Comparison of Noninvasive High-Intensity Focused Ultrasound with Radiofrequency Ablation of Osteoid Osteoma

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Objective To evaluate clinical feasibility and safety of magnetic resonance imaging-guided high-intensity focused ultrasound (MR-HIFU) treatment of symptomatic osteoid osteoma and to compare clinical response with standard of care treatment.

Study design Nine subjects with radiologically confirmed, symptomatic osteoid osteoma were treated with MR-HIFU in an institutional review board–approved clinical trial. Treatment feasibility and safety were assessed. Clinical response was evaluated in terms of analgesic requirement, visual analog scale pain score, and sleep quality. Anesthesia, procedure, and recovery times were recorded. This MR-HIFU group was compared with a historical control group of 9 consecutive patients treated with radiofrequency ablation.

Results Nine subjects (7 male, 2 female; 16 ± 6 years) were treated with MR-HIFU without technical difficulties or any serious adverse events. There was significant decrease in their median pain scores 4 weeks within treatment (6 vs 0, $P < .01$). Total pain resolution and cessation of analgesics were achieved in 8 of 9 patients after 4 weeks. In the radiofrequency ablation group, 9 patients (8 male, 1 female; 10 ± 6 years) were treated in routine clinical practice. All 9 demonstrated complete pain resolution and cessation of medications by 4 weeks with a significant decrease in median pain scores (9 vs 0, $P < .001$). One developed a second-degree skin burn, but there were no other adverse events. Procedure times and treatment charges were comparable between the 2 groups.

Conclusion This pilot study shows that MR-HIFU treatment of osteoid osteoma refractory to medical therapy is feasible and can be performed safely in pediatric patients. Clinical response is comparable with standard of care treatment but without any incisions or exposure to ionizing radiation. *(J Pediatr 2017;190:222-8).*

Trial registration ClinicalTrials.gov NCT02349971

Osteoid osteoma is a painful bone tumor that occurs commonly in the cortex of long bones in children and adolescents and accounts for 10% of all benign bone tumors.[1,2] The osteoid osteoma nidus is a highly vascularized central region that produces excess prostaglandins, causing local vasodilation, inflammation, and pain.[3] Adjacent periosteal nerve fibers amplify the pain, which characteristically worsens at night, sometimes waking children from sleep.[4] Pain associated with osteoid osteoma is alleviated by nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen.[5] Treatment with NSAIDs relieves pain in the short term but carries long-term toxicities.[6] In addition to pain, other symptoms of osteoid osteoma include bony deformity, growth disturbance, and painful scoliosis.[7,8]

Surgical resection of osteoid osteoma as the definitive treatment is less common because of difficulty in intraoperative visualization of the lesion, which leads to significant bone resection and collateral damage to surrounding tissue. Morbidity is related to weakening of the remaining bone and prolonged recovery times with weight-bearing and mobility restrictions.[5] Radiofrequency ablation (RFA) has replaced surgery to become the current standard of care because it is less invasive and causes less collateral damage and morbidity.[7,9] During RFA, a needle is guided and advanced into the osteoid osteoma lesion under direct visualization with the use of computed tomography (CT) imaging and heated to 90°C to ablate the nidus.[10]

Thermal ablation of the nidus and adjacent periosteal nerves eliminates pain within a few days.[1] Although RFA has an 80%-98% success rate,[11] treatment is invasive and potentially can cause collateral tissue damage as well as expose patients and operators to ionizing radiation.[12,13]

CT	Computed tomography
MR-HIFU	Magnetic resonance imaging-guided high-intensity focused ultrasound
MRI	Magnetic resonance imaging
NSAID	Nonsteroidal anti-inflammatory drug
RFA	Radiofrequency ablation
VAS	Visual analog scale

