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Osteoid osteoma treated with radiofrequency ablation in non-operating room anesthesia. A different way of approaching ablative therapy on osteoid osteoma

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Abstract. – OBJECTIVE: The purpose of this study is to verify the effectiveness and complications occurrence of radiofrequency ablation (RFA) in the treatment of osteoid osteoma (OO) in non-operating room anesthesia (N.O.R.A.).

PATIENTS AND METHODS: From 2014 to 2017, 61 patients affected by OO (40 men and 21 women) with an age of 20.7 years on average (range, 4-51 years; 12 patients aged 20 years or younger) underwent computed tomography-guided percutaneous radiofrequency ablation (RFA) in N.O.R.A. (Non-Operating Room Anesthesia). Lesion sites treated were: femur (27), tibia (22), pelvis (2), talar bone (3), distal radius (1), and humerus (6). Mean follow-up time was 36 months. In each case, anesthesiologic support followed a new protocol (N.O.R.A. protocol), approved by our Institute. Primary success rate, complications, symptom-free intervals, and follow-up results were evaluated.

RESULTS: Pain relief (evaluated with Visual Analogue Scale – VAS) was significant in 97% of patients; it disappeared within 24 hours of the procedure in 44 patients, within 3 days in 10 patients, and within 7 days in 7 patients. After 6 months of observation time, 60 of 61 patients were successfully treated and had no more complaints. In 2 patients, two major complications were found: infection of the site treated, healed with antibiotics, and a nerve lesion, healed with steroid therapy. No other complications were observed.

CONCLUSIONS: RFA is a highly effective, efficient, minimally invasive and safe method for the treatment of OO following N.O.R.A. protocol.

Key Words:
Osteoid osteoma, Radiofrequency ablation, Interventional radiology, Follow-up, Non-operating room anesthesia, Conscious sedation.

Abbreviations

ASA: American Society of Anesthesiologists; CT: Computed tomography; MRI: Magnetic resonance imaging; NIBP: Non-invasive blood pressure; N.O.R.A.: Non-operating room anesthesia; OO: Osteoid Osteoma; RFA: Radiofrequency ablation; RF: Radiofrequency; VAS: Visual Analogue Scale.

Introduction

Osteoid Osteoma (OO) is a slowly growing benign bone tumour. First described in 1935 by Jaffe[1], it has a major incidence in male children and young adults, but mature skeletons may also be involved. It accounts for approximately 10% of benign bone tumours and mainly affects long bones diaphyses (50% affects femur or tibia)[2,3].

Osteoid Osteoma is typically single and small (usually less than 1.5 cm) lesion characterized by a nidus of osteoblasts surrounded by sclerotic bone, endowed with nerve and blood supplies.

The main symptom is bone pain, which is discontinuous at the beginning and becomes constant if not treated. The pain is not related to physical exercise or movements, and it has a

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typical nocturnal exacerbation which may cause sleep deprivation[4]. Less common manifestations include: growth limitation, bone deformity, and painful scoliosis[5].

OO generally responds well to salicylates or other non-steroidal anti-inflammatory drugs (NSAIDs). Some Authors believe that pain might be due to prostaglandin release, which could explain the relief provided by prostaglandin inhibitors[6]. However, long-term pain management is unacceptable for most patients because relief is often inadequate and gastrointestinal complications can occur. Computed tomography (CT) is the gold standard for diagnosis and localization of OO.

Nowadays, percutaneous radiofrequency ablation (RFA) is the gold standard treatment and it is associated with low rate of complications and shorter hospitalization. Surgery is the second treatment option, but it is frequently associated with major morbidity and a prolonged hospitalization. OO is a small benign but painful lesion with specific clinical and imaging characteristics[7]. From a histological point of view, OO is a benign osteoblastic lesion characterized by a round or oval nidus[7] (less than 1.5 cm in diameter) of osteoid tissue (or even mineralized immature bone) surrounded by sclerotic reactive bone. The typical radiological finding is an intra-cortical nidus surrounded by fusiform cortical thickening and bone-marrow edema. There is a wide variety of diagnostic imaging techniques used to detect OO[4]. Their role is to identify and accurately localize the tumour before any surgical or percutaneous treatment (surgical excision, laser treatment or RFA).

At X-ray the detection of the lesion depends on the suffering body region. For example, the complex anatomy of the spine makes the detection and localization of a radio-lucent nidus much more difficult than in a long bone.

