"IMAGE GUIDED RADIO FREQUENCY ABLATION OF BONE TUMOURS"

Dissertation submitted to

THE TAMIL NADU Dr.M.G.R. MEDICAL UNIVERSITY

in partial fulfillment of the requirements of

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APRIL 2017

BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled "IMAGE GUIDED RADIO FREQUENCY ABLATION OF BONE TUMOURS" is a bonafide original work of Dr.N.SUDHIR under the guidance of Dr.K.GOPINATHAN, M.D., D.N.B., Associate Professor, Department of Radiodiagnosis, Govt Kilpauk Medical College & Hospital, Chennai -10 in Partial Fulfillment of the regulations of the Tamil Nadu Dr. M.G.R Medical University for M.D RADIO DIAGNOSIS BRANCH VIII examination to be held in April 2017.

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"IMAGE GUIDED RADIO FREQUENCY ABLATION OF BONE

TUMOURS" was prepared by me at the Govt Kilpauk Medical College

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CONTENTS

SL.NO	TITLE	PAGE
1	Introduction	1
2	Aims and objectives	3
3	Review of Literature	4
4	Materials and Methods	38
5	Cases	47
6	Statistical Analysis and Results	59
7	Discussion	76
8	Conclusion	84
9	Bibliography	
	Annexures	
	Abbreviations	
	Ethical Committee approval	
	Plagiarism	
	Proforma	
	Consent Forms	
	Master Chart	
1	1	1

INTRODUCTION

Bone neoplasms has been routinely treated by either chemotherapy or radiotherapy/surgery. Current practice, in treatment of benign neoplasms like osteoid osteoma is inclining towards minimally invasive procedures like chemo or thermo ablation (1).

In ablative procedures, neoplastic cells are cooked to temperatures more than 60°C and destroyed completely. This can be achieved by radiofrequency (RF) energy, microwaves or laser therapy. Cryotherapy is also a form of ablation technique in which neoplastic cells are destroyed by freezing to temperature less than - 20°C(1). MR guided focused ultrasound is an advanced non- invasive radiation free modality, sharp focus of ultrasound waves targeted towards lesions eventually leads to thermo-ablation (> 57°C).

Image guided radio frequency ablation (RFA) is leading among all minimally invasive procedures in Skeletal oncology. Because, it's a safe, cost effective & less morbid treatment tool for bone lesions. It is relatively newer technique with better success.

Success of procedure usually depends upon image guidance. CT leads over other imaging modalities like ultrasound or magnetic resonance imaging in guidance. Because, images are acquired faster with better bone resolution (1).

Radiofrequency ablation is a recently developed treatment modality in which neoplasms in liver, lung & bone can be effectively treated with less morbidity (2).

Benign bone tumours like osteoid osteoma and osteoblastoma can be completely cured using RFA. It is also effective in alleviating pain in malignant lesions like metastasis (2).

Osteoid osteoma is an extremely painful benign bone lesion typically smaller than 1.5cm (2), with pain getting worsened in night and relieved by salicylates which has predilection for young boys. Image guided radiofrequency ablation is the current treatment modality of choice in treating osteoid osteoma with 95 to 100% cure rate (1,2).

Our study is focused in evaluating the technical and therapeutic efficacy of radiofrequency ablation of osteoid osteoma at our institution, to assess the technical limitations and post procedural complications.

AIM

To evaluate the therapeutic efficacy of Image Guided Radio frequency ablation in benign bone tumour osteoid osteoma.

OBJECTIVES:

The objectives of this study were,

- 1. To assess the technical success in radiofrequency ablation procedure.
- 2. To compare the Pre- operative visual analog score with Post procedure visual analog score at one week and four weeks and, assessing the clinical success rate.
- 3. To correlate the nidus size and histopathological report.
- 4. To compare pre-operative imaging with post procedure follow up imaging at 4 weeks.

REVIEW OF LITERATURE

OSTEOID OSTEOMA:

Jaffe in the year 1935 (3,12) described "core" or "nidus like focus" this later termed as "nidus" refers to tumour itself which has various stages of bone maturity in a rich vascularized connective tissue (4,13).

Nidus center as the highest mineralization with varying amounts of mineralization (Figure 1).

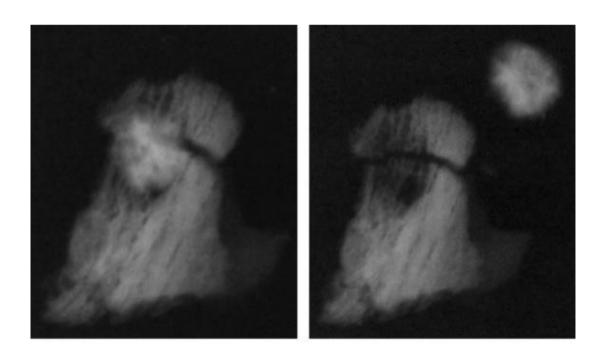


Figure 1 - Specimen radiograph (4): Calcified round nidus separated from normal bone.

