUS, although they should be considered based on the accessibility of the

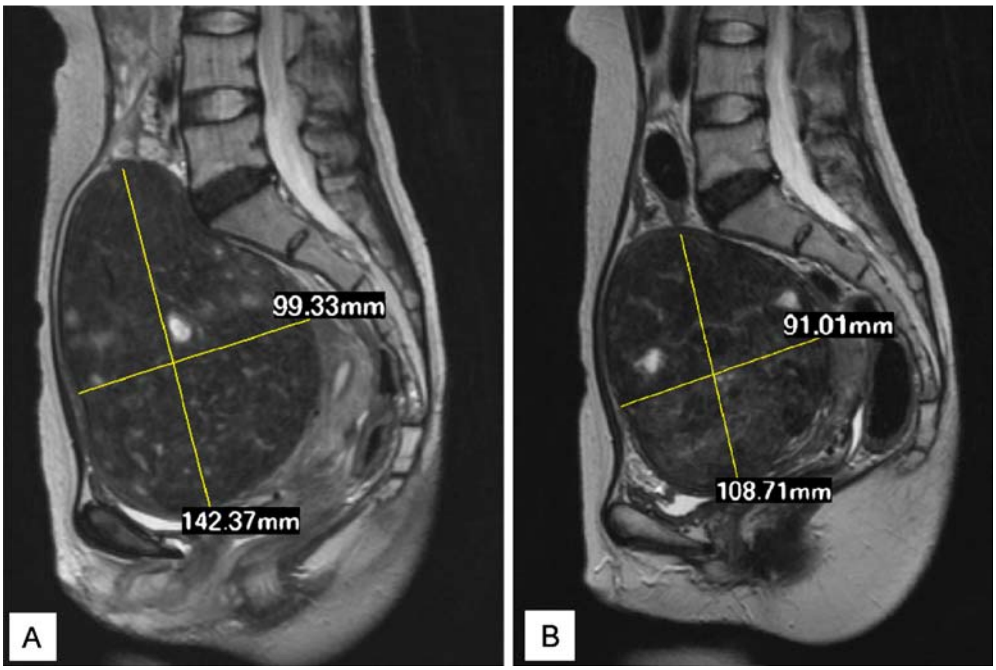
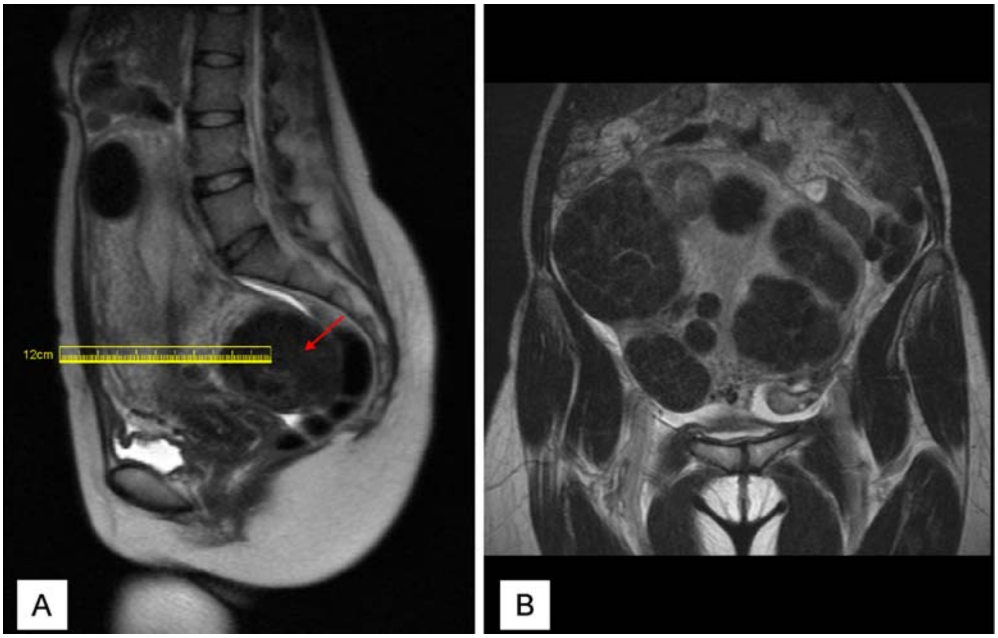