CT is the most commonly used diagnostic technique and also the most sensitive (96.4%). It is considered the gold standard for radiological diagnosis of lesion and detection of the nidus. OO is typically showed as a low-attenuation nidus with central mineralization and different degrees of perinidal sclerosis. Indeed, reactive sclerosis ranges from soft cancellous sclerosis to extensive periosteal reaction with new bone formation. An area of high attenuation, which represents mineralized osteoid, may be seen centrally[8].

Bone scan scintigraphy may be useful for confirming the diagnosis. The sensitivity of bone scan scintigraphy for detection is virtually 100%[9], but it has a very low specificity. The typical scintigraphy features in OO is the "double-density sign" on bone scan. There is a central focus of very high bone turnover corresponding to the nidus ("hot area") surrounded by a larger area of less-intense radio-tracer uptake ("cold area")[10]. Three-phase scintigraphy is used in selected cases for differential diagnosis between OO and inflammation. It provides a map of distribution of the Technetium within the skeleton, highlighting the degree of osteoblastic activity in different skeletal sites, through chromatic variations which are proportional to local radioactivity. Inflammation and OO have different type of osteoblastic activity and – as a consequence – different chromatic variations at three-phase scintigraphy[10].

At Magnetic Resonance Imaging (MRI) imaging, the nidus can have a very heterogeneous appearance. Most tumors have low signal intensity on T1-weighted images and different signal intensity on T2-weighted images, depending on vascularization and presence of calcification in the tumor. The use of gadolinium can help detection of OO more frequently than non-enhanced MR imaging. Indeed, the nidus could have strong enhancement after administration of gadolinium. Furthermore, MR imaging is sensitive in detecting non-specific changes – such as edema in adjacent bone marrow and soft tissue – which may have a misleading aggressive appearance.

As far as treatment options are concerned, surgical excision of the nidus is curative and provides symptomatic relief. Despite being successful in 88-100% of cases, surgery has many disadvantages such as difficult localization of the lesion intraoperatively, need of prolonged hospitalization, risk of postoperative complications ranging from an unsatisfactory cosmetic result to fracture.

Gold standard treatment is RFA. Radiofrequency ablation consists of inducing necrosis in OO through the use of thermal coagulation of the nidus. It is the best non-invasive treatment for OO but the interventional radiologist needs CT, MRI or fluoroscopy to perform the procedure. CT is the most available radiological guide for the operator; it provides high resolution of bone structures with rapid frame rate and low costs. Purpose of this study is to verify the effectiveness and complications occurrence of RFA in the treatment of OO in non-operating room anesthesia (N.O.R.A.).

Patients and Methods

Patients

From January 2014 to November 2017, 61 patients affected by OO were treated with RFA. The mean follow-up was 6 months. The diagnosis was clinical and radiological: history of pain (typically with nocturnal occurrence, with relief after non-steroidal anti-inflammatory drugs administration) and characteristic morphological features detected in diagnostic imaging (CT and/or MRI). We did not perform a biopsy during the procedure and – as a consequence – we did not have any histological analysis.

An experienced orthopedic surgeon had evaluated all patients before treatment.

The cohort of patients consisted of 61 patients affected by OO (40 men and 21 women) with a mean age of 20.7 years on average (range: 14-51 years old). All the patients were treated with CT-guided percutaneous RFA (RF generator: RITA 1500 system – AngioDynamics Queensbury NY USA). This technique uses a 150-250 Watt generator to create an alternating current that oscillates between the radiofrequency (RF) electrode (cathode) inserted in the tumour and a neutral electrode on the body surface (unipolar system). While the current oscillates in this circuit, frictional processes at the tip of the RF electrode create heat (Joule effect), destroying adjacent tumour tissue. The associated dehydration in the target tissue leads to an increase of tissue resistance during ablation thus limiting energy application. As a consequence, ablation area has a limited expansion.

Lesion sites were in the cortical side of the femur (27 cases), tibia (22 cases), pelvis (2 cases), talar bone (3 cases), distal radius (1 case), and humerus (6 cases). Mean follow-up was 6 months.

None of the patients had previously undergone surgery for the lesions.

The procedure was performed on a 64-rows CT scanner in aseptic conditions by an interventional radiologist, and an anesthetist.

