CLINICAL STUDY

A Bicentric Propensity Score Matched Study Comparing Percutaneous Computed Tomography–Guided Radiofrequency Ablation to Magnetic Resonance–Guided Focused Ultrasound for the Treatment of Osteoid Osteoma

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ABSTRACT

Purpose: To assess the safety and efficacy of computed tomography–guided radiofrequency (RF) ablation and magnetic resonance–guided focused ultrasound (MRgFUS) in the treatment of osteoid osteoma with a long-term follow-up study.

Materials and Methods: Database research was performed at 2 different centers with experience in musculoskeletal interventions. Both centers, one performing RF ablation and the other MRgFUS, identified 116 patients who underwent either RF ablation or MRgFUS procedures for the treatment of symptomatic osteoid osteoma and retrospectively evaluated data regarding pain scores using a visual analog scale (VAS). Complications were recorded according to the Cardiovascular and Interventional Radiological Society of Europe classification system. Propensity score matching for multiple variables was performed. Pain scores before and after therapy were compared.

Results: Of 116 patients treated, 61 and 55 underwent RF ablation and MRgFUS, respectively. Before treatment, the mean reported pain in the 2 groups were 9.1 ± 0.88 (RF ablation) and 8.7 ± 0.73 (MRgFUS) VAS units. After treatment, a statistically significant ($P < .00001$) overall reduction in pain symptomatology was recorded. No statistically significant difference was observed between the mean values of pain after treatment in both groups ($P = .256$). Over a mean of >2 years of follow-up, 4 cases of relapse (RF ablation, 1; MRgFUS, 3) and 1 complication (RF ablation) were observed. The analysis from propensity score matching that identified a matched cohort of 48 patients showed similar results.

Conclusions: The 2 techniques for the treatment of osteoid osteoma resulted in profound and similar pain relief. The presence of thick cortical bone over the nidus can reduce the effectiveness of MRgFUS.

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ABBREVIATIONS

IR = interventional radiology, MRgFUS = magnetic resonance–guided ultrasound, OO = osteoid osteoma, RF = radiofrequency, SD = standard deviation, US = ultrasound, VAS = visual analog scale

RESEARCH HIGHLIGHTS

- A propensity score–matched comparison of treatment of osteoid osteoma by radiofrequency ablation at one hospital and by magnetic resonance-guided focused ultrasound at another hospital was performed. Forty-eight patients were matched in each cohort, with mean 2-year follow-up.
- Comparison showed no significant differences in outcomes, with very high rates (94%–98%) of successful, complete, and durable relief of symptoms and very few serious adverse events (0%–2%).
- Focused ultrasound has the advantage of less invasiveness, especially for lesions more superficial on the bone surface, but radiofrequency ablation may be more effective for osteomas requiring penetration of thicker cortical bone.

STUDY DETAILS

Study type: Clinical, Observational, Retrospective Cohort Study
Study phase: Phase IV

Osteoid osteoma (OO) is a benign, focal, and painful bone lesion that accounts for approximately 10% of all bone tumors. It typically affects children and adults younger than 30 years of age and mainly men (male-to-female ratio, 2–4:1) (1,2). Clinically, OO is characterized by continuous pain, regardless of physical exercise, usually worsening at night, and relieved by nonsteroidal anti-inflammatory drugs. On radiographs, it appears as a focal radiolucent lesion (nidus), and it is usually surrounded by inflammatory reaction (into the bone and in the surrounding tissues), clearly visible on magnetic resonance (MR) imaging (3). Depending on its location, it can be classified as subperiosteal, intracortical, or endosteal (or intramedullary). Subperiosteal and intracortical localizations are the most common (up to 95%); intra-articular lesions are rare and usually found in the hip (4,5).

The natural course of OO is unknown, and without definitive treatment, patients face long-term treatments with anti-inflammatory drugs (1). Intervention is therefore strongly indicated to reduce symptomatology. Surgery no longer represents the gold standard, owing to the difficulty in identifying and removing the nidus with the consequent high recurrence rates (6). Surgical complication rates are higher than those observed using minimally-invasive, imaging-guided interventional radiology (IR) techniques (6), such as computed tomography (CT)–guided percutaneous ablation either by radiofrequency (RF) or laser, and MR-guided focused ultrasound (US) (MRgFUS) (5–12). At the time of reporting, RF ablation represented the gold standard for the treatment of symptomatic OO. Using this technique, the tip of a needle electrode is positioned in the nidus and destroys the lesion by heat in a few minutes (10). MRgFUS is a noninvasive technique that employs high-intensity US beams, generated by a transducer. The beams cross the skin and soft tissues focusing on the target area. On the bone surface, the mechanical energy is converted into heat and destroys the lesion (13,14).