CLINICAL PRESENTATION:

10 -12% of benign bone tumours and 2 to 3% primary bone tumours are osteoid osteomas with peak age at 2^{nd} decade (3,14) (Figure 2). Male to female ranges from 1.6:1 to 4:1(3,14).

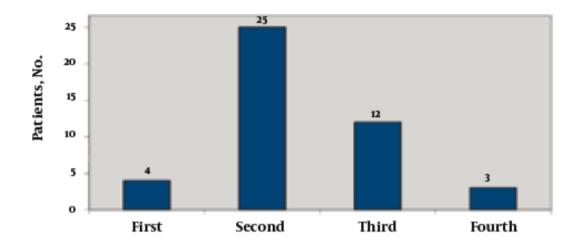


Figure 2: Distribution based on age decade of osteoid osteoma presentation (5).

Patients invariably presents with deep, aching, and intense pain last for weeks or months before diagnosis, which worsens at night and pain relieved by taking aspirin (3).

Clinical course varies depending upon location like intra articular lesions with synovitis & joint restriction & spinal lesions with painful scoliosis(3).

SKELETAL DISTRIBUTION:

Can arise anywhere in appendicular/axial skeleton. Most common location was lower extremities either femoral or tibial (Figure 3) diaphysis / Metadiaphysis region (3,14).

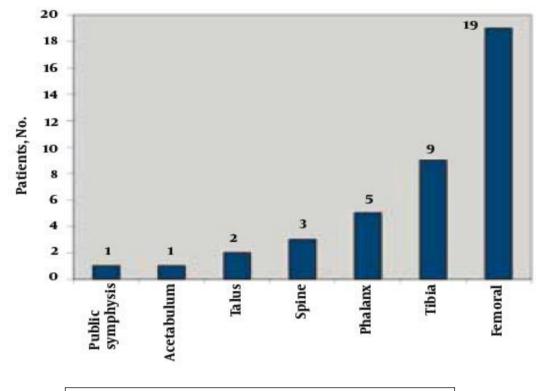


Figure 3: Anatomical Sites of Origin (5).

Lesions distribution can be cortical, medullary & sub-periosteal (Figure 4). Among them cortical lesions are more common and medullary/ sub-periosteal lesions are uncommon and noted in intraarticular or juxta-articular location (3,14).

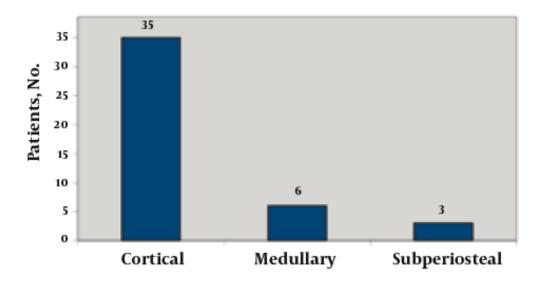


Figure 4: Distribution of Disease According to the Site of Origin (5).

HISTOPATHOLOGY AND PATHOGENESIS:

These osteoblastic tumours measures 1.5–2 cm in diameter and rarely exceeds. The nidus, contains interconnected trabeculae of osteoid/woven bone. Osteoblasts and variable amount of osteoclasts are surrounded by loose fibrovascular connective tissue (3,13) (figure 5).

Central nidus has abundant mineralization, going for the calcification within the lucent area. Perilesional sclerosis is not a part of the tumour. Though sclerosis is reversible, it is due to the pressure exerted by richly vascularized lesion within the host bone. Bone marrow elements, cartilage & mitotic figures are generally not seen.(3,13,15).

Exact pathogenesis of osteoid osteoma remains unclear. Mungo et al., study in 2002 reveals raised levels of COX – 2 in nidus and also shows, high

levels of PGE₂ & prostacyclin, leading to local inflammation and vasodilation. In addition, high concentrations of unmyelinated nerve fibers within nidus causes excruciating pain. (3,16)

Thus, COX-2 inhibition has become a theorized mechanism by which aspirin (NSAIDs) provide symptomatic relief for osteoid osteomas(3,16).

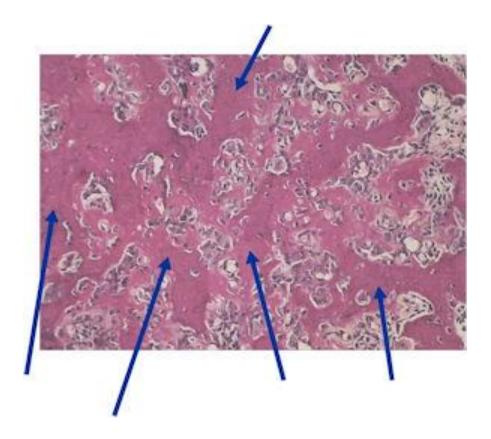


Figure 5: Osteoid osteoma – Interlacing trabeculae of woven bone and osteoid(arrows) with osteoblastic rimming. Highly vascularized intervening stroma.

