

Magnetic Resonance Imaging—Guided Focused Ultrasound Ablation of Lumbar Facet Joints of a Patient With a Magnetic Resonance Image Non-Conditional Pacemaker at 1.5T

Jacinta E. Browne, PhD; Christin A. Tiegs-Heiden, MD; Vance T. Lehman, MD; Zaiyang Long, PhD; Nicholas J. Hangiandreou, PhD; Robert E. Watson, MD, PhD; Gina K. Hesley, MD; and Krzysztof R. Gorny, PhD

Abstract

Objective: To provide an initial report that patients with magnetic resonance imaging (MRI) non-conditional cardiac implanted electronic device (CIED) can undergo state-of-the-art magnetic resonance imaging—guided focused (MRgFUS) ablation procedures with careful planning and integration of the procedure into an established CIED MRI practice.

Patient and Methods: We describe an MRgFUS ablation treatment of lumbar facet joints in a patient with an MRI non-conditional CIED (pacemaker), completed in accordance with our institutional CIED/MRI practice guidelines.

Results: A risk-benefit analysis by a coordinated multidisciplinary team before this treatment was performed to account for the risks associated with the MRI non-conditional pacemaker in the context of the MRgFUS procedure.

Conclusion: The patient had no adverse cardiac event during or following this procedure.

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From the Department of Radiology, Mayo Clinic, Rochester, MN 55905.

Magnetic resonance imaging-guided focused ultrasound (MRgFUS) is a minimally invasive thermal treatment modality that uses a phased-array ultrasound transducer embedded inside the MRgFUS patient table integrated with the magnetic resonance imaging (MRI) scanner. During MRgFUS treatment, ultrasound (US) energy is selectively focused within target tissues causing localized thermal ablation. MRI is used for treatment planning, guidance of the US beam, real-time magnetic resonance (MR)—thermometry, and for treatment assessment.¹ MRgFUS systems have been successfully used to treat a variety of conditions, such as symptomatic uterine fibroids,¹⁻⁴ essential tremor,^{5,6} prostate cancer,⁷ and facet joint pain.⁸ Facet joint treatments in our practice use the Exablate 2100 MRgFUS system (Insightec, Haifa, Israel) integrated with a

60-cm bore 1.5-T MR scanner (Signa Excite, General Electric, Waukesha, WI). The use of MRI can pose significant safety challenges for patients with cardiac implanted electronic devices (CIEDs), potentially excluding them from treatment. Presently, there has only been one other case report of MRgFUS treatment of essential tremor in a patient with implanted MRI-conditional pacemaker.⁶ This study describes an MRgFUS ablation of lumbar facet joints in a patient with implanted MRI non-conditional pacemaker.

CLINICAL PRESENTATION

The patient was an 80-y-old male with chronic axial low back pain. Previous lumbar facet joint steroid injections provided only short-term benefit. Comparative medial branch blocks of the bilateral L4-5 and L5-S1 facet

joints were performed and provided 80% to 90% temporary relief of the patient's typical pain. Subsequent radiofrequency ablation of these medial branches did not provide substantial relief, however. Therefore, MRgFUS ablation treatment of the bilateral L3-4, L4-5, and L5-S1 facet joint capsules was performed as has been described previously.⁸

The patient's medical history was significant for coronary artery disease, hypertension, and symptomatic sinus bradycardia (50 beats/min and 2:1 block), which led to placement of a dual chamber transvenous pacemaker system in 2015 (Assurity DR 2240 pulse generator, Model 1642T right atrial lead, Model 1646T right ventricular lead, all MRI non-conditional, Abbott, IL) in the right chest. The patient was not pacemaker-dependent.

Before MRgFUS treatment, a risk-benefit analysis was performed given the MRI non-conditional CIED system, and the decision was made to proceed with treatment. The risk-benefit analysis was performed in accordance with our established CIED/MRI practice procedure, which has been used to safely scan more than 3000 patients for diagnostic indications.⁹ This practice involves a coordinated team of radiologists, cardiologists, MRI physicists, cardiology pacing nurses, and MRI technologists. The risks associated with the treatment procedure were explained to the patient before commencement of treatment.