This study aimed to compare RF ablation and MRgFUS employed at 2 centers with experience in musculoskeletal IR, by evaluating the results collected from a large series of patients.

MATERIALS AND METHODS

This is a retrospective study performed on patients with radiologically confirmed OO and treated with RF ablation or MRgFUS. This study was conducted in accordance with the Helsinki declarations. Institutional review board approval was obtained (University of L′Aquila, protocol number 39/2020; approved November 17, 2020).

RF ablation procedures were performed in Athens (by D.F., >15 years of experience in musculoskeletal interventions); MRgFUS procedures were performed at L′Aquila (by F.A. and L.Z., with >5 and 15 years of experience, respectively, in musculoskeletal interventions).

Patient Selection

The patients were selected through the picture archiving and communication systems (PACS) of the 2 hospitals; they were included in the study provided that the following inclusion criteria were met: diagnosis of painful OO (>4 on visual analog scale [VAS]), diagnosis by clinical and imaging data; lesion treated with RF ablation (Athens) or MRgFUS (L′Aquila); and follow-up of at least 6 months to ensure the detection of possible relapses. The study included patients treated from 2013 to 2020. A flow chart summarizes the data (**Fig 1**).

Treatment Details

Over the entire study period, both procedures were conducted by the same operators and performed on hospitalized patients previously referred for anesthesiology evaluation.

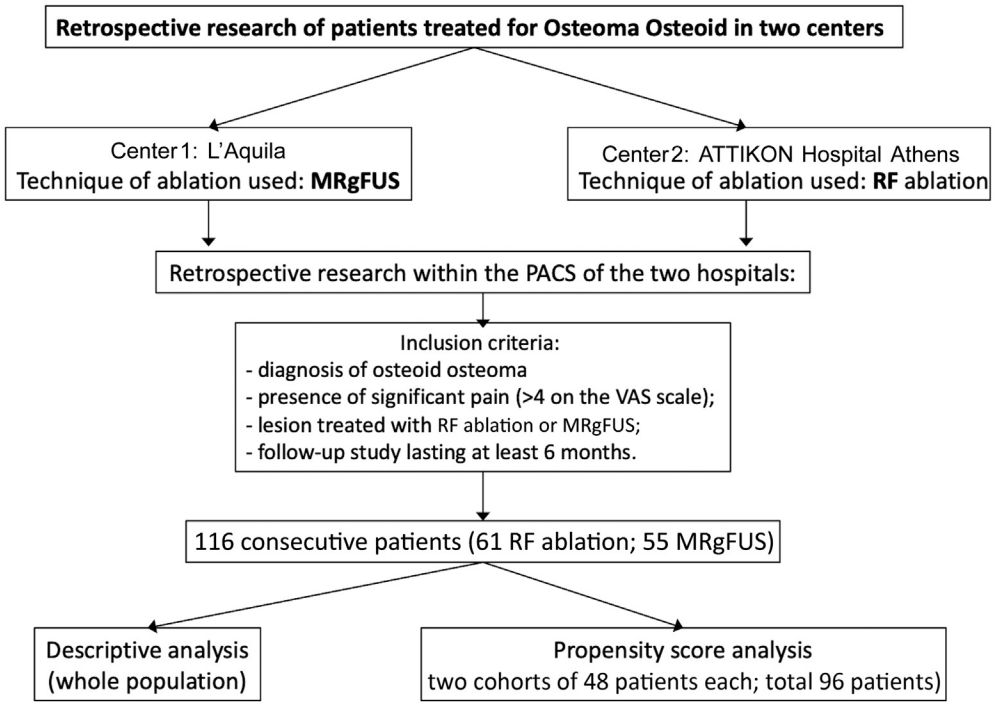

Figure 1. Flow chart summarizing the study design. MRgFUS = magnetic resonance-guided focused ultrasound; RF = radiofrequency; PACS = picture archiving and communication system; VAS = visual analog scale.

Prior to treatment, spinal anesthesia, locoregional nerve block, or general anesthesia were performed depending on the location of the lesion and the experience of the anesthetist.