Non-Operating Room Anesthesia (NORA) Requirement and Protocol

Anesthetic support followed N.O.R.A. protocol. From an anesthetic point of view, all patients included in the study, were classified as ASA I (patient in good condition and without comorbidity), as a consequence they were available for anesthetic procedures in a non-operating space.

Anesthetic preparation followed the international guidelines of NORA approved for oncological patients.

Pre-Anesthesia Evaluation

The anesthetist analyzed ECG and coagulation and laboratories tests, as well as the clinical history of all patients. Anti-aggregating and anti-coagulant therapy were suspended, as appropriate. Patients were asked to fast 2 hours for clear liquids and 6 hours for solid meals before treatment.

Intra-Procedural Management

Before beginning treatment, all patients were monitored for: SaO_2, ECG, cardiac and respiratory frequencies, non-invasive blood pressure (NIBP). The anesthetic protocol used in our center is based on the association of a local anesthesia on the puncture site (performed by an Interventional Radiologist), and an intravenous conscious sedation. Intravenous conscious sedation protocol administered during the procedure, consisted of Midazolam 2-2.5 mg as initial dose, followed by titrated dose of 1 mg; Remifentanil with continuous infusion ranging from 0.025 γ/Kg/min until a maximum of 0.12 γ/kg/min; O_2 3 L/min.

Monitoring vital parameters by oximetry, electrocardiogram, cardiac and respiratory frequency is mandatory.

Radio-Frequency Ablation (RFA) Procedure

Patients were informed of further alternative treatments and they signed the informed consent. Depending on the localization of the lesions, patient was positioned on the CT table in a prone, oblique or supine position.

After the positioning of radiopaque cutaneous markers, a new CT scan was performed on the site of interest (with a range of 10 cm cranial and caudal to the lesion), to ensure the most suitable percutaneous access. The best approach is considered when the needle is perpendicular to the cortical surface of the bone providing the shortest path through the bone, looking out to avoid neuro-vascular structures (Figure 1a, b, c).

After track planning, disinfection of the skin was performed and intradermal and bone surface local anesthesia on site of access (Carbocaine, 2%, 10 ml) was administered. Then, the interventional radiologist performed percutaneous needle insertion.

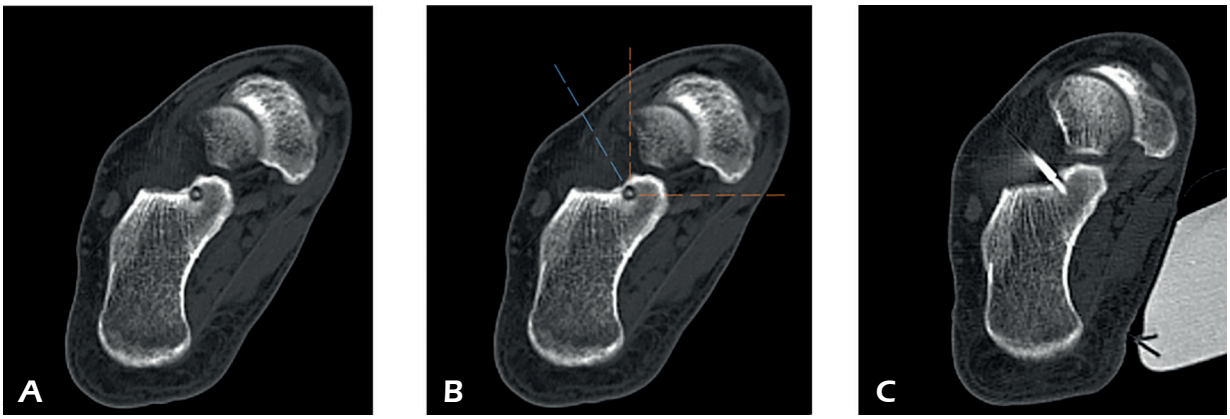

Figure 1. RFA for a 6 mm diameter osteoid osteoma of the right calcaneus **A,** An axial computed tomography (CT) image shows the nidus surrounded by sclerosis (*arrow*). **B, C,** Axial CT image shows the correct approach to the lesion (*blue lines*). The electric needle is inserted at the center of the nidus along the shortest distance through the bone paying attention to neurovascular structures.

An 11 G trocar (Teflon RITA) was inserted inside the needle toward the OO nidus. Spot CT images were obtained during insertion so as to check appropriate positioning (Figure 2a).