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An optimal therapy for osteoid osteoma in children would be precise, completely non-invasive, and free from ionizing radiation. Magnetic resonance imaging-guided high-intensity focused ultrasound (MR-HIFU) is a novel therapy that recently has gained popularity as a noninvasive alternative for the treatment of painful bone metastases, uterine fibroids, essential tremor, and prostate cancer in adults.[14] An external ultrasound transducer is used to focus sound waves and precisely deposit acoustic energy into targets inside the body. The focal energy deposition causes local heating and coagulative necrosis (ie, thermal ablation) of the target while sparing surrounding tissues. Magnetic resonance imaging (MRI) is used to localize the target, plan treatment, and monitor temperature changes in real time to avoid damage to nearby critical structures. Recently, a study in which the authors used MR-HIFU ablation to treat adult patients with osteoid osteoma showed a clinical success rate of 90% without any major adverse events.[15,16]

The feasibility and safety of MR-HIFU ablation in children, however, has not been well studied. Moreover, among pediatric patients, painful osteoid osteoma treated with MR-HIFU has not been compared with RFA, the standard treatment at most US hospitals. Therefore, we sought to determine safety and feasibility, as well as clinical response, of this novel therapy in a pediatric sample through an open-label, Food and Drug Administration–monitored, institutional research board–approved clinical trial. We also compared clinical response in the MR-HIFU group with a historical control group of children treated with RFA at our institution.

Methods

Nine patients with symptomatic osteoid osteoma refractory to medical treatment were enrolled prospectively on a safety and feasibility trial (ClinicalTrials.gov: NCT02349971) between January 2015 and May 2016. Eligibility criteria were age ≤25 years, radiographically confirmed diagnosis, and lesions targetable with MR-HIFU. Patients with spinal osteoid osteoma or lesions located <1 cm from the skin, major nerve, or physis were excluded in this pilot study. All eligible patients were offered MR-HIFU. Primary outcomes of safety and feasibility were determined at 28 days. A historical comparison group consisted of 9 patients with osteoid osteoma consecutively treated with RFA at our institution between September 2013 and May 2016. Patients in the RFA group underwent routine clinical follow-up for up to 1 month, as clinically indicated.

Lesion Characteristics

Nidus volume was calculated with the spheroid volume formula and CT-based measurements of the nidus diameter in 3 orthogonal planes. Periosteal thickness was measured as the distance from the surface of the new periosteal reaction to the closest boundary of the osteoid osteoma nidus on CT imaging. Symptom duration before ablative therapy was recorded as reported by each patient, family, and referring physician.

MR-HIFU Therapy

All procedures were performed with the patient under general anesthesia with continuous supervision by an anesthesiologist, who used standard American Society of Anesthesia hemodynamic monitoring.[17] The MR-HIFU system used in this study was Sonalleve V2 (Philips, Vantaa, Finland) integrated with an Achieva 1.5T MR scanner (Philips, Best, The Netherlands). After anesthesia, all patients were positioned on the MR-HIFU table with the osteoid osteoma lesion centered on the treatment window. Acoustic coupling was achieved by the use of cooled ultrasound gel pads (Philips, Vantaa, Finland), and ultrasound coupling gel (Clear Image, Next Medical Products, Branchburg, New Jersey), diluted in degassed water.

Subsequently, T1- and T2-weighted MR images were obtained to localize the osteoid osteoma and plan treatment. Treatment planning ensured complete coverage of the osteoid osteoma nidus and adjacent bone cortex. The projected focused ultrasound beam path was assessed to ensure avoidance of critical structures within 1 cm of the target. Temperature monitoring scans and low-power test sonications were performed to verify MR-HIFU targeting accuracy and to estimate the power needed for therapeutic sonications. Acoustic power and sonication duration were varied depending on the size and depth of the osteoid osteoma and overlying bone thickness. To ensure safety, heating of the osteoid osteoma and adjacent tissues was monitored during therapy with the use of MRI thermometry.[18] A post-treatment MRI scan with intravenous contrast (Dotarem [0.2 mL/kg]; Guerbet LLC, Bloomington, Indiana) was obtained to confirm the ablated volume and determine residual vascularity of the nidus before transporting the patient to the postanesthesia care unit for recovery.