RF ablation and MRgFUS procedures were performed as described in the literature (5,9,13,15). RF ablation procedures were performed under CT guidance; a bone biopsy needle was used to reach the nidus of the OO. After removal of the bone biopsy trochar, an RF needle electrode was coaxially positioned within the nidus. Energy was delivered to maintain a temperature of 90°C for 6 minutes. MRgFUS procedures were performed under MR imaging guidance. The patient was positioned on the MRgFUS table and multiple deliveries of US energy were administered until complete ablation of the lesion was achieved. To be suitable for MRgFUS treatment, however, the lesion had to be well exposed to the US beam penetration with an adequate acoustic window, the conical pathway located between the transducer (which generates the US beam and is in contact with the skin) and the target lesion. Patients with intervening metallic devices, scars, or other elements that may have hindered the transmission and focalization of the US beam on the lesion were excluded from treatment. Likewise, because MRgFUS is not able to treat lesions located deeply in the bone, such as intramedullary OOs or OOs covered by a thick layer of cortex or reactive bone, patients with lesions with these characteristics were also excluded from MRgFUS treatment.

The follow-up time was the same for both groups. The first clinical follow-up was fixed at 7–10 days after the procedure; further evaluations were fixed at 6 months and 1 and 2 years. However, any suspicion for recurrent symptomatology that arose between the scheduled follow-up studies prompted immediate evaluation.

Data Collected and Outcomes

Upon fulfilling the inclusion criteria, demographic data were collected together with information regarding the location and site of the lesions, pain before and after treatment (using the VAS), relapses of pain, and duration of follow-up studies. The treatment was considered to be successful when the VAS value dropped to 0 or 1 within 7–10 days. The other parameters were analyzed administering dichotomy tests (yes/no). Complications were recorded according to the Cardiovascular and Interventional Radiology Society of Europe classification system for complication reporting (16). A propensity score matching analysis was performed to evaluate the rates of clinical success, complications, and relapses.

Statistical Analysis

Continuous variables were presented as mean and standard deviation (SD) in parentheses, whereas categorical variables were presented as counts and percentages. For the comparison of variables deriving from normal distributions according to the Kolmogorov-Smirnov goodness-of-fit normality test, the unpaired Student *t* test was used to determine the significance of difference. Mann-Whitney and Dunn multiple comparison tests were used for the

Table 1. Demographic Characteristics of the Patients

Patients	No.	Age (range; mean; SD) y	Sex (F:M)	VAS Before (mean value; SD)	VAS After (mean value; SD)	Follow-Up (mean value; SD)
Whole population						
RF ablation	61	5–46; 19.3; 8.7	20:41 (32.8%:67.2%)	9.1; 0.9	0.01; 0.12	26.6; 17.9
MR-guided focused ultrasound	55	8–60; 23; 10	20:35 (36.4%:63.6%)	8.7; 0.7	0.45; 1.91	24.1; 12.6
Total	116	5–60; 21	40:76 (34.5%:65.5%)			
Propensity score matched						
RF ablation	48	6–46; 20; 8.9	15:33 (31.2%:68.8%)	8.9; 0.9	0.02; 0.14	24.4; 17.4
MR-guided focused ultrasound	48	8–46; 21; 7.7	17:31 (35.4%:64.6%)	8.8; 0.7	0.52; 2.04	25.3; 12.3
Total	96	6–46; 20.5; 8.3	32:64 (33.3%:66.7%)			

MR = magnetic resonance; RF = radiofrequency; VAS = visual analog scale.

nonparametric testing of continuous variables not deriving from normal distributions. Group proportions were compared using the chi-square test or the Fisher exact test in cases of small counts of events ($n < 5$). The propensity score matching model was developed using logistic regression analysis. The variables used for propensity score matching were gender, age, side (right or left) and location of the lesion, VAS score before the procedure, and follow-up period. The above-mentioned variables were chosen using a nonparsimonious approach. Statistical analysis was performed using the SPSS/PASW software (version 21.0, 2012; IBM, Armonk, New York) and the Prism statistical software (Graphpad Prism, version 5.0; San Diego, California). All statistics were 2-tailed. The threshold of statistical significance was set at $P < .05$