When the co-axial needle together with the trocar were inside the OO nidus, the trocar was removed and an RF-electrode inside coaxial needle was inserted (Figure 2b). If the cortical bone

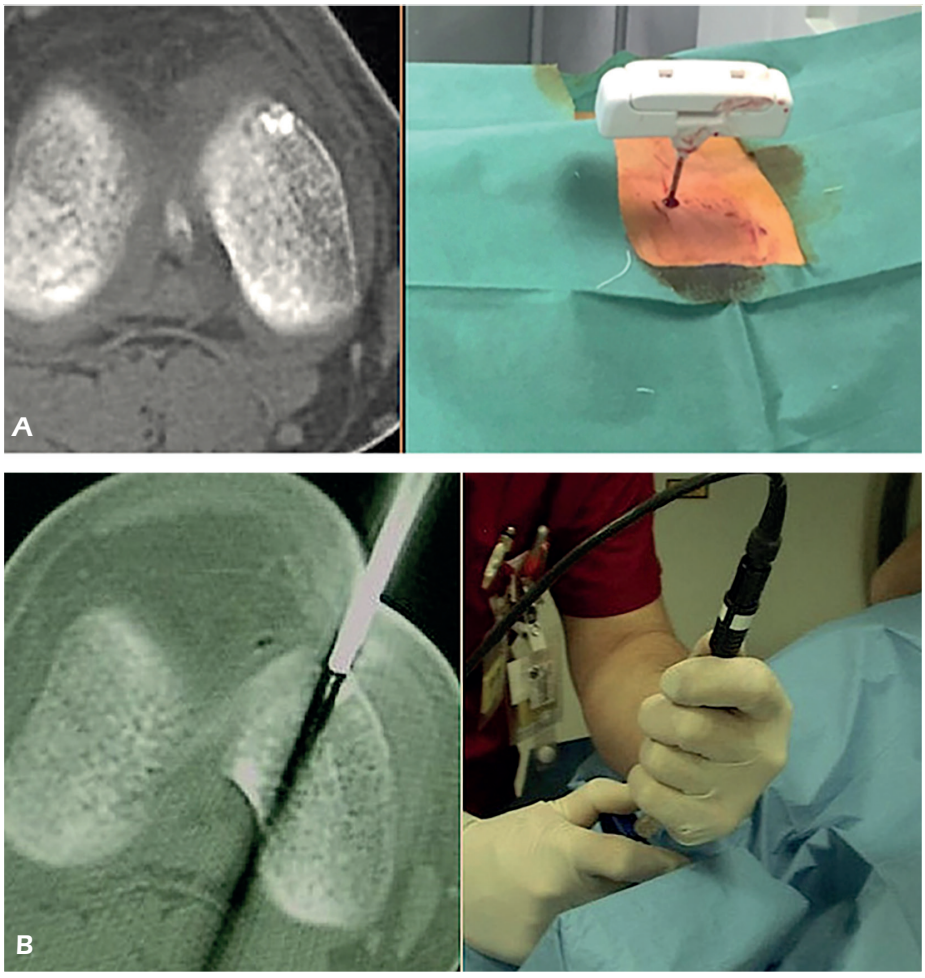

Figure 2. RFA technique used in osteoid osteoma. **A,** Co-axial needle with the trocar is inserted inside nidus. **B,** Insertion of the electrode through the trocar and into the lesion.

was too strong to be pierced, we used a drill to reach the OO nidus (12 cases). Finally, the RF-electrode was connected to the RF generator (Figure 3a, RITA 1500X, AngioDynamics, Inc., USA). According to the tumor size and location, one or more RF electrodes with a single or multiple hook needle (Figure 3b) were used.

Thermal ablation was obtained with a temperature of 90°C for a total time length of 4-10 min. At the end of ablation, the interventional radiologist removed the electrode and a local anesthetic was administered through the co-axial needle as pain relief.

CT scan was performed at the end of procedure, (15 cm cranial and caudal to the lesion) (Figure 4a, b, c).

Patients were discharged 6 hours after the treatment, unless pain was too severe. In collaboration with orthopedics, clinical and diagnostic follow-up was planned both one month and six months after the procedure. All the patients could be mobilized at the end of treatment, whereas pain relief was complete two weeks later on average.

The present study was planned in accordance with the Ethical standards of the responsible Committee on human experimentation and conformed to the principles of the Declaration of Helsinki.