RFA Therapy

RFA was performed under CT imaging guidance (GE Healthcare, Chicago, Illinois) with the RITA Model 1500X system (AngioDynamics, Latham, New York). Patients were positioned on the CT scanner, and general anesthesia was administered. A limited CT scan was obtained to localize the osteoid osteoma. All patients received preprocedural antibiotic prophylaxis.

The skin was sterilized and local anesthesia administered with 1% lidocaine. A bone drill was advanced from the skin through intervening muscle into the bone cortex under CT guidance.

Drill advancement to the target was performed with intermittent CT imaging and readjustment of the trajectory as needed. Once the drill was positioned appropriately at the target, a radiofrequency needle probe was placed through the drill into the osteoid osteoma nidus and slowly heated until a target temperature of 90°C was reached. Once at that temperature, the heating was maintained for an additional 6 minutes. Following completion, the probe and drill were removed, the wound was dressed, and the patient was transported to the postanesthesia care unit for recovery.

MR-HIFU and RFA Therapy Characteristics and Outcome Measures

Anesthesia time was measured from onset of anesthesia to extubation. Procedure time was measured from the beginning of patient positioning on the MR-HIFU table or CT scanner to patient transport for recovery. Recovery time was defined

as the period from the end of anesthesia to time of discharge. Clinical feasibility for MR-HIFU was defined by successful completion of planned therapy. Safety of MR-HIFU was evaluated through clinical assessments on the day of treatment and 1, 7, 14, and 28 days post-therapy. The National Cancer Institute Common Terminology Criteria for Adverse Events, Version 4.0, was used to document adverse events.

Patients were asked to complete pain score and medication use logs (dose and frequency) for 5 days before treatment and up to 28 days after therapy. Pain response for both MR-HIFU and RFA groups was evaluated with the visual analog scale (VAS). Complete response was defined as total resolution of pain (VAS = 0) and cessation of all pain medication use by 1 month. Partial response was defined as decrease in pain and medication use. Presence or absence of sleep disruption was documented for all patients. Patients who underwent RFA were seen in clinic or contacted by telephone 1 week and 1 month after the procedure as part of routine clinical follow-up.

Statistical Analyses

Adverse effects and toxicities were summarized descriptively and tabulated based on the type, severity, and relationship to treatment. Patient-reported VAS pain score, sleep disruption, and medication use were summarized. Pairwise comparisons between the 2 treatment groups were performed with the Mann-Whitney *U* nonparametric test. Repeated, matched clinical observations (pain scores, etc) were compared as nonparametric data (due to the ambiguity of normality tests for n = 9) with the Friedman test, followed by a Dunn post hoc test. Results were reported as median and range of measurements for n = 9, unless otherwise specified. Two-tailed *P* values were used, and $P \leq .05$ was considered significant.

We queried our billing department to record quantifiable patient charges, including charges for MRI and CT use and disposable equipment required for each therapy. Our intent was not to perform a complete comparative cost analysis but rather to gain a preliminary understanding of relative charges at our institution. Because charges for anesthesia, recovery, and treatment team personnel are based on hourly rates, time requirement provides a comparison between MR-HIFU and RFA therapies for these 3 cost inputs. Given similar times, we reasoned that patient charges for these also should be similar. A 3-member treatment team is required to perform both therapies. For MR-HIFU, this team consists of physician, MRI technologist, and engineer, whereas RFA treatment requires a physician, CT technologist, and a surgical technologist. Given this team makeup, the personnel costs are similar.

Results

Twenty-five consecutive candidates were screened; 16 met inclusion criteria, and 9 were excluded (**Figure 1**). Of the 9 who were excluded, 4 were based on lesion location (2 spinal lesions and 2 lesions located <1 cm from a major nerve), 3 because of lesion inaccessibility to the HIFU beam (1 deep in the pelvis and 2 deep medullary lesions in the femur), and 2 others because of metal artifact that precluded treatment planning based on MRI. Of the 16 eligible patients, 7 elected not to participate. All 9 enrolled patients underwent successful MR-HIFU ablation, including 1 patient who previously underwent both surgical resection and RFA without durable pain relief.