Fig. 3 Sagittal T2-weighted images of a patient with a very large fibroid that was administered gonadotropin-releasing hormone (GnRH) prior to the MRgFUS treatment. **a** Before the GnRH, showing a 14.2×9.9-cm transmural fibroid, which is too large for the treatment. Following three consecutive shots of GnRH (1 each month), the fibroid size shrank to 10.8×9.1 cm (**b**) and was now treatable

Fig. 4 T2w images of a patient with multiple fibroids; specifically one of the fibroids is very posterior and more than 12 cm from the skin line (marked with an arrow in **a**) and is outside the range of the ultrasound transducer

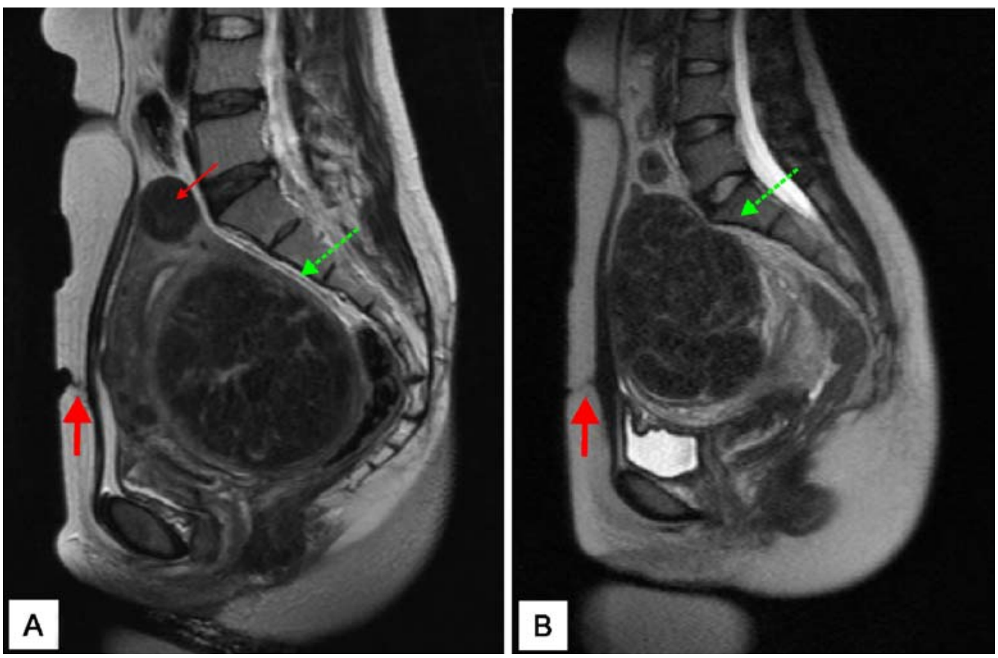


fibroids and their presumed role in the patient's symptoms. Figure 4b was acquired from a patient presenting with approximately 20 fibroids, some of which are not treatable due to close proximity to the sacrum or because of a posterior position that is outside the transducer range.

Distance from sacral bone surface

Bone absorbs ultrasound waves more readily than soft tissue, and low energies are sufficient to heat a bone surface to high temperatures. Nerves that are adjacent to a heated bone surface may be exposed to temperatures that can cause pain and, in extreme cases, may damage the nerve [15]. Fibroids that are close to the lumbosacral plexus or to another bone surface should be considered carefully before the patient is deemed suitable for MRgFUS. At smaller distances, sacral bone heating may stimulate the adjacent sacral nerves, potentially causing treatment-limiting pain that may result in incomplete treatment that is likely to reduce the efficacy of the procedure. However, mitigation techniques such as tilting the beam path to avoid bone

Fig. 5 Sagittal T2-weighted images of two patients with abdominal transverse scars (marked with thick arrow) and fibroids adjacent to the spine. Patient 5A has a scar in the center of the potential beam path, which will be very difficult to avoid. In addition she has a small superior subserosal fibroid, probably asymptomatic (marked with a thin arrow), that cannot be treated due to its proximity to the bone in the far field. A large portion of the large intramural fibroid is also adjacent to the spine and may cause heat on the bone during the treatment. Patient 5B has a scar in the lower part of the potential of the beam path, which can be avoided by angling the beam. In addition, only a small portion of her fibroid is adjacent to the spine



heating in the far field or rectal filling to push the fibroid away from the bone may be considered.