Per practice guidelines, before entry into the MR scanner room, the cardiology pacing nurse programmed the pacemaker to DOO (dual chamber, absence of sensing with no response to sensed input) mode of 80 beats/min. Subsequently, patients with MRI non-conditional pacemakers are positioned on an undocked MR table outside MR scanner room (zone III) and then transferred into the scanner room (zone IV) where the table is docked to the scanner.⁹ This is done to minimize risks of motion-induced eddy currents as well as magnetic forces or torque (usually minor) on the CIED as the patient approaches the steeply increasing magnetic field in proximity to the bore opening. Additionally, all MRI scans are performed in the normal mode with pulse sequence parameters adjusted so that the whole-body specific absorption rate (SAR) does not exceed 1.5 W/kg for the entirety of the exam.⁹ For these reasons, SARs associated with every sequence planned

to be used during the treatment was evaluated (using MRI scanner SAR algorithm) before the procedure corresponding to patient's weight of 77 kg.

In this case, however, the patient could not be transported into the scanner room on the MR table for two reasons. First, the MRgFUS table had to remain docked to the MRI scanner and connected to the in-wall umbilical cables (connecting to Exablate electronics in the equipment room) following the pre-ablation quality assurance (QA) phantom testing; disconnecting the table would require shutting down the Exablate system and repeating the start-up procedure (setup shown in Figure). Second, as part of the required calibration procedure for the MRgFUS system, a pair of pre-programmed sagittal and axial calibration scans (see Table for details) are automatically executed by the Exablate workstation on the MRI scanner at the start of every treatment. The whole-body SAR associated with these sequences for our patients' input weight was 1.73W/kg, which exceeded our practice safety limit of 1.5 W/kg. Therefore, calibration scans could not be performed with the patient and were performed using the dedicated QA phantom instead. Following calibration scans, the MRgFUS table was retracted into the home

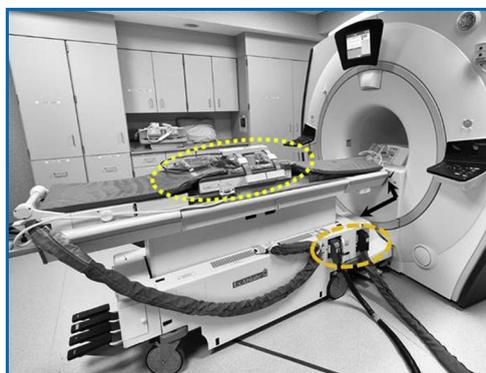


FIGURE. Photograph of the magnetic resonance imaging-guided focused ultrasound (MRgFUS) system with the pre-treatment quality assurance (QA) setup. MRgFUS table docked into the magnetic resonance imaging (MRI) scanner (black arrows) and connected to Exablate control electronics via “umbilical” cables (dashed orange oval). The pelvic coil with the pre-treatment QA phantom inside is indicated with the yellow dotted oval.

TABLE. Details of MR Sequences and Image Acquisition That Were Used During the MRgFUS Ablation Procedure and the Corresponding Whole-Body SAR Values for Each Image Sequence^a