Patient and Lesion Characteristics

Distribution of lesion locations (**Figure 2**; available at www.jpeds.com) was consistent with that reported in the literature.[19] Patient characteristics in both groups are described in **Table I**. Patients in the MR-HIFU group were much older ($P = .029$) and heavier ($P = .049$) than patients in the RFA group. In terms of lesion characteristics, nidus volume was larger in the RFA group ($P = .047$), but periosteal thickness was similar ($P = .753$). Patients in both treatment groups had similar symptom duration before therapy ($P = .565$).

Comparison of MR-HIFU and RFA Therapies

MR-HIFU ablation was feasible, reaching ablative temperatures (>65°C) at the bone surface in all 9 patients. Similar temperatures were reached in the adjacent soft tissues, as shown by real-time MR thermometry, but ablative heating did not extend beyond preplanned treatment margins. This therapy was tolerated well, with no treatment-related serious adverse events noted during the follow-up period (**Table I**). A representative patient from each treatment group was chosen to

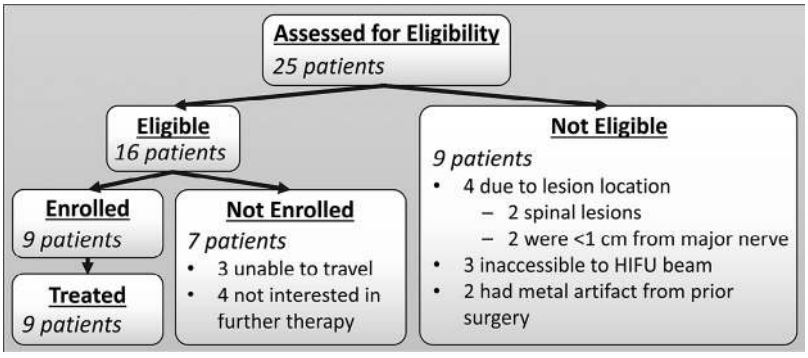

Figure 1. Patient screening and enrollment for MR-HIFU clinical trial.

Table I. Patient, lesion, and therapy characteristics

Characteristics	MR-HIFU Median (range)	RFA Median (range)	Comparison *P* value
Patient			
Age, y	16 (7-24)	7 (3-23)	.029*
Sex, male/female	7 / 2	8 / 1	
Weight, kg	61.6 (25.2-75.2)	21.6 (15.1-82)	.047*
Height, cm	167.5 (120-177)	123 (99.5-177)	.08
Body mass index	19.7 (14.4-27.3)	16.6 (13.6-26.2)	.03*
Lesion			
Symptom duration, mo	10 (3-16)	6 (3-36)	.565
Osteoid osteoma nidus volume, cm^3	0.82 (0.4-0.8)	3.22 (0.7-5.6)	.049*
Periosteal thickness, mm	2.3 (0-14)	2.8 (0-12.4)	.753
Osteoid osteoma location	Femur: 3; tibia: 3; talus: 1; calcaneus: 1; phalanx: 1	Femur: 5; tibia: 1; humerus: 1; ulna: 1; ischium: 1	
Therapy			
Anesthesia time, min	148 (116-240)	162 (135-193)	$P = .30$
Procedure time, min	128 (101-195)	110 (96-141)	$P = .39$
Recovery time, min	271 (229-364)	260 (138-551)	$P = .29$
Adverse events, n	0	1	N/A
Clinical response, CR/PR	8/9 CR; 1/9 PR	9/9 CR	N/A

CR, complete response; *N/A*, not available; *PR*, partial response.
Nine patients were treated in each treatment group and compared. Median and range are reported.
*$P \leq .05$ was considered significant in pair-wise comparisons with the Mann-Whitney *U* nonparametric test.