RESULTS

Table 1 summarizes the patient demographics and pain scores. Table 2 summarizes the lesion characteristics. The whole population included 116 consecutive patients (61 treated with RF ablation; 55 with MRgFUS). The mean age of the treated patients was 21 years, with no significant statistical difference ($P = .024$) between the RF ablation and MRgFUS groups and male predominance in both groups. The most common location was the femur, regardless of the group, followed by tibia. The localization in the inferior limb, from the acetabulum to the metatarsal bones, was observed in more than two thirds of the lesions. The MRgFUS group did not include spinal lesions. The mean values of pain before treatment in both groups were 9.1 (RF ablation, SD = 0.88) and 8.7 (MRgFUS, SD = 0.73), with no significant statistical difference ($P = .018$). After the treatment, a statistically significant ($P < .00001$) overall reduction in pain was recorded (0.01 vs 9.1; 0.45 vs 8.7, for RF ablation and MRgFUS, respectively). No statistically significant difference was recorded when comparing the mean values of both groups after the treatment ($P = .256$). Four cases of relapse were observed: 1 in the RF ablation group and 3 in the MRgFUS group. All relapses occurred in the tibia within 2 months following treatment. All of these patients underwent a second treatment with RF ablation, resulting in complete pain relief. Only one grade 2 complication was recorded in the RF ablation group, resulting in a transient mobility impairment lasting for 6 hours. The mean follow-up time was 26.6 months (SD, ±17.9 months) for the RF ablation group and 24.1 months (SD, ±12.6 months) for the MRgFUS group.

Following propensity score matching, a matched cohort of 48 patients was identified in each group (96 patients in total). Table 1 presents all data of the matched cohort. The mean age of the matched cohort was 20.5 years (SD, ±8.3 years) (RF ablation: 20.0 years ± 8.9 years; MRgFUS: 21.0 years ± 7.7 years; $P = .55$). Male predominance was again noted in both groups (female-to-male ratio was 32:64). The femur was again the most common location regardless of the group. The mean VAS values of pain before treatment were similar between the 2 treatment groups (RF ablation: 8.9 [SD±0.9] vs MRgFUS: 8.8 [SD±0.9]; $P = .762$). The median VAS score before treatment was 9 (interquartile range: 8–10) for the RF ablation group and 9 (interquartile range: 8–9) for the MRgFUS group. After the treatment, a statistically significant ($P < .0001$) overall reduction in pain symptomatology was recorded (RF ablation: 0.02 [SD±0.14] vs MRgFUS: 0.54 [SD±2.0]). According to the Dunn multiple comparisons test, the VAS values after the treatment were similar between the 2 groups ($P < .05$) (Fig 2). Complications (RF ablation: 1/48 [2.1%] vs MRgFUS: 0/48 [0%]; $P = .15$) and symptom relapse (RF ablation: 1/48 [2.1%] vs MRgFUS: 3/48 [6.3%]; $P = .15$)

Table 2. Lesion Characteristics

Lesions	Location	No.		Side (R/L)		Relapse	Complications
		WP	PSM	WP	PSM		
Radiofrequency ablation	Acetabulum	2 (3.3%)	2 (4.2%)	2/0 (3.3%/ 0.0%)	2/0 (4.2%/0.0%)	-	-
	Ankle/calcaneus/foot	3/1/1 (8.2%)	1/0/0 (2.1%)	3/2 (4.9%/3.3%)	0/1 (0.0%/2.1%)	-	-
	Femur (head/neck/diaphysis)	3/9/12 (39.3%)	2/7/11 (41.7%)	15/9 (24.6%/14.8%)	12/8 (25.0%/16.7%)	-	-
	Metatarsal bone	1 (1.6%)	1 (2.1%)	0/1 (0.0%/1.6%)	0/1 (0.0%/2.1%)	-	-
	Fibula head	4 (6.6%)	1 (2.1%)	2/2 (3.3%/3.3%)	1/0 (2.1%/0.0%)	-	-
	Tibia	17 (27.9%)	16 (33.3%)	6/11 (9.8%/18.0%)	6/10 (12.5%/16.4%)	1	-
	Humerus (head/diaphysis)	3/2 (8.2%)	2/2 (8.3%)	1/4 (1.6%/66.7%)	1/3 (2.1%/6.3%)	-	-
	Spine	3 (4.9%)	3 (6.3%)	1/2 (1.6%/3.3%)	1/2 (2.1%/4.2%)	-	1
	Total			30/31 (49.1/50.9%)	23/25 (47.9%/52.1%)		
MR-guided focused ultrasound	Acetabulum	1 (1.8%)	1 (2.1%)	1/0 (1.8%/0.0%)	1/0 (2.1%/0.0%)	-	-
	Ankle	5 (9.1%)	5 (10.4%)	3/2 (5.5%/3.6%)	3/2 (6.3%/4.2%)	-	-
	Elbow	2 (3.6%)	1 (2.1%)	0/2 (0.0%/3.6%)	0/1 (0.0%/2.1%)	-	-
	Femur (head/neck/diaphysis)	1/14/15 (54.5%)	1/11/12 (50.0%)	14/16 (25.5%/29.1%)	11/13 (22.9%/27.1%)	-	-
	Metatarsal bone/finger phalanx	2/1 (5.5%)	2/1 (6.3%)	1/2 (1.8%/3.6%)	1/2 (2.1%/4.2%)	-	-
	Humerus (head/neck/diaphysis)	1/2/2 (9.1%)	1/2/2 (10.4%)	3/2 (5.5%/3.6%)	3/2 (6.3%/4.2%)	-	-
	Tibia	9 (16.4%)	9 (18.8%)	5/4 (9.1%/7.3%)	5/4 (10.4%/8.3%)	3	-
	Total			27/28 (49.1%/50.9%)	24/24 (50.0%/50.0%)		