Sequence	Purpose	Whole-body SAR (W/kg)
Single-shot fast spin echo pulse sequence (TE/TR, 126/2108 ms; ETL, 1; FA, 90°; NEX, 1; slice, 6 mm; skip, 1.5 mm; FOV, 440 mm; BW, 31 KHz; matrix, 256 × 224 mm ²)	Calibration —transducer localization in MRI coordinates performed using QA phantom as SAR exceeded pre-determined threshold of 1.5 W/kg	1.73
3D-localization T2 (TE/TR, 1.42/4.98 ms; ETL, 1; FA, 30°; NEX, 1; slice, 7 mm; skip, 12 mm; FOV, 440 mm; BW, 244 Hz/px; matrix, 256 × 224 mm ²)	Anatomical reference images of treatment areas for MRgFUS treatment planning	0.26
Fast spin echo sequence — axial T2 (TE/TR, 81/3400 ms; ETL, 10; FA, 90°; NEX, 1; slice, 3 mm; skip, 3 mm; FOV, 160 mm; BW, 122 Hz/px; matrix, 256 × 192 mm ²)	Pre-ablation planning images	1.13
Fast spin echo sequence — sagittal T2 (TE/TR, 81/4200 ms; ETL, 12; FA, 90°; NEX, 1; slice, 3 mm; skip, 4 mm; FOV, 200 mm; BW, 81.4 Hz/px; matrix, 256 × 224 mm ²)	Pre-ablation planning images	0.95
Fast spin echo sequence — coronal T2 (TE/TR, 1.42/4.98 ms; ETL, 1; FA, 30°; NEX, 1; slice, 3 mm; skip, 3 mm; FOV, 440 mm; BW, 244 Hz/px; matrix, 256 × 224 mm ²)	Pre-ablation planning images	0.94
Echo planar imaging — gradient echo (phase-sensitive gradient-recalled echo sequences) — axial (TE/TR, 18/250 ms; ETL, 1; FA, 35°; NEX, 2; slice, 3 mm; skip, 1 mm; 5 slices; BW, 62 kHz)	Thermal mapping of the treatment zone	0.01
Fast spin echo sequence with fat suppression — axial T2 (TE/TR, 40/4701 ms; ETL, 15; FA, 90°; NEX, 1; slice, 3 mm; skip, 3 mm; FOV, 160 mm; BW, 122 Hz/px; matrix, 320 × 192 mm ²)	Post-procedure evaluation	1.12

^a3D = three-dimensional; BW = bandwidth; ETL = echo train length; FA = flip angle; FOV = field-of-view; MR = magnetic resonance; MRgFUS = magnetic resonance imaging-guided focused ultrasound; MRI = magnetic resonance imaging; NEX = number of excitations; QA = quality assurance; SAR = specific absorption rate; T2 = spin-spin relaxation time; TE = echo time; TR = time to repetition.

position, and the phantom was removed. The patient was then walked slowly into the MR scanner room and was guided by the clinical team into the feet-first supine position with his back located directly above the transducer; the table was slowly advanced to iso-center. An emergency code cart and monitor cart were readily available just outside the MR scanner room for use in case of an emergency. The procedure would have been stopped if at any point the patient communicated chest discomfort or if the cardiac monitoring was lost.

A cardiology nurse and medical physicist were present for the entire procedure. The cardiology nurse continually monitored electrocardiography, pulse oximetry, and blood pressure. All MRI was performed in the normal scan mode. The MR physicist assisted the MRI technologist in both, adjusting sequence parameters to ensure SAR was limited to 1.5 W/kg, and monitoring real-time SAR (via the scanner's real-time SAR monitor which is based on 10-s averages). Details of all MRI pulse sequences used during the treatment are shown in [Table](#).

The target locations of the individual focused US (FUS) ablations (ie, “sonications”) were planned using the FUS treatment software on the Exablate 2100 workstation. The anatomical spin-spin relaxation time (T2)–weighted fast spin echo sequences, in axial, sagittal, and coronal planes (SAR, 1.13, 0.95, and 0.94W/kg, respectively) were first executed on MRI scanner. The resulting image data sets were subsequently loaded onto the Exablate workstation for treatment planning. MRgFUS ablation of the bilateral L3-4, L4-5, and L5-S1 facet joints was performed, the exact details of the treatment protocol are described in Tieggs-Heiden et al.⁸ In summary, target accuracy was confirmed at a low-power test dose of 18 W, and the treatment doses were between 40 and 60 W with each sonication lasting 25 s. A total of 22 individual sonications were delivered during the procedure, which lasted 206 min in total. Each sonication was monitored in the axial plane using phase-sensitive gradient-recalled echo sequences (SAR, 0.01W/kg) acquired for the purpose of real-time MR thermometry feedback with temporal resolution of 6 s. Following each sonication, the patient was asked to rate his pain level on a scale of 0 to 10 and the sonication position and energy was modulated based on the patient’s rated pain score. Additionally, moderate sedation was administered throughout the procedure to keep the patient comfortable. The treatment was completed as planned and no alteration to sonication parameters was required because of the presence of the pacemaker. Upon completion of the treatment, T2-weighted fast spin echo sequence with fat suppression (SAR, 1.12W/kg) was acquired to assess treatment effects (ie, edema around the target joints). The patient was discharged on the same day as the procedure. He did not experience any new or increasing post-procedural pain, and required no supplemental pain medications after the procedure.