Statistical Analysis

Statistical analysis was used to assess any significant difference in number of reduced, increased, and stable VAS in a homogeneous sample. A Statistical analysis (*t*-test) was conducted for all cases that showed a reduction of VAS to compare the data at the beginning of the procedure (before treatment) with data at the discharge (8 hours after treatment) and at the first clinical follow-up (6 months after treatment). Data were analyzed with SPSS (SPSS v22.0, IBM, Armonk, NY, USA).

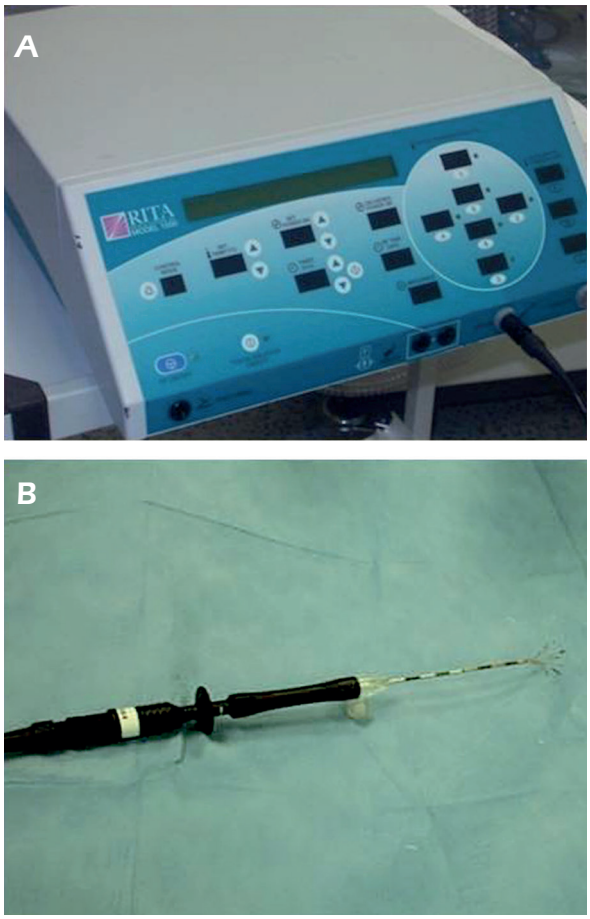

Figure 3. Device RFA specifics **(A)**. RF generator RITA 1500 system (Angiodinamic Queensbury NY, USA). **B,** Electric needle multiple hooks.

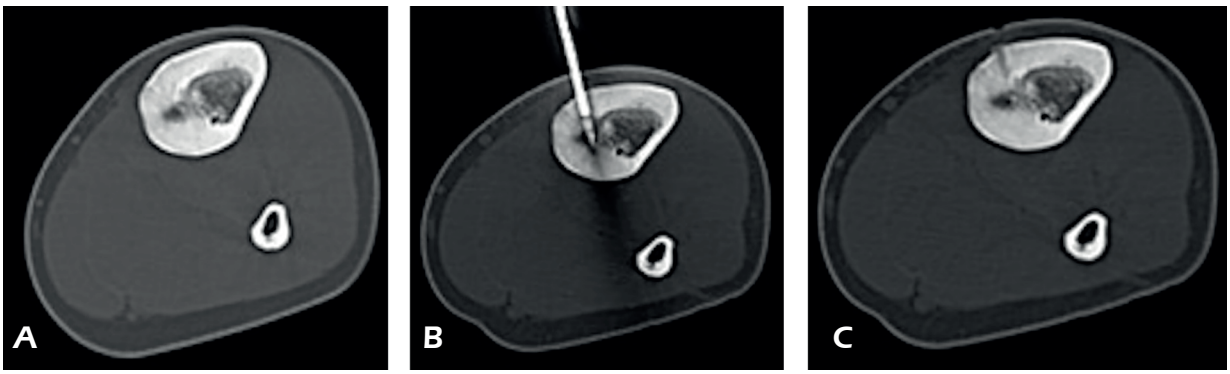

Figure 4. RFA for a 16 mm diameter osteoid osteoma of the left tibia. **A,** An axial computed tomography (CT) images shows an ovoid lesion with central calcification and surrounding sclerosis. **B,** CT scan shows the position of the electrode (*arrow*) within the nidus. **C,** Control CT scan at the end of the procedure.