MR = magnetic resonance; PSM = propensity score matched; WP = whole population.

remained similar between the 2 study groups after propensity score matching. The mean follow-up time of the matched cohort was 24.4 months (SD, ±17.4 months) and 25.3 months (SD, ±12.3 months) for the RF ablation and MRgFUS groups, respectively ($P > .05$).

Because of the small number of events of treatment failure (3 RF ablation vs 1 MRgFUS), the treatment effect in the overall unmatched patient sample was also investigated by fitting a generalized linear model using treatment group (RF ablation vs MRgFUS), pain before treatment, age, sex, and side and location of the lesion as the independent variables and pain level after the treatment as the dependent (outcome) variable, while offsetting for the natural logarithm of follow-up time. There was a minor numerical difference in the pain levels after the treatment. The VAS score after the treatment was estimated to be 0.57 units ± 0.30 ($P = .064$), lower in the case of RF ablation compared with MRgFUS.

Data of 15 patients belonging to the MRgFUS cohort has been previously published in (17).

DISCUSSION

Prior to the introduction of IR, OOs were treated either surgically, with high rates of complications and low rates of success (6), or conservatively, exposing the patients to long-term treatments with nonsteroidal anti-inflammatory drugs. Currently, IR techniques ensure excellent results in terms of effectiveness, safety, and hospitalization times and costs. First reported in 1995 (12), RF ablation has been quickly established as the gold standard technique for the treatment of OO as an alternative to surgery. A recent systematic review (14), including studies conducted on a total of >1,700 patients, confirmed the excellent outcomes in terms of success (close to 100%) and safety (overall complication rates, approximately 2.1%). Recently, an innovative, less invasive technique, MRgFUS, has been investigated to ablate lesions located on the bone surface without damaging the soft tissues interposed between the skin and the lesion itself (13). The advantages of this technique include its minimal invasiveness, lack of radiation exposure, and possibility to perform intraoperative thermal monitoring. MRgFUS works with convergent US beams that pass through the soft tissues without effects on them while destroying only the target tissues. However, a severe limitation is that to obtain optimal heat concentration, the lesions must be located on the bone surface (17–19). In fact, a thick bone cortex and/or a periosteal reaction above the nidus may impair the delivery of a sufficient amount of energy. Ideal candidates for treatment are patients with cortical or periosteal OO (13). Despite compliance with this selection criterion, 3 cases of relapse occurred, most likely due to thick intervening bone, which resulted in incomplete ablations (17).

Unfortunately, it is not possible to define exactly how thin the bone covering the nidus must be to be suitable for