Figure 5a shows a patient that is suitable for MRgFUS. This patient has a small superior subserosal fibroid that is not treatable due to its proximity to the bone and is probably not related to the patient's symptoms. While the large symptomatic intramural fibroid also is close to bone surface, angling the beam towards the patient's coccyx should avoid bone heating; rectal fill also may be considered to draw the fibroid away from the bone. In addition, it is also possible to target initial treatment to the anterior portion of the fibroid, which is not close to the bone, conducting subsequent treatment several months later, after fibroid shrinkage has increased the distance between the tumor and the bone. Figure 5b shows a patient with a fibroid; part of it is adjacent to vertebra L5-S1, which can be avoided by angling the beam, and the rest of the fibroid can be treated regularly.

Obstacles to the ultrasound beam path

Ultrasound energy is absorbed by high-density tissues, such as bone, and reflected by areas of low density, such as air. The energy pass zone should be clear of air-containing tissues or bone between the transducer and the fibroid. Such tissues include a mass of intestines. In some cases, angulation of the beam path may avoid passing through the intestine. In other cases, bowel mitigation techniques should be implemented. These techniques may require rectal fill to push the uterus anterior, thus moving the bowel to the periphery, or bladder fill with saline to enable sonication through the filled bladder to the targeted fibroid. Figure 6a shows a patient with a retroverted uterus and a large amount of bowel interposed between the uterus and the abdominal wall, a situation that is not amenable to MRgFUS. Figure 6b and c show a rectal and bladder fill, respectively, which was done during patient positioning in order to remove the bowel from the beam path.