IMAGING:

RADIOGRAPH:

The nidus is either oval or round shaped with size smaller than 2 cm, i.e radiolucent focus is seen in the center of reactive sclerosis. The nidus shows a varying amounts of calcification(mineralization), with adjacent cortical thickening, usually seen in diaphysis of long bones (4) (figure 6). Epimetaphyseal lesions may show minimal sclerosis surrounding the nidus. Medullary lesions, produce mild-to-moderate eccentric sclerosis (3). Decreased bone density because of disuse due to pain (4,17).

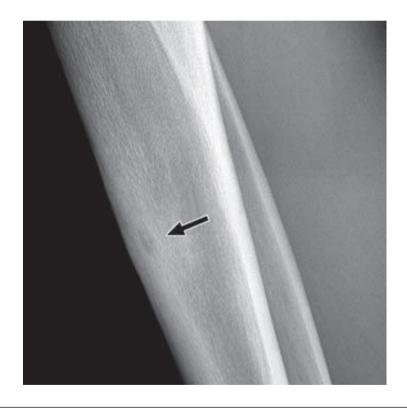


Figure 6: Lateral radiograph shows oval lucent nidus (*arrow*) within tibial cortex with perinidal sclerosis (3).

CT:

Diagnostic modality of choice for tumor identification and characterization. Thin-section CT (1–2-mm slices) reconstructed in bone algorithm with multiplanar reformats is ideal (3,14). Usually, the nidus is well demarcated with less density (4) (figure7). Nidus mineralization, may be amorphous /punctate or ringlike (3,14) (figure 8). Reactive perinidal sclerosis will be seen varying from mild - severe in which, it may completely obscures the nidus (4,17.)

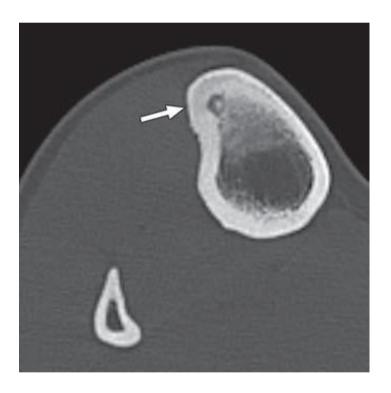


Figure 7: Axial plain CT shows central calcification within nidus (arrow) in tibial cortex, with sclerosis in anterior tibial medullary cavity (3).

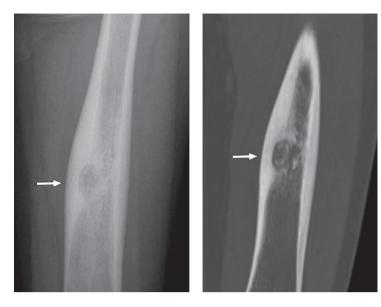


Figure 8: AP radiograph and coronal CT shows lucent nidus (*arrows*), with ringlike, calcifications noted on inner aspect of femoral cortex (3).

The amount of perinidal, inflammation for lesions within or around the joint is variable, ranges from mild sclerosis to florid marrow signal changes and periarticular edema. (3) (figure 9).

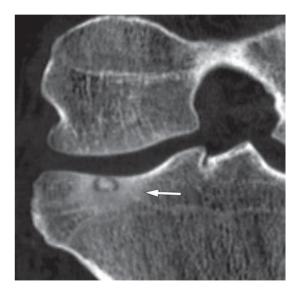


Figure 9: Coronal plain CT knee - Nidus (*arrow*) with relatively mild degree of perinidal sclerosis in subarticular position within lateral tibial plateau (3).

Spinal osteoid osteomas are better characterized by CT. lesions typically presents as low attenuation nidus in posterior elements. Ipsilateral pedicle/lamina/transverse process may show reactive sclerosis. Ipsilateral scoliosis concavity also seen (3,19)(figure 10).





Figure 10: Spinal osteoid osteoma - AP radiograph of lumbar spine reveals left convex scoliosis and subtle sclerosis (*arrow*) involving right aspect of L4 vertebral body. Axial plain CT, shows hypodense nidus (*arrow*) with mild lesional sclerosis in Lumbar right inferior facet (3).

Dynamic CECT:

Tumor nidus shows rapid early arterial enhancement (25 - 30 s), classically more than 40 HU above the unenhanced CT with persistent venous phase enhancement (90 -120s), with gradual washout of contrast and return to unenhanced CT attenuation (3,20,21).