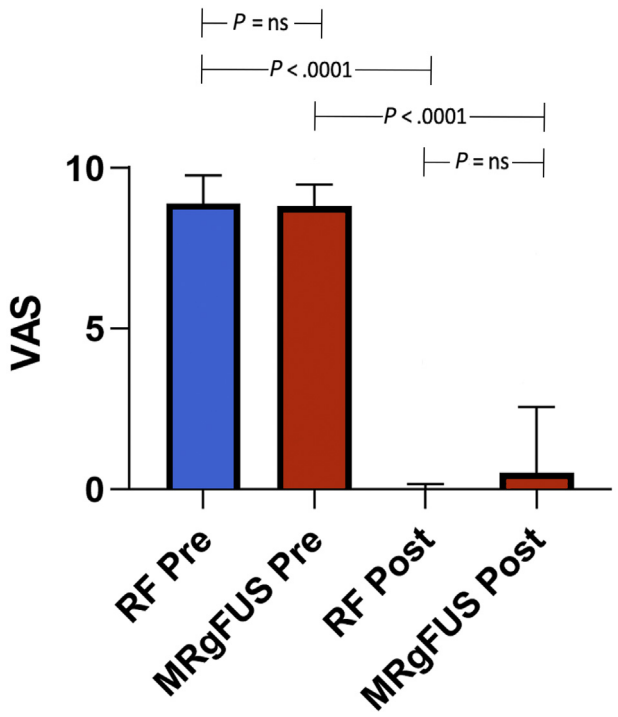

Figure 2. Box plot representation of pain assessment before and after the procedure according to VAS scores in the matched cohort.

treatment. Thermal energy produced by US can penetrate several millimeters into the bone; lesions covered by 2–3 mm of bone were successfully treated with MRgFUS (**Fig 3**) directly through an effective ablation of the nidus. Conversely, some treatments were impaired by the presence of thicker bone layers (although composed of immature and reactive bone) (**Fig 4**) (17). In these cases, to obtain an effective pain palliation with MRgFUS treatment, a large ablation of the periosteal surface (which is richly innervated) was required. This concept is also applied in the MRgFUS treatment of painful bone metastases (20). Delivering high levels of energy, however, increases the risk of damaging the surrounding structures (muscles, nerves, joints, etc) (13,21), whereas the direct delivery of energy via a needle positioned within the nidus (RF ablation) allows for an effective ablation using relatively small amounts of energy (**Figs 4**, **5a–c**). This was illustrated in the 3 cases of relapse after MRgFUS, wherein the second treatment, this time by RF ablation, resulted in the complete resolution of the symptomatology.

This study confirmed the effectiveness of RF ablation. Only 1 case of relapse (1.6%) was observed in a patient with a very large-sized nidus with a diameter of 1.8 cm. In the second successful ablation, a more aggressive approach was used and the RF electrode was placed in 2 different positions inside the nidus to obtain a larger ablation cavity. In contradistinction, if the lesion is suitable for MRgFUS, the nidus size does not represent a challenge, because it can be entirely covered with sonications under MR imaging guidance. One single transient complication was observed in the RF ablation group, wherein a slight and sublethal thermal injury to a nerve branch close to the lesion occurred, which completely regressed. In the RF ablation treatment, the temperature reached in the region of treatment can be monitored by means of a thermocouple positioned as a second needle. This device is frequently used to monitor a specific area of interest and not the whole area surrounding the region of treatment. In contrast, MRgFUS provides real-time thermometry (13) of the entire region of treatment that offers quite reliable measures of the temperatures reached within and around the target area. Moreover, MRgFUS allows the delivery of multiple small, discreet amounts of energy (sonications), which are gradually administered until the entire lesion is ablated. This limits the risks of damaging the sensitive structures around the lesion, and it is even possible to ablate only 2–3 mm^2 of tissue. Collateral damage may therefore be reduced using MRgFUS. No differences in the anesthesiology approach or hospitalization times were recorded between RF ablation and MRgFUS. The need to undergo MR imaging may represent a limitation to a claustrophobic patient, but the contributions of the anesthesiologist may facilitate the completion of MRgFUS procedures.

The results of this retrospective, 2-center study demonstrated that RF ablation and MRgFUS were equally safe and effective for the treatment of OO. Pain was significantly reduced in both groups, whereas complication and symptom relapse rates were similar in both study groups. The long follow-up period (2 years) allowed for the capture of relapses. These findings were observed both in the overall and propensity score–matched cohorts. The present study adds to the growing number of case series showing that both percutaneous RF ablation and MRgFUS of OO may be considered efficacious and safe techniques in terms of symptom control (22–26). MRgFUS is a relatively new technique that is able to treat superficial lesions without the risk of infection or other complications related to the physical damage caused by needles passing through the tissues. Furthermore, it ensures a more accurate intraprocedural control of the treatment owing to the real-time monitoring of the temperature reached. Conversely, RF ablation is more versatile and does not present limitations related to the lesion position; in fact, the accuracy and experience of the operators were sufficient to reach all targeted lesions, including the spinal lesions. However, due to proximity to the nerve roots, MRgFUS has not received approval for treatment of spinal lesions because of the theoretical risk of severe thermal damage to bone and nerve roots.