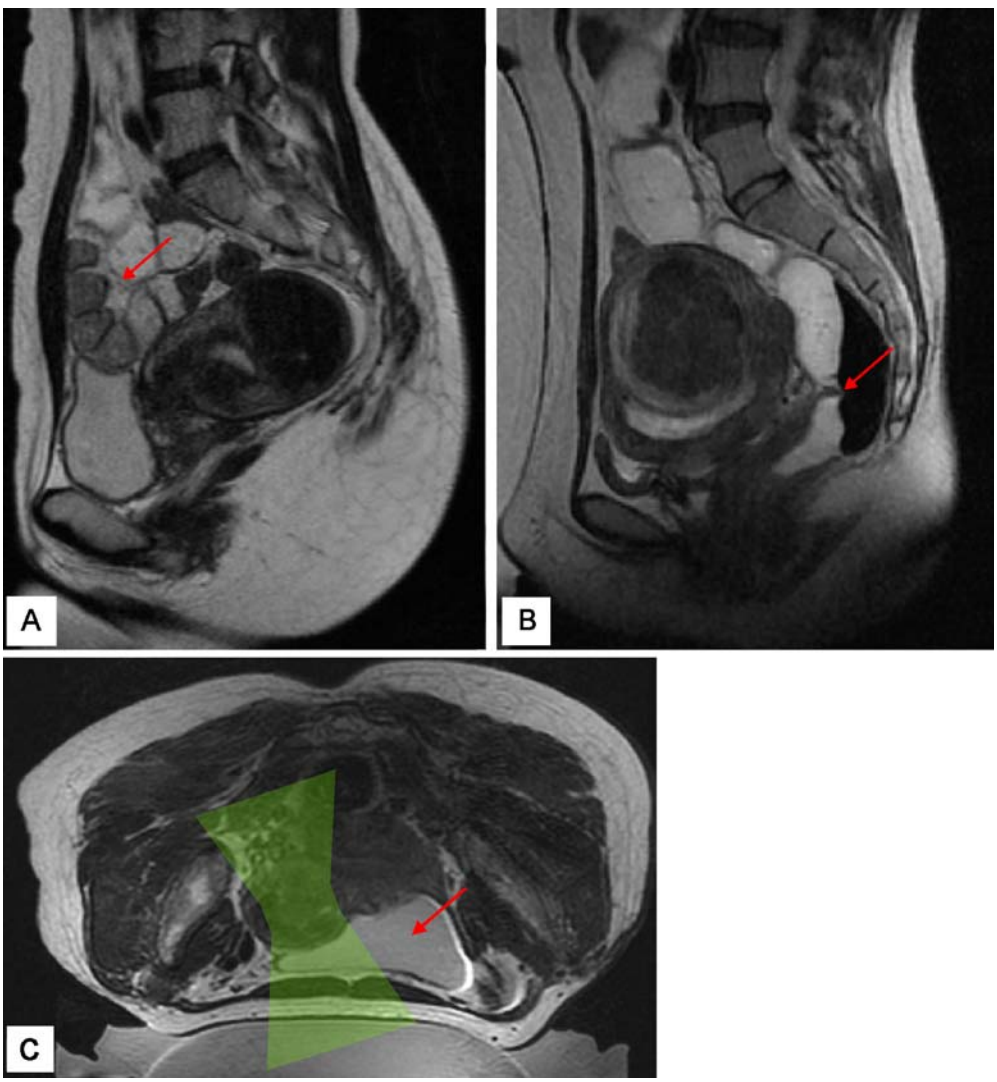


Fig. 6 T2-weighted images of a patient with bowel in the beam path. **a** Shows a retroverted uterus and a large amount of bowel (marked with an arrow) interposed between the uterus and the abdominal wall. In **b** the patient had rectal fill (marked with an arrow) in order to push the uterus anterior, thus pushing bowels away from the beam path. In **c** the patient had bladder fill (marked with an arrow) in order to directly push bowels away from the beam path. The ultrasound beam path is not passing through bowels (highlighted on the image in green)

Attention should also be paid to extensive abdominal scarring. Abdominal scars have enhanced energy absorption relative to surrounding tissue, which may lead to heating at the site of the scar [15]. Figure 5a shows an example of a transverse scar on the center of the potential beam path. This needs to be considered while treating, and special attention should be given to potential heating in the scar area. Figure 5b shows an example of a transverse scar on the lower part of the abdomen. This scar can be avoided using small bladder fill and/or beam angulation, techniques that would make this patient suitable for MRgFUS.

Fibroid vascularity

Hypervascular fibroids are difficult to treat because the blood vessels effectively carry heat away from the treatment area, resulting in subtherapeutic temperatures within the target tissue. High signal intensity within a fibroid relative to the uterine wall on T2W imaging may indicate a hypervascular fibroid [16, 17]. Such fibroids can be further evaluated with contrast-enhanced imaging to determine if the high signal intensity is due to increased vascularity or other causes. Figure 7 depicts a fibroid that is hyper-intense in T2-weighted image (7a) and has evidence of increased vascularity after injection of contrast (7b). This fibroid was not treated. Publications show that injection of GnRH agonist for 3 consecutive months may result in diminished vascularization of the fibroids [10, 18].

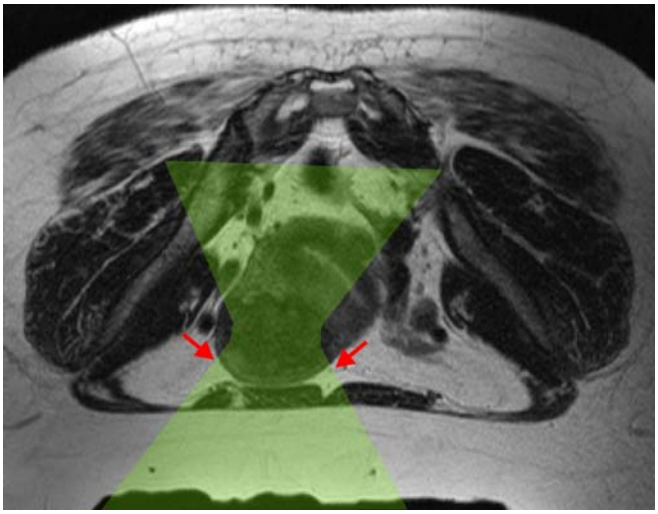
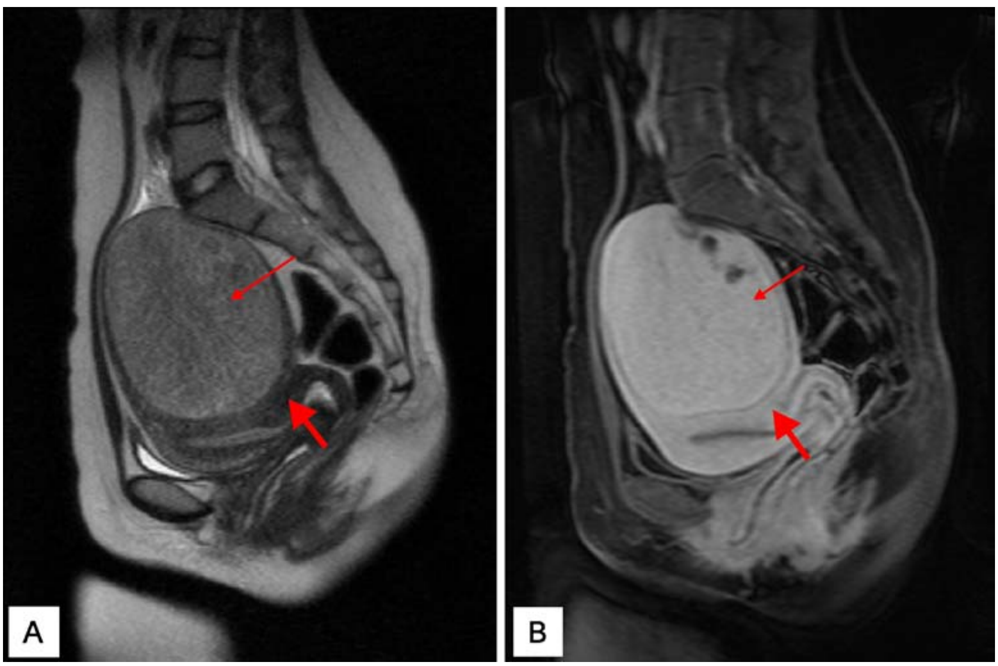