All data were included in a dedicated electronic database, periodically checked. It was considered statistically significant a p-value < 0.05. Other values in the manuscript have been evaluated with a descriptive analysis of the results, without adopting any statistical test.

Results

All 61 procedures did not have any technical or equipment failures. The procedure time was after about 50 to 80 min on average, depending on the site of lesion and thickness of the sclerosis around the OO nidus.

We evaluated our treatment with Visual Analogue Scale (VAS, 0 represented "no pain" and 10 represented "terrible pain") and considered as a clinical response the complete symptoms relief (VAS 0), and a failure the reduction of less than 50% of the initial VAS score.

In our case series, 60 of 61 patients had complete symptoms relief 24-48 hours after treatment (VAS 0, $p < 0.05$), with 98.4% of primary success.

1 patient only (1.6% of our cases) did not have symptoms relief four weeks after ablation therapy (VAS 7 before treatment, VAS 5 after treatment). In this specific case, we decided to treat the OO again with the same RFA procedure, achieving clinical success (VAS 0). In conclusion, all of the patients achieved complete pain relief without any physical activity restriction after RFA (100% of clinical success).

We did not report any intraoperative or postoperative major complications related to the analgesic protocol adopted. Patients showed a physical rehabilitation (as far as balance and mobility were concerned) faster than patients treated with general anesthesia. In only 4 patients we reported nausea, resolved during the next 12 h. The clinical results of the anesthetic protocol adopted are extremely satisfactory and encourage its use.

Before discharge, each patient was monitored for bleeding, swelling, burn, neurovascular complications and other treatment-related problems. Only two RFA related major complications occurred, in two different patients.

In the first case, the orthopedic surgeon reported an infection of the percutaneous site access in a patient with low compliance during and after the procedure. Infection was treated with antibiotic therapy and successfully healed in three weeks (Figure 5 a, b, c).

In the second case, a patient affected by OO of the proximal radius, developed a reversible neurological lesion. This complication was probably due to the proximity of the anatomical site treated to the numerous nervous structures.

Neurological lesion healed in 3 months with steroids and occupational therapy. No anesthesia-related complications and no fractures of weight bearing bones or other delayed complications occurred.

Following the scientific protocol accepted by the Ethics Committee and subscribed by all the patients, a clinical and radiological follow-up was performed in order to confirm the clinical success. As a consequence, patients were evaluated with MRI six months after the procedure. In case of absolute pain relief (evaluated with VAS) and no recurrence in the radiological exam, it was classified as a complete response to RFA therapy. Patients treated had 0% long and short-term recurrence.

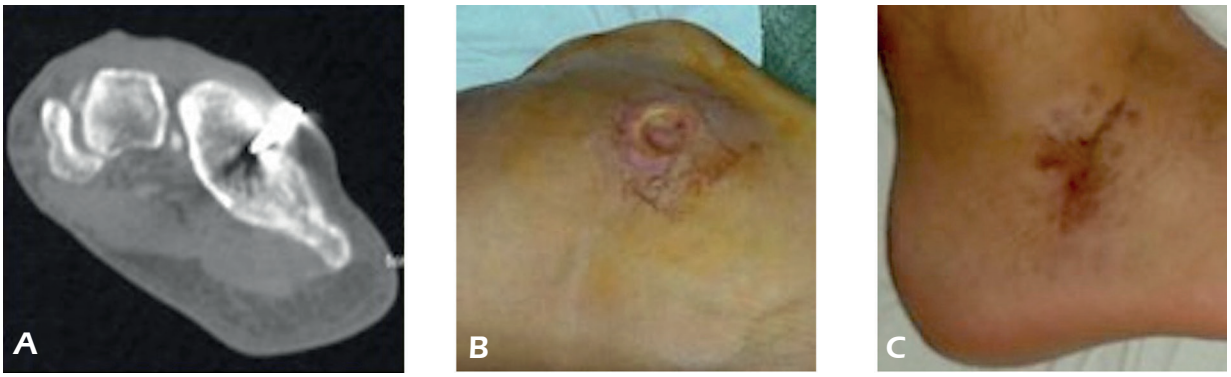

Figure 5. Infection of the percutaneous site access. **A,** Position of the electrode during procedure. **B,** Infection of the site of needle puncture 2 weeks after procedure. **C,** 1 month control shows the infection healed after 3 weeks with antibiotic therapy.