This study has several limitations. The nonrandomized design may have led to selection bias, partially corrected by the propensity score analysis; the retrospective design may have resulted in some missing data; and the relatively low number of patients included may have limited the validity of

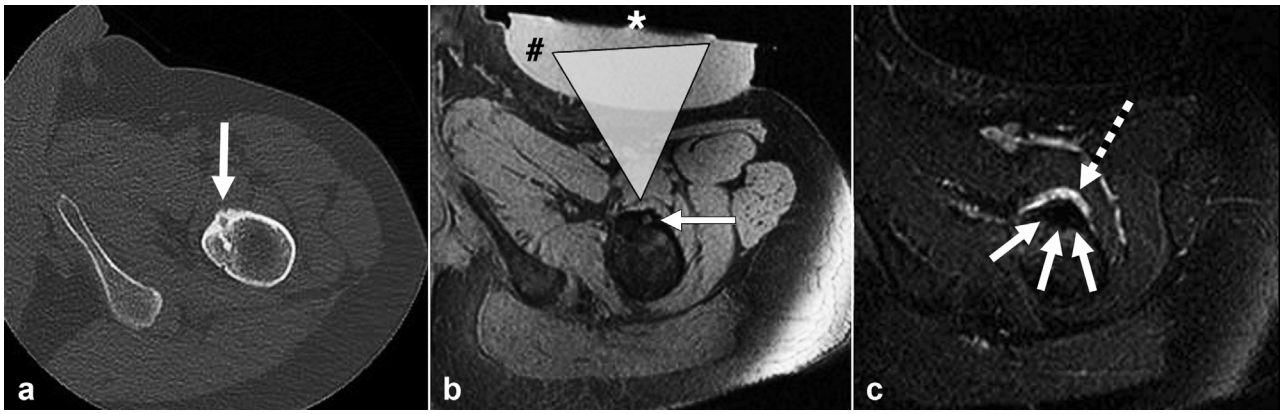

Figure 3. Cortical osteoid osteoma of the femur. (**a**) Axial CT image of the lesion (arrow). Note the thin layer of bone bordering the lesion. (**b**) Intraprocedural image during MRgFUS treatment: * marks the therapeutic US transducer, # marks the water bag that creates space between the transducer and the lesion to transmit and focus the US beam, the gray triangle represents the US beam, and the white arrow indicates the nidus. (**c**) Axial MR imaging after treatment (contrast enhanced T1-weighted image with fat suppression) showed the absence of contrast enhancement in and around the nidus (solid arrows), confirming successful ablation. Dashed arrow indicates the reactive phenomenon on the bone surface.