Perilesional arteries enhancement parallels the lesion enhancement both in degree & timing of enhancement. This enhancement pattern helps to differentiate osteoid osteoma from its mimics like bone cysts & brodie's abscess because, both are avascular (3,20,21).

BONE SCINTIGRAPHY:

Technetium-99–labeled bone scan helpful for confirming the diagnosis of osteoid osteoma with sensitivity of nearly 100% (3,22). "Double-density sign" is the classic scintigraphic finding on bone scan with high specificity, particularly in appendicular skeleton (3,23). The nidus shows central focus of very high bone turnover. Peri nidal portion shows less-intense radiotracer uptake, representing immune response (3,23) (figure 11).

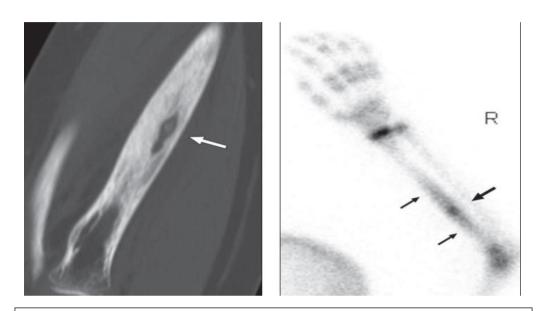


Figure 11: Coronal CT image – oval shaped nidus (*arrow*) with central calcification in radial diaphysis with surrounding sclerosis. Technetium-99 bone scintigraphy shows double-density sign (3).

In 1987 study by Helms et al., all patients who are histologically proven osteoid osteoma exhibited this scintigraphic appearance. The sign is less specific with spinal lesions, because of the less sclerosis in the vertebrae (3,23) (figure 12).





Figure 12: Osteoid osteoma - C4 left pars interarticularis. CT cervical spine shows oval lytic mildly expansile lesion (*arrow*) with central calcification in left posterior elements with mild sclerosis of adjacent facet. Left lateral view of cervical spine bone scan shows focal (*arrow*) radiotracer uptake, corresponding to tumor nidus.no double density sign (3).

Regarding imaging technique, the double-density pattern is better picked up by pinhole magnification scintigraphy compared to high-resolution planar scintigraphy. Imperiale et al., stated that the tumor nidus shows 18F-FDG avidity, whereas the surrounding sclerosis does not (3,24).

PET will be helpful in both diagnostic and post treatment assessment.

Because,4 weeks after Radiofrequency Ablation, the nidus was no longer hypermetabolic (3).

MRI:

Nidus appearance varies in MRI. The nidus shows low to- intermediate T1-weighted signal and heterogeneously high signal on T2-weighted/STIR sequences. On both T1- and T2-weighted sequences nidus central calcification appears as hypointense (3,15,25,26) (figure 13).

On both T1- and T2-weighted sequences, peri nidal sclerosis appears as fusiform hypointensity. MRI also shows edema in adjacent bone marrow as well as surrounding soft tissues (3,25,26).

Nidus enhancement pattern is variable; most of them enhance diffusely as a result of their intrinsic vascularity. however, few of them may show heterogeneous rim enhancement (3,25) (figure 14).

A study by Assoun et al., concluded that thin slice CT was more accurate than MRI in detecting tumor nidus in $2/3^{rd}$ of cases (3,26).

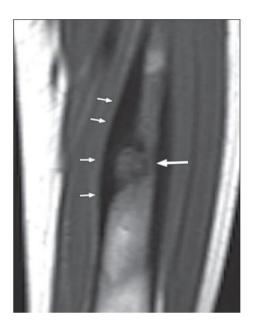




Figure 13: Femoral osteoid osteoma – Pre contrast T1-weighted image reveals hypointense nidus (large arrow) with fusiform cortical thickening (small arrows) overlying nidus. Post contrast T1-weighted image shows homogeneous nidus enhancement (arrow) (3).

A study by Davies et al., reported that using MRI alone as imaging modality missed 1/3rd (15/43) of osteoid osteoma cases. The 15 cases included 6 lesions were not identified at all and 9 lesions were poorly visualized. Small lesions difficult to identify on MRI because the nidus signal as similar intensity to that of the surrounding cortex (3,25).