highlight the differences between MR-HIFU and RFA therapies (**Figure 3**). Both patients had similar osteoid osteoma lesions in the femur, but the patient who underwent MR-HIFU therapy was treated noninvasively and without ionizing radiation exposure. MR thermometry provided real-time imaging feedback, improving treatment control and safety. Furthermore, successful ablation was confirmed immediately after treatment by a contrast-enhanced MRI showing elimination of perfusion in the nidus (**Figure 3**, A). In contrast, the patient who underwent RFA (**Figure 3**, B) required drilling through the skin, muscle, and bone to place the RFA probe under CT guidance. The CT imaging subjected both the patient and operator to ionizing radiation. Furthermore, this approach provided no real-time feedback on treatment safety or immediate confirmation of treatment success.

Treatment characteristics for both therapies are compared in **Table I**. There was no significant difference in median anesthesia (148 vs 162 minutes), procedure (128 vs 110 minutes), or recovery time (271 vs 260 minutes). No serious treatment-related adverse events were observed in the MR-HIFU group.

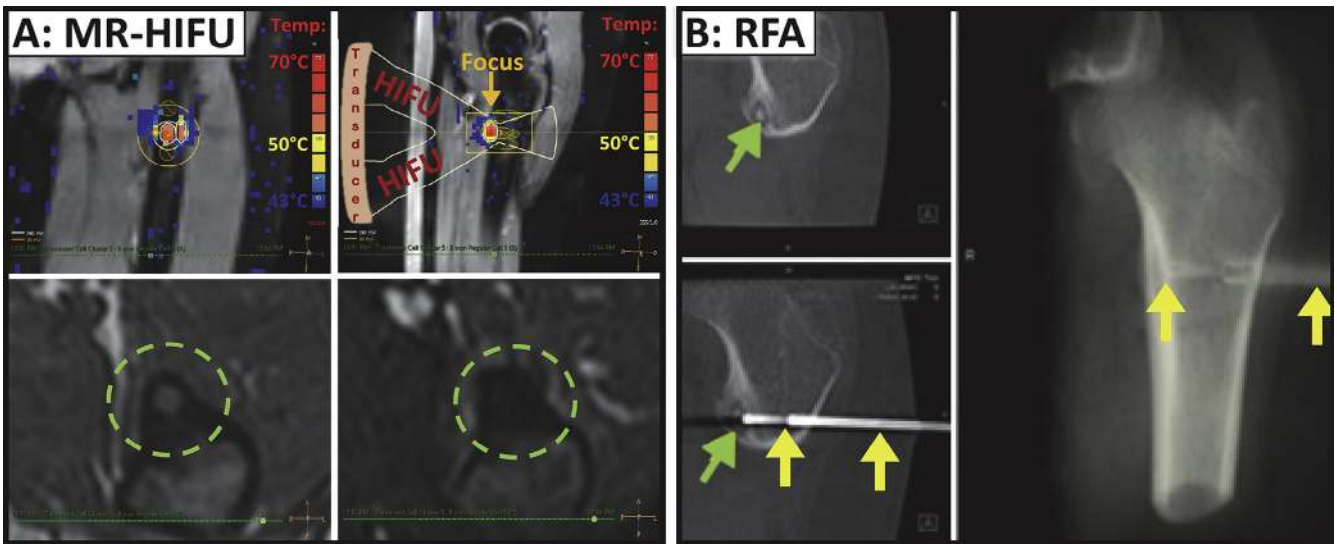

Figure 3. MR-HIFU vs RFA: comparison of different treatment techniques. A, 9-year-old patient with osteoid osteoma of the femur treated with MR-HIFU. MRI was used to localize the osteoid osteoma nidus, plan the HIFU beam path (*yellow outline*), and monitor target heating. Post-treatment MRIs show that the osteoid osteoma nidus has been ablated and no longer enhanced with contrast (*green dashed circles*). B, 7-year-old girl with osteoid osteoma of the femur (*green arrows*) treated with RFA. Note the bone drill and probe (*yellow arrows*) placed through skin, muscle, and bone.