Fig. 8 T2-weighted image of a patient with a large subcutaneous fat and a non-homogenous fat layer. The ultrasound beam shown on the image as highlighted green may pass through different thicknesses of fat and muscle (marked with arrows) and therefore has different attenuations resulting in aberration of the beam and reducing the focus of the spot

Beam aberration

An irregularly shaped layer of the rectus muscle and extremely large subcutaneous fat layer may distort the focused ultrasound beam. Such an example is shown in Fig. 8. The large subcutaneous fat layer, combined with the

Fig. 7 A patient with vascular fibroid. **a** Shows a T2-weighted image of a fibroid that shows high signal intensity compared with the uterus. **b** Shows the T1-weighted image showing hyper vascularity following injection of a contrast agent



rounded shape of the abdominal muscle in the beam path, creates a secondary lens in the path of the beam. This may lead to potential aberrations of the ultrasound beam and distortion of the focal point. Consequently, it may be difficult to achieve sufficient temperatures within the targeted fibroid in such patients.

Adenomyosis

Adenomyosis is the presence of endometrial tissue within the myometrium. Symptoms of adenomyosis are bleeding, pressure and pain, and are very similar to fibroid symptoms [19]. We encountered several patients that were initially diagnosed with fibroids and subsequently found to have adenomyosis after MR imaging. There is still no evidence to demonstrate that treatment of adenomyosis results in long-term clinical benefit, although positive results have been reported anecdotally [20].

Figure 9 shows two patients with adenomyosis. Patient 9a has adenomyoma that occurred focally. Technically, this may be considered a uterine fibroid, and the patient may be considered for treatment with MRgFUS. Patient 9b shows a diffuse adenomyosis, which is technically difficult to treat due to an inability to define a target treatment area within the mass.

Malignancy

Although leiomyosarcomas are very rare [21], atypical signal intensity on T2W imaging may be indicative of malignant degeneration of the fibroid or of another mass mimicking a fibroid. Figure 10 shows cases of three patients that were diagnosed with uterine fibroids by their gynecologists; however, the MR screening imaging revealed other pathology. Figure 10a,b shows T2-weighted and contrast-enhanced T1-weighted images of a 33-year-old patient, and the fibroid intensity and necrotic area findings are suspicious for the existence of leiomyosarcoma. Patients with such findings should undergo additional evaluation to characterize the mass and plan appropriate treatment. Figure 10c describes a previously undetected 1.5-cm polypoid mass with relatively high signal intensity in the endometrial cavity. This was diagnosed as endometrial cancer, and the patient underwent surgery [22]. Figure 10d shows a patient that was also identified with a large teratoma in the right ovary. Following our clinical evaluation, we decided that the patient needed surgery for her teratoma. Therefore, her fibroid could be treated during this pelvic surgery.