No adverse cardiac event occurred during or immediately following the MRgFUS procedure. Pacemaker interrogation revealed no damage or alteration to it, and it was reprogrammed to its original DDDR (dual chamber paced – dual chamber sensed – dual modes of response – rate modulation) at 60 beats/min. Informed consent for publication from the patient was obtained; although our

institutional review board does not review single case reports.

DISCUSSION

We report a first case of MRgFUS ablation of lumbar facet joints in a patient with refractory low back pain and MRI non-conditional pacemaker. Facet joint MRgFUS is a relatively new treatment for facet joint pain^{8,10,11}; this procedure has the advantage of not requiring skin incision, and uses MRI for treatment planning and monitoring of the ablation in the real-time.

More than 1.8 million people in the United States have pacemakers or implantable cardioverter-defibrillators.¹² Facet joint degenerative changes and pain often occur in older demographics, including those with confounding cardiac morbidities, and a substantial number with CIEDs. Additionally, candidates for MRgFUS treatment of essential tremor and prostate may also have cardiac pacemakers. Therefore, an appropriate risk-benefit analysis for such cases is of paramount importance. CIEDs from multiple manufacturers have been specifically engineered and are labeled as MRI-conditional. Other CIEDs are not specifically designed as being MRI-conditional, but multiple studies have been performed showing the ability to perform an MRI with these MRI non-conditional CIEDs,^{9,13-18} and there is now increasing acceptance of protocols to minimize risk of MRI in these patients.¹⁹

The key to this MRgFUS case was the successful integration of the existing CIED/MRI practice to this interventional procedure. Specifically, a cardiology pacemaker nurse performed CIED programming and patient monitoring, and the MRI physicist monitored the real-time SAR related to the CIED; all of which permitted the procedural radiologist to concentrate on the MRgFUS procedure and achieve the desired outcome. In this case study, the patient maintained stable vital signs and cardiac function throughout the procedure and there were no changes in pacemaker function or in pacing threshold post MRgFUS facet joint ablation.

CONCLUSION

This study reports a successful MRgFUS lumbar facet joint ablation in a patient with an MRI non-conditional pacemaker. By careful

use of our MRI CIED protocol,^{9,19} we have shown that the MRgFUS ablation treatment of facet joints can be performed, and going forward can be offered to patients with CIEDs on a case-by-case basis.

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MRgFUS use for facet joint treatment is an off-label use in the United States.

Abbreviations and Acronyms: CIED = cardiac implanted electronic device; MRgFUS = magnetic resonance imaging-guided focused ultrasound; MRI = magnetic resonance imaging; QA = quality assurance; SAR = specific absorption rate; T2 = spin-spin relaxation time

Potential Competing Interests: The authors report no competing interests.

Correspondence: Address to Krzysztof R. Gomy, PhD, Department of Radiology, Mayo Clinic, 200 First St SW, Rochester MN 55905 (gomy.krzysztof@mayo.edu).

ORCID

Jacinta E. Browne: <https://orcid.org/0000-0002-3207-0367>; Christin A. Tiegs-Heiden: <https://orcid.org/0000-0003-3794-6003>; Robert E. Watson: <https://orcid.org/0000-0002-3271-5962>; Krzysztof R. Gomy: <https://orcid.org/0000-0001-8785-3070>

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