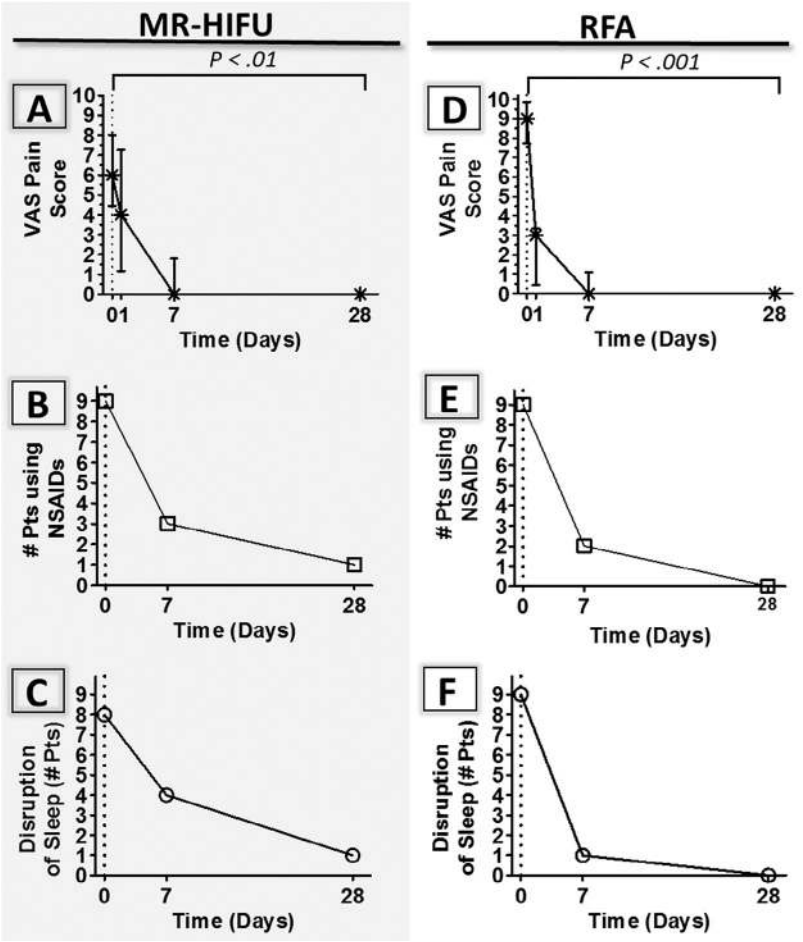

Figure 4. Clinical response for MR-HIFU vs RFA. Significant pain resolution was seen in both groups by day 28. Median values with 95% CIs are shown for VAS pain scores. Incidence of NSAID use and pain-associated sleep disruption also decreased after both treatments in all but 1 patient in the MR-HIFU group. Panels A, B, and C show clinical improvement after MR-HIFU, and panels D, E, and F show corresponding improvement after RFA.

One patient developed minor focal bruising at the edges of the treatment window, which was attributed to inadequate padding at this location. This bruising was visible but caused minimal discomfort and resolved without additional treatment within 1 week. In the RFA group, 1 patient with a lesion in the anterior tibial cortex close to the skin surface experienced a second-degree skin burn that caused significant pain but resolved with conservative treatment over several weeks. At 28 days after treatment, complete response rates were similar for both therapies: 89% in the MR-HIFU ablation group and 100% in the RFA group.

Clinical response to both therapies appeared to be comparable. For the MR-HIFU group, clinical response showed significant overall improvement ($P = .0002$, Friedman). Pain resolution was similar for both therapies, as median VAS score decreased from 6 to 0 in the MR-HIFU group ($P < .01$, Dunn post hoc test) and from 9 to 0 in the RFA group ($P < .001$, Dunn post hoc test) by day 28 after treatment (**Figure 4**, A, D). Reduction in NSAID use was similar in both groups; 8 of 9 patients in the MR-HIFU group were no longer taking medication, and all patients who underwent RFA were off medication by day 28 (**Figure 4**, B, E). Furthermore, patients in both groups reported similar improvement in sleep quality following treatment. Pain-associated sleep interruption decreased significantly overall following MR-HIFU ablation ($P = .0013$, Friedman). The number of patients with pain-related sleep disruption decreased from 8 to 1 in the MR-HIFU group and from 9 to 0 in the RFA group (**Figure 4**, C, F).