Contrast enhancement

Contrast-enhanced imaging studies can discriminate between fibroids with intact vasculature and those that are devascularized or necrotic. An absence of enhancement in contrast imaging studies indicates that the fibroid already is non-perfused, which is the purpose of the ExAblate treatment. In the case of a patient with a fibroid that already has become necrotic, there is a low chance of additional benefit from the MRgFUS treatment.

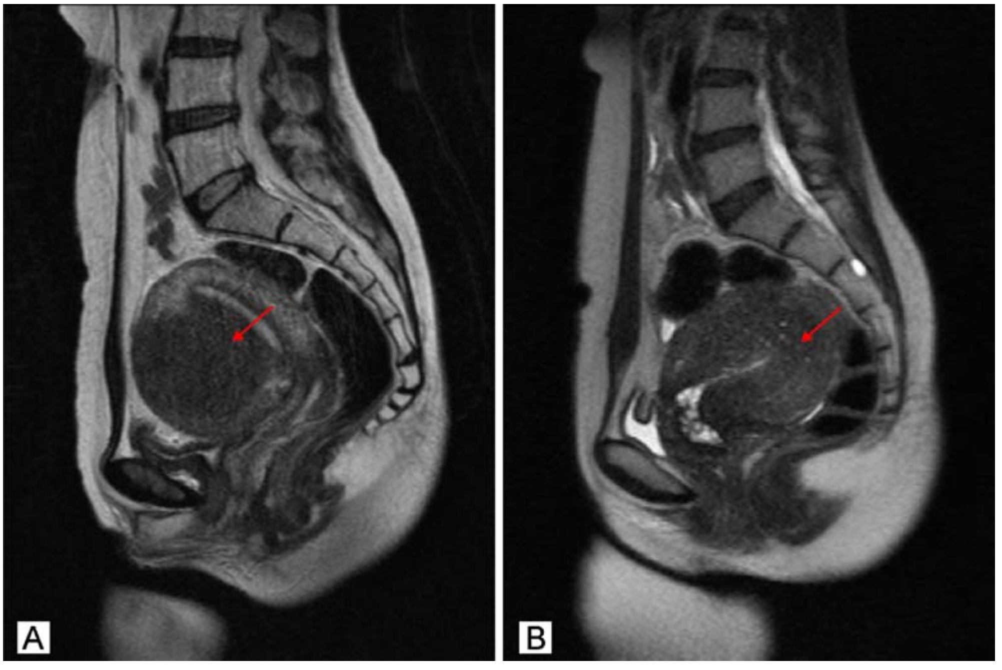


Fig. 9 T2-weighted sagittal images of a patient with adenomyosis (marked with an arrow). Patient 9A has focal adenomyosis on the anterior wall of the uterus, and patient 9B has diffuse adenomyosis within the uterus