Discussion

First described by Rosenthal et al[8] in 1992, a great number of researchers have demonstrated that RFA is a safe and effective treatment for OO[11].

Computed tomography-guided percutaneous RFA, is minimally invasive, safe, widely available, and repeatable, with reported success rates ranging from 80% to 100%[12-14]. Furthermore, its cost is significantly lower than surgery due to the reduced hospital stay.

In our case load, clinically successful treatment was performed in 98.4% of cases (60/61). This result is not different from the results reported by many other researches[11,15,16], that achieved a very high efficacy rate (ranging from 74-100%).

In 1 patient only with no pain relief after 4 weeks, the second RF treatment was clinically successful. A similar case occurred at Asayamaet et al[11] in one patient, 4 months after the RF treatment. They reported a successful treatment in 87.5% of cases of OO localized on lower bone extremities.

In the study of Çakar et al[17], they had the clinical success of 100%, without any complications but with a limited number of patients and with a short follow-up period.

Rosenthal et al[18] reported good results in a series of 557 patients and recommended modifications to electrode parameters, duration of ablation with regard to the size, and morphology of the lesion.

Roger et al[19] demonstrated satisfactory results in 14/16 patients treated with percutaneous CT-guided excision. The two failures were attributed to the proximity of the lesion to the articular margin and extensive periosteal reaction preventing access. Sans et al[20] demonstrated an effective rate of 84% at 3.7 years postoperatively follow-up. Muscolo et al[21] reported superior outcomes of CT-guided minimally invasive surgery rather than open surgery. Peyser et al[22] and Neumann et al[23] concluded that CT-guided percutaneous RFA of OO is a safe, effective, and minimally invasive procedure with a high success rate and no recurrence.

However, RFA is not free from complications. Skin burns may occur with superficial procedures. Extreme precautions should be taken in case of spinal OO to avoid neural injuries. Moreover, RFA could not be performed in the presence of a lesion which is near to neurological structures (distance < 5 mm)[23,24]. Rimondi et al[25] described unusual cases of cellulitis, bleeding or infection of the skin entry site and intraoperative vasomotor instability[26].

In our study, the two major complications occurred, were treated successfully with no consequences. In all the patients treated, furthermore, night pain had relief in 48 hours after the procedure.

According to literature, the failure rates were low (< 3%) and complications were not concerned with procedure, but depended on operator mistakes, avoidable by a more careful postoperative management.

Together with the study of Mylona et al[24], this is the first study in literature where an analgesic/anesthetic protocol that does not require general anesthesia or deep sedation is applied from the beginning of the procedure. In this study, we applied a new concept of "dynamic anesthesia" that starting from a light sedation evolves during the same procedure according to the different phases of the treatment. This protocol provides an active role of the anesthetist in the non-operating room. The anesthetist interacts not only with the patient (monitoring his vital parameters), but also with the interventional radiologist, applying a short deeper sedation before the most painful stages of treatment. Our protocol did not cause any intra and post-procedural complications. On the other hand – thanks to a rapid mobilization of the patient – we registered a reduction of the typical side effects of general anesthesia (such as nausea or vomiting). As a consequence, the N.O.R.A. protocol has as a direct consequence on the hospitalization with a lot of advantages from an economic point of view also.

In conclusion, physician and surgeon should consider that admission time in the case of RFA treatment of OO is about 12 hours on average, a significantly shorter time range compared to conventional surgery that considers 72 hours of hospitalization on average.

Conclusions

RFA is a minimally invasive treatment option for patients affected by OO. This interventional radiological procedure provides excellent clinical results with a low complication rate. Patients with recurrences should be treated with a second session of RFA treatment rather than with surgical resection. The results of our study are not statistically different from the results

reported by many Authors, but we followed a different anesthetic protocol that reduces the use of general anesthesia. The anesthetic strategy adopted in N.O.R.A. reduces the risks of general anesthesia, providing adequate comfort levels (thanks to anxiolysis, amnesia and conscious sedation) and analgesia for the patient, and maintaining a good level of cooperation with the interventional radiologist during the different stages of the procedure. As a result, the protocol described avoids a lot of side effects of general anesthesia and reduces the hospitalization and rehabilitation period of patients.

In conclusion, we suggest that interventional radiologists should start performing RFA treatment together with the technical support of an anesthesiologic team, avoiding intubation and general anaesthesia and reducing the intraoperative and postoperative time.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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