Although limited, the comparison of treatment charges between MR-HIFU and RFA suggests that both therapies carry similar cost (**Table II**; available at www.jpeds.com), especially when factoring in the additional charges of disposable supplies required for RFA (surgical tray, bone drill, radiofrequency probe, medications).

Discussion

Our results show that MR-HIFU ablation of painful osteoid osteoma is safe and feasible with clinical response rates similar to RFA at our institution as well as those reported in the literature.[3] Anesthesia, treatment, and recovery durations also were similar for both therapies. However, the completely

noninvasive and radiation-free nature of MR-HIFU is advantageous over RFA, particularly in children and adolescents for whom collateral damage and radiation exposure may cause long-term morbidity.[5,20] MR-HIFU is a promising new paradigm for local treatment of pediatric tumors that stands apart from current invasive interventions and requires further study and evaluation in a larger cohort.

We observed no serious treatment-related adverse events in any of the 9 patients who underwent MR-HIFU. This finding is consistent with previously published studies in adults[15,16] and likely attributable to the ability to monitor and adjust the MR-HIFU treatment in real time. All treatments were performed on an outpatient basis without overnight admission. The minor focal bruising due to inadequate padding at edges of the HIFU treatment window can be addressed by ensuring that adequate padding and careful positioning are used in the future. This is especially important when treating small, thin, pediatric patients with lower body mass index than adult patients, especially because nearly all pediatric patients require general anesthesia. In the RFA group, 1 patient with an osteoid osteoma in the anterior tibial cortex located close to skin developed a second-degree burn, which caused significant pain and required >4 weeks to heal. Skin burn from thermal injury has been reported as a complication of RFA, especially when treating osteoid osteoma in this particular location.[21,22]

An important difference between the 2 therapies is exposure to ionizing radiation, which was not present in the MR-HIFU group. Although radiation exposure due to CT guidance during RFA routinely was minimized, it was variable and ranged from 91 to 1397 mGy-cm (data not shown) in our 9 patients. The main reason for this variability is that advancing the bone drill to the target osteoid osteoma nidus can require multiple readjustments based on the anatomic location and depth of the osteoid osteoma. The greater the number of readjustments needed, the greater the number of interval CT scans obtained, and the greater the resulting radiation exposure. In contrast, this step is eliminated in MR-HIFU treatment.

MR-HIFU ablation was feasible in all 9 patients who consented to this treatment. However, 9 of 25 screened patients were excluded based on technical limitations. A minimal distance of 1 cm between lesion and critical structures such as spinal cord, major nerve, or skin generally is accepted[23] as a safety margin for MR-HIFU at present. In addition, because the potential effect of MR-HIFU ablation on the physis and future bone growth in young children is unknown, no lesions within 1 cm of the physis were treated in this pilot study. Once safety concerns have been addressed adequately through clinical experience and continued improvement in technology, this 1-cm margin will likely be overcome. This is supported by recent reports demonstrating ability to safely perform MR-HIFU ablation close to the spine in treatment of spinal facet-related joint pain.[24-26]

The single patient with partial response following MR-HIFU ablation had an osteoid osteoma located in the medullary cavity of the femur, rather than the cortex. This location required lethal heating deep within the bone to reach the nidus, pushing the current technical limits of this technology. Post-treatment MRI in this patient showed that periosteal nerves were ablated but the nidus remained viable. This explains partial improvement but not complete resolution of symptoms in this patient at 1-month follow-up. This patient underwent RFA, which completely resolved his symptoms. Previous reports also suggest that intramedullary lesion locations may be difficult to treat completely with current MR-HIFU technology,[15,16] but ongoing technical refinement may allow for treatment of intramedullary lesions in the future. Importantly, 1 patient who had previously undergone unsuccessful surgical resection and RFA demonstrated a complete response after MR-HIFU ablation, suggesting that this therapy may be useful in refractory cases.