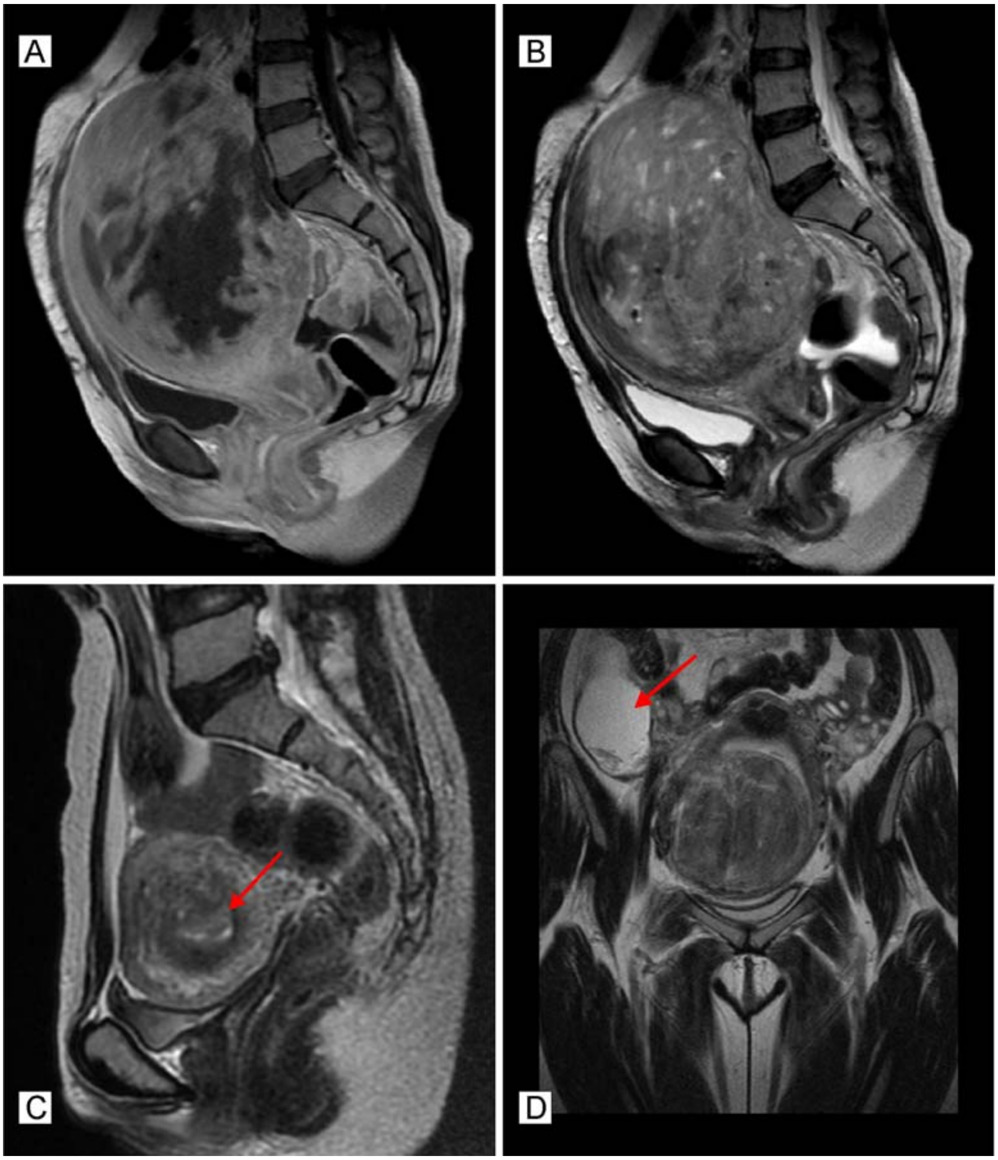


Fig. 10 Additional pathologies found during uterine fibroid MRI screening. **a** and **b** show contrast-enhanced T1-weighted and T2-weighted images of a fibroid mimicking tumor with atypical signal intensity and degeneration, suspected of being leiomyosarcoma. **c** shows a 1.5-cm sized polypoid mass with relatively high signal intensity in the endometrial cavity (marked with an arrow), suspected of being endometrial cancer. **d** shows a uterine fibroid and right ovarian teratoma (marked with an arrow)

Discussion

Appropriate patient selection is a very important factor in the successful application of MRgFUS for the treatment of uterine fibroids. The use of screening pelvic MRI, in conjunction with the patient's age, symptoms, and future childbearing plans, is essential for effective evaluation of patients who are candidates for the procedure. Knowledge of the various factors that impact the safety and efficacy of MRgFUS should allow physicians to guide patients with uterine fibroids toward the treatment strategy most likely to provide them with an optimal outcome. Pre-planning of the treatment is also critical for successful outcomes. MR screening images can help the physician identify how best to position the patient at the time of treatment and allow for consideration of mitigation techniques that may improve suitability and outcomes.

Additionally, it is also important to advise the patient about the advantages and disadvantages of MRgFUS treatment for her individual fibroid symptoms and to make her a partner in her own treatment. In cases of large or multiple fibroids, the patient can be advised that several sessions may be needed to achieve optimal symptom relief. Where appropriate, patients also should be informed of potential technical limitations related to scar tissue or bowel obstruction of the beam path, as well as mitigation techniques that may be used to overcome these limitations.

In cases where the results of screening MRI indicate that a patient is not suitable for MRgFUS, the data acquired from the MR images are likely to provide important information about the overall anatomy of the uterus and fibroids, and to distinguish among fibroids, adenomyosis or other abnormalities. This information should help in the selection of treatment options most likely to yield optimum results.

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