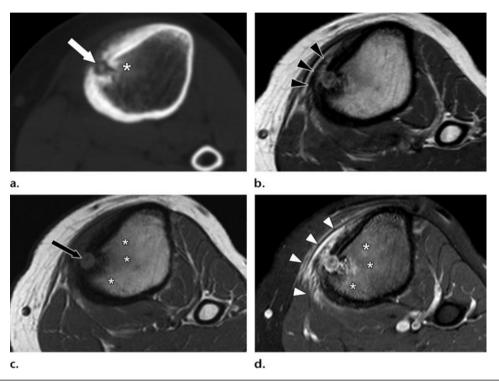


Figure 14: Tibial Intracortical osteoid osteoma - (a) CT shows nidus (arrow) with central calcification and adjacent sclerosis (*) (b) Axial T2W MR reveals heterointense nidus. (c, d) Axial plain and Post contrast T1W MR reveals low-signal intense nidus with strong enhancement, with adjacent edema (*) (4).

INTRA-ARTICULAR OSTEOID OSTEOMA:

Rare, clinical variety in which lesion seen within or near a joint. Joint tenderness and joint effusion are the common symptoms. Hip is the most commonly involved joint (4,27).

Imaging findings varies in intraarticular osteoid osteoma, there is minimal or absent reactive cortical thickening (figure 15), and it is believed to be due to absence of the innermost periosteal layer i.e cambium (4,27). However, newer studies have shown that the femoral neck periosteum has osteogenic potential (4,28).

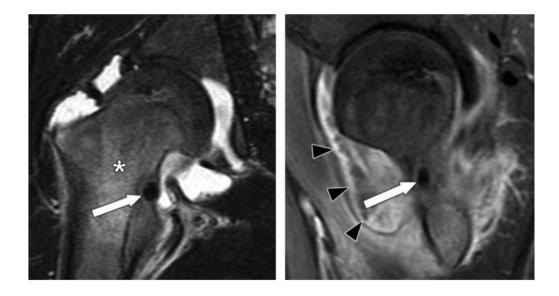


Figure 15: Intraarticular osteoid osteoma femur. Coronal T2WI MR showing a mineralised nidus (*arrow*) in neck with adjacent marrow edema (*). Large joint effusion is noted. Sagittal post contrast T1WI image shows mineralized nidus and marked synovial enhancement (4).

OSTEOBLASTOMA:

Similar to osteoid osteoma in both histologically and clinically. but, Osteoblastoma is less aching than osteoid osteoma and won't respond to aspirin (4). Moreover, osteoblastoma has progressive growth and may turn into malignant (4). At imaging, osteoblastoma measures larger than 2 cm, more expansile with less reactive sclerosis (4,36) (Fig 16).



Figure 16. Osteoblastoma in humerus proximal diaphysis. AP radiograph showing well defined, expansile lytic cortical lesion (arrow) with sclerosis in proximal humeral diaphysis. Axial plain CT image reveals identical findings.

Axial T2W MRI depicts the high intense lobulated lesion (arrow) (4).

UNCOMMON LOCATIONS OF OSTEOID OSTEOMA:

Less common locations are spine, hands, or feet. The least common sites are the skull, mandible, scapula, ribs(figure 17), and patella(4).

A reactive inflammation which begins within hand spreads to nearby bones and joints. Lesions in hands and feet will have prominent swelling which mimics infection or inflammatory arthritis (4,13).

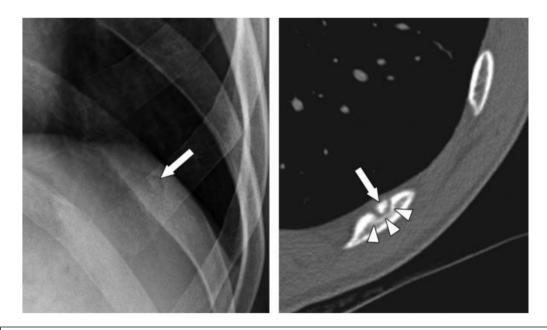


Figure 17: Osteoid osteoma in posterior rib. AP radiograph reveals a nidus in rib with central calcification and mild sclerosis. CT axial plain image depicts nidal calcification (arrow) in rib's anterior cortex(4).

OSTEOID OSTEOMA MIMICS:

Diagnostic dilemma of osteoid osteoma arises when certain conditions like chondroblastoma, stress fracture, Intra - cortical abscess / hemangioma and compensatory hypertrophy of the pedicle (4).

Stress Fracture:

Fracture occurring when stress on a bone overtakes the capacity of the bone to repair by its own. Common sites: the femoral neck and diaphysis of lower extremity bones (4,29).

Imaging:

- Osteoid osteoma shows a round nidus. But, stress fracture shows central linear infarcted area within the thickened cortex (4,30)(figure 18).
- 2. Stress fracture, shows cortical thickening ranging from a linear cortical ridge to florid thickening in both aspects i.e periosteal and endosteal. whereas in osteoid osteoma, no linear cortical ridges are seen with varying cortical thickening (4,30).
- 3. On scintigraphy, osteoid osteoma shows typical "double-density" sign. whereas, in stress fracture marked linear uptake can be seen (4,30).
- 4. In follow-up images, Cortical lesions size decreases in stress fracture rather than in osteoid osteoma(4,30).

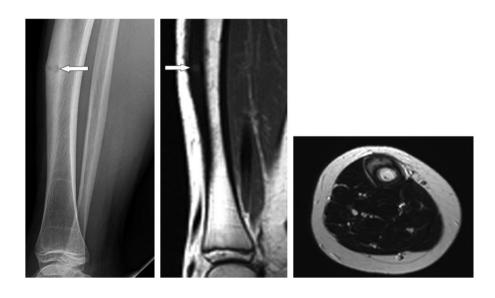


Figure 18: Tibial stress fracture - Lateral radiograph of the left leg reveals mild tibial bowing, with adjacent cortical thickening, and raindrop like a radiolucent lesion (arrow) with tiny central calcification. Sag T1WI MR shows the hypointense lesion (arrow)with thickened cortex. Axial T2WI MR reveals the irregular shape of the lesion (4).

Intracortical Abscess:

In plain radiograph, a typical osteoid osteoma cannot be differentiated from an intracortical abscess with sequestrum (4,31).

In CT, osteoid osteoma very well differentiated from an intracortical abscess. osteoid osteoma shows smooth nidal inner margin, with a central round mineralization. whereas, an intracortical abscess reveals inner irregular margin with eccentric irregularly shaped sequestrum (4,32) (Fig 19).

In MRI, Intracortical abscess appears as hypointense on T1 and hyperintense on T2, with no central enhancement on contrast. But, in osteoid osteoma there will be avid nidal enhancement (4,33).

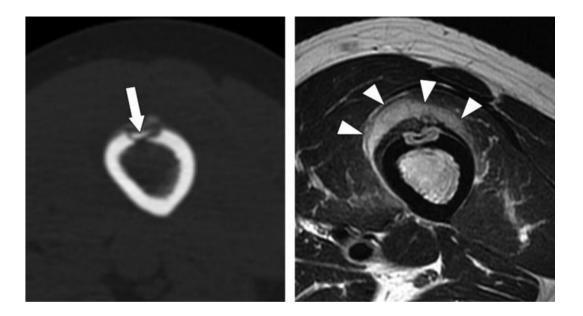


Figure 19: Intracortical abscess of the femoral shaft. CT showing a lytic lesion with an irregular margins and eccentric sequestrum (arrow). Axial T2WI MR image showing hyperintense lesion with adjacent periosteal reaction(arrow heads) (4).

Intracortical hemangioma:

Rarest tumor with tibial predominance. Radiograph reveals a radiolucent intracortical lesion with horizontally oriented trabecular intralesional calcifications with cortical thickening/periostitis(4).

CT shows a hypodense lesion which is intracortical with net like internal calcification, i.e "wire-netting appearance" (4,34).

MRI shows a high intense lesion with low intense septa and thickened cortex(4)(figure 20).

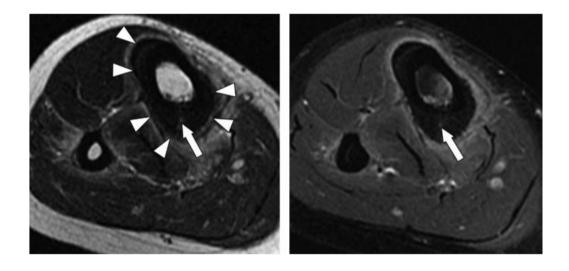


Figure 20. Intracortical hemangioma of the tibia - Axial T2WI/Post contrast T1WI MR images revealing diffuse cortical thickening (arrowheads) with intracortical small lesion (arrow) and adjacent soft-tissue edema(4).

Chondroblastoma:

Benign tumour with young age predilection & common in femur, humerus, and tibial epiphysis. Aggressive lesions with significant periosteal reaction and large bone marrow edema. Small lesions are indistinguishable from subarticular osteoid osteoma. Chondroblastoma shows typical punctate mineralization, whereas osteoid osteoma shows central mineralization (4,35) (Fig 21).

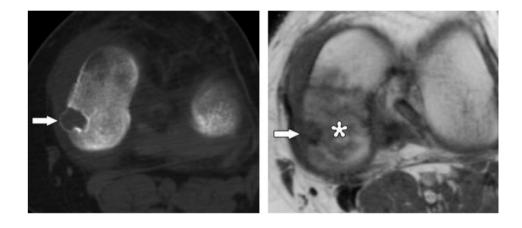


Figure 21. Chondroblastoma of the left medial femoral condyle – Axial plain CT shows an eccentrically placed epiphyseal lucent lesion (arrow) with expanded cortex. Axial T1W MR image reveals the low intense lesion (arrow) with adjacent bone marrow edema (*) (4).

TREATMENT:

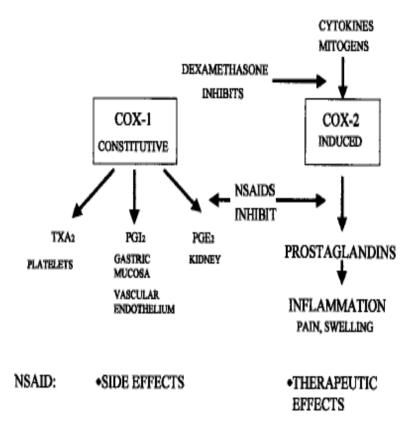
Generally three approaches are used in treatment of osteoid osteomas: medical, surgical and percutaneous management(3,38).

i) Conservative management:

Treated with NSAID's initially, and studies have found NSAID'S to be first choice medications with respect to long-term symptomatic relief. Goto et al., supported this in his study, 92% (11/12) of patients with osteoid osteoma treated with NSAIDs got pain relief at a mean interval of one and half years after treatment initiation (39). Several studies states that, the natural course of these lesions is spontaneous regression and NSAID's accenuates this process (3,39).

In 2002, a study by Mungo et al., Proposed that the mechanism behind is central osteoblastic nidus has overexpression of cyclooxygenase-2. Another study reveals that, there is high levels of prostaglandin E2 and prostacyclin, thereby causing local vasodilatation and inflammation leading to pain (3,16).

NSAID's being nonselective inhibitors of the enzyme cyclooxygenase, blocks production of the cyclooxygenase-1 and -2 isoenzymes. thereby, cyclooxygenase-2 blockage has become a theorized mechanism by which these drugs provide symptomatic relief for osteoid osteomas (3,16).



However, patients getting long-term NSAID's therapy, won't tolerate drugs because of its side effects on GI tract and pain recurs, once these drugs are discontinued. Adding to that, many patients encountered serious complications like growth disorders, scoliosis, degenerative arthritis, and in long usage muscles can be atrophied. (6,40).

ii) Surgical management:

In conventional open surgery, the aim is to do total resection. This procedure leads to reducing the durability of bones. Sometimes, bones can be fractured too. So, additional surgical procedures such as bone grafting, internal fixation and postoperative immobilization may be required (6,41).

As per literature, Surgery gives 88% to 100% success rate. But, 4.5% to 25% recurrence rates (6,41).

Absolute indications for Surgical treatment are (3,41):

- 1) Doubtful HPE of the lesion,
- 2) Lesions occuring within 1–1.5 cm to the neurovascular structures, and
- 3) Failed percutaneous ablation procedure not once. but, atleast twice.

Surgery leads to some practical problems like difficulty in intraoperative localization of the lesion, prolonged morbidity due to long stay in hospital and also takes long time for rehabilitation (3).

iii) Image guided percutaneous ablation:

Techniques used are (6,41):

- 1. Alcohol injection,
- 2. Laser photocoagulation,
- 3. Cryoablation,
- 4. Microwave and Radiofrequency Ablation
- 5. MR guided focused US therapy.

Alcohol ablation usually combined with minimally invasive CT guided [drill] resection. It is technically easier and cost effective method compared to other procedures. but, alcohol spreads to adjacent neurovascular bundles and tissues leads to failure and unnecessary complications (6,41,42).

MR Guided (MR compatible) Laser ablation and MR guided focused US therapy has success rate similar to the RFA, but not a cost effective one. Major setback is that, it does not allow the HPE confirmation and minor complications are comparatively higher than the RFA (6,41,43).

Another recent MR guided cryoablation which is a high cost method (1,6). Advantages are real time monitoring of changes happening during the process, provides better soft tissue contrast and no radiation. (6,44).

RADIOFREQUENCY ABLATION:

Rosenthal et al., first described about minimally invasive procedure using RF in the year 1992(6,45).

It is comparatively newer modality for the treatment of osteoid osteoma with less morbidity and excellent cure rate (2).

Many traders are now circulating RFA devices for therapeutic purpose including: STAR med, RITA Medical System, Boston Scientific, Berchtold Medical Electronics, Tyco Healthcare and Radionics (2).

Success of RFA depends upon image guidance. CT leads MRI/USG/Fluoroscopy to treat bone lesions. Because, CT images are acquired faster with better bone resolution (1).

Importance of image guidance at each step of the procedure:

Pre-procedure:

- To measure the lesion size, and to select appropriate active electrode tip with exact size (1).
- 2. To plan for easy and safer tract to reach the nidus, without disturbing neurovascular bundles (1).

During procedure:

Constant monitoring of active electrode tip can be done (1).

Post-procedure:

- 1. To minimize radiation dose, MRI is preferred over CT in post treatment follow-up (1,46).
- 2. To assess the procedure's technical success.

INSTRUMENTATION AND MECHANICS:

The RF device contains a RF generator which was connected with grounding pads and active electrode tip (1,47). The RITA device contains AC power generator with mobile electrode hub and multiple curved tips (2).

Radionics has a cooled tip probe with single needle and internal channel through which saline circulates. Thereby, helps for cooling it and also has numerous holes which permits saline leakage in order to increase tissue conductivity (1,2,46).

An artificial electrical circuit was made in patient by placing electrode tip in bone lesion and dispersing pads on thighs or back. The electric current from the RF generator flows via the electrode into the patient as radiofrequency waves/energy and goes out through the dispersing pads back to the generator(1)(figure 22).

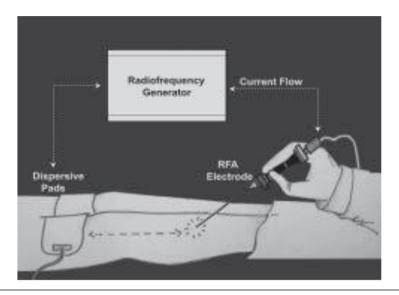


Figure 22: RF generator with its working principle (1).

RF machine generates an alternating current of high RF waves which goes via the electrode tip into the lesion and transfers energy as heat which eventually causes cell death and coagulation necrosis (1).

Heat is generated by impedance (resistive forces) that produce ionic and molecular coagulation(agitation) in the area(tissues) surrounding the electrode, while radio waves attempts to return to the ground pads (1).

RF energy is transferred via the metal electrode (14 to 21 Gauge), and the entire electrode was insulated except at the tip, with an active tip length varying from 0.7 to 3 cm (1).

Different types of electrodes are available (1):

- 1. Unipolar with single electrode,
- 2. Dipolar with two electrodes,
- 3. Cluster with 3 or more closely spaced electrodes of 1 cm, and
- 4. Umbrella type expandable electrodes, with multiple electrode tines (array like) that expands from a centrally placed cannula.

Cooled tip probe is the one which is internally cooled by saline that flows into the lumen, but without having direct contact with tissue. Perfusion tip probe will have small apertures at the tip that allow fluids to be infused into the tissue (1).

The variety of electrode and size of active tip chosen is vital in success of ablation. A single rod electrode is generally more appropriate in bone lesion treatment, because single electrode can be inserted via the drilled hole. Rod like monopolar electrodes distributes heat to surroundings in cylindrical way with rounded edge (1).

Maximum heat is generated in tissues with least resistance, and cortical than marrow bone has higher tissue resistivity. So, cortical tissue offers higher resistant to heating. Thereby, has better insulating effect when intact, and protects adjacent soft tissues and cartilage (1,47).

Dispersive grounding pads were applied on either side of patient's thighs, in correct alignment with each other and with appropriate skin contact; both of them were kept at almost equal distance from the place of ablation and as nearest to the ablation site to allow the smallest current path via the patient (7) [Figure 23]. Right placement of these pads is a vital step in the procedure.

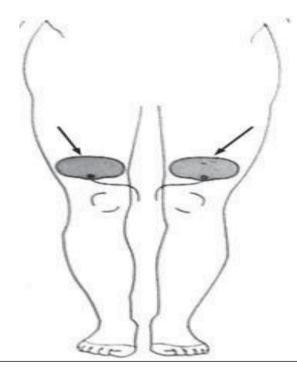


Figure 23: Schematic anteroposterior diagram showing right placement of dispersing pads (arrow)(7).

Anaesthesia:

In children mostly general anaesthesia was preferred over local anaesthesia (2). However, in lower extremities lesions spinal anaesthesia is preferred and local anesthesia was given for betterment of procedure.

Lesion localization:

The lesions were marked/targeted with the help of a MDCT scanner, with multiplanar evaluation to assess accurate needle position within the lesion (7). To minimize ionizing radiation exposure, KVP and MAS values were chosen as per ALARA (as low as reasonably achievable) principle (6).

A grid can be kept over the patient's skin in that particular area, before the first CT run to mark localization of a starting point (2). Markings on the grid can be visualised on the CT scan & helps to estimate distance across the skin (2).

PROCEDURE:

They used Single tip probe with exposed tip around 5 mm and that much is needed to ablate 1.5cm sized nidus. With the tip of the probe in correct position, the end of the cord plugged into the RF machine. The cord should be clamped to the patient to avoid any displacement while the CT table goes in and out of the scanner (2).

It is necessary to add saline to the system to reduce impedance and favour ablation without over "burning" the lesional area (2). They kept RF machine settings at 90°C for 6 minutes. The RF machine will slowly elate the temperature, and timer gets started, when 90°C is reached (2,48). After 6 minutes, the machine temperature will revert back to room temperature(2).

Post procedure:

The average