The true cost of MR-HIFU ablation for osteoid osteoma is unknown, because there are no existing billing codes for this indication. Furthermore, this relatively new technology is not yet widely available, and a complete understanding of all associated costs is lacking. These charges are likely to be variable across different centers, as is the case with many established procedures, including RFA.

Although our analysis is limited, our comparison of treatment charges suggests that both therapies have a similar expense. However, the additional advantages of no radiation exposure, precise real-time treatment control, and a completely noninvasive therapy without wound healing or infection risk are difficult to quantify in monetary terms.

This pilot study is limited by a small sample size in both treatment groups. Some of the patients in both groups had previous treatments that might affect sensitivity to MR-HIFU or RFA. In addition, the use of a retrospective historical RFA control group precluded comparison to all of the data collected prospectively for the MR-HIFU group. Furthermore, both the small sample size and the retrospective comparison group make matching based on patient or lesion characteristics challenging. A larger, prospective randomized clinical trial directly comparing MR-HIFU with RFA would address these limitations.

There is growing evidence demonstrating that MR-HIFU ablation is a safe surgical alternative for several adult conditions ranging widely from painful bone metastases to essential tremor. Our experience with MR-HIFU ablation of osteoid osteoma shows that this therapy is feasible and safely performed in pediatric patients. The benefits of MR-HIFU therapy are of particular relevance to the pediatric population, in whom the optimal therapy would be precise, noninvasive, and radiation-free elimination of tumors without collateral damage. MR-HIFU provides a new paradigm for delivering such an optimized therapy. ■

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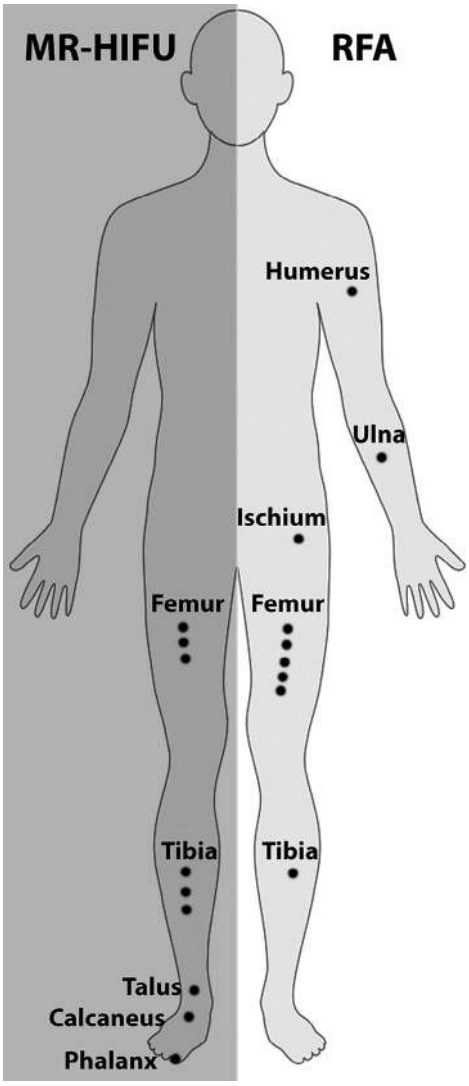

Figure 2. Location of the osteoid osteoma in treated patients.

Table II. Patient charge estimates for MR-HIFU and RFA

Patient charges	MR-HIFU charges, $	RFA charges, $
Scanner use (2 h)	7283	4737
Disposables		
Bone drill	N/A	375
RFA probe	N/A	2425
Surgical tray	N/A	102
Antibiotics/miscellaneous	N/A	115
Gel coupling pads	200	N/A
Total (variable patient charges)	7483	7754

N/A, not applicable.