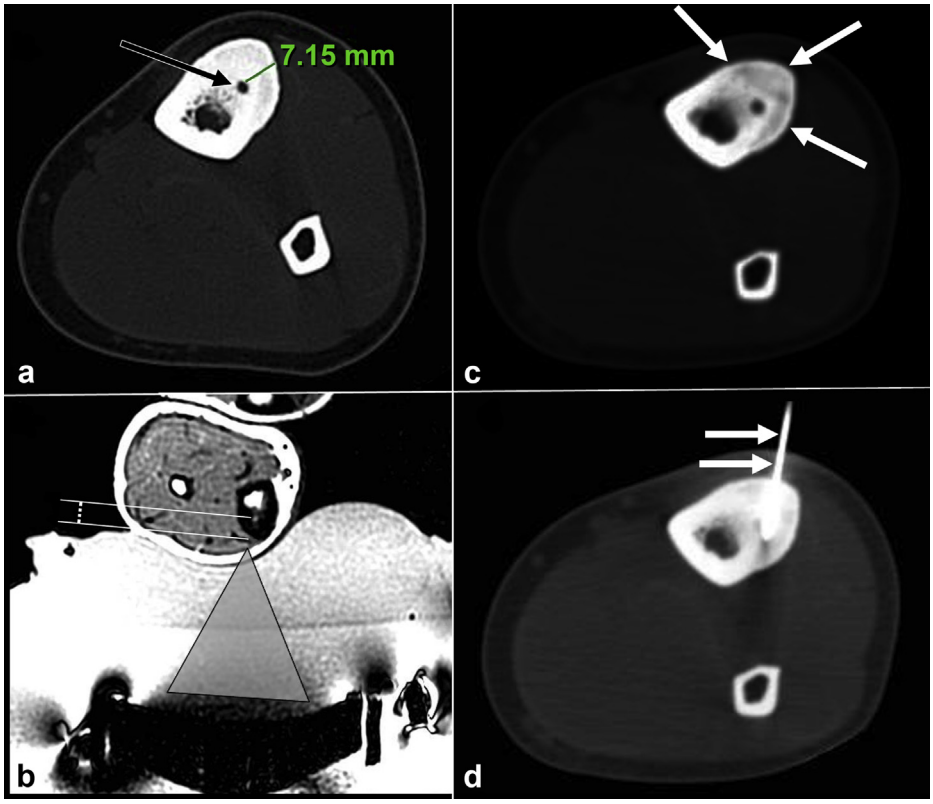

Figure 4. Osteoid osteoma of the tibia. (**a**) Axial CT image of the lesion (black arrow). Note the thickness of the surrounding bone reaction (7.15 mm). (**b**) Intraprocedural image during MRgFUS treatment. The gray triangle represents the US beam, the parallel line calipers represent the bone thickness needed to penetrate to treat the nidus. (**c**) Axial CT image after treatment showed the "ring," the interface between ablated and non-ablated bone tissue. Note that the nidus is not within the ablated area. (**d**) Axial CT image of subsequent RF ablation treatment with the probe (arrows) within the nidus.

the statistical analysis, whereas the nonparsimonious model used in this study could be less generalizable to other data sets. Another limitation, the maximum threshold of bone thickness protecting the nidus, which is crucial when choosing between MRgFUS and RF ablation, remains to be defined. These data were intentionally omitted for 2 reasons: first, the 3 cases of relapse were probably too low a number to be of any statistical relevance; second, besides thickness, bone density (mature bone cortex or periosteal reaction) is significant in the evaluation and selection of the lesions. These questions will need to be addressed in future studies based on a larger cohort of patients.

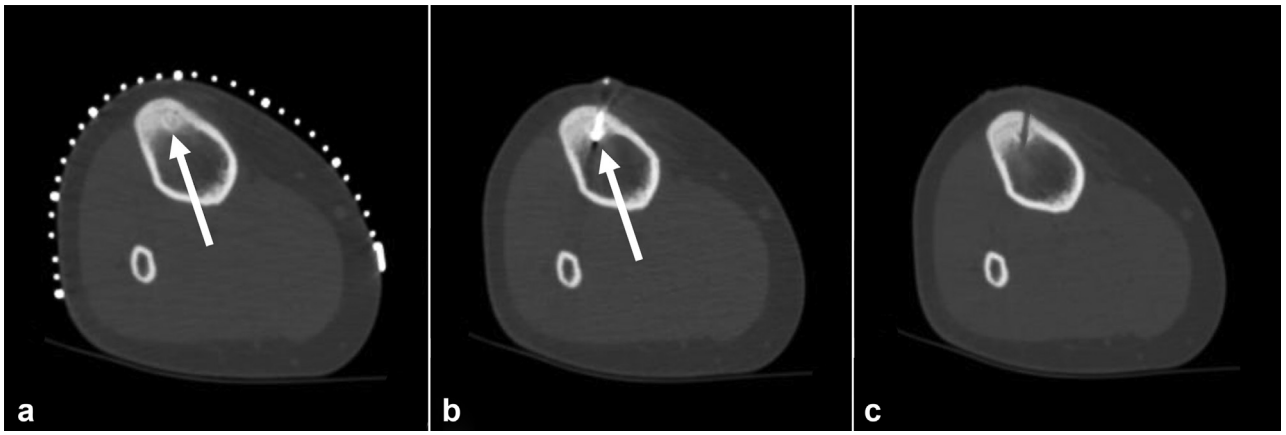

Figure 5. Subcortical osteoid osteoma of the tibia. (**a**) Axial CT image of the lesion (arrow). (**b**) A trocar and bone biopsy needle were used for access. After biopsy, a coaxial RF probe was inserted into the nidus (arrow). (**c**) Axial CT image immediately after ablation depicted the access route cortical defect through the nidus.

In conclusion, RF ablation is confirmed as a safe and effective technique for ablation of almost all OOs, regardless of their site. MRgFUS has stricter anatomical selection criteria, limiting its application. For patients selected according to appropriate criteria, however, the rate of effectiveness is comparable to that of RF ablation. Furthermore, for lesions that are on the bone surface, MRgFUS treatment has the advantages of less invasiveness and ability to treat larger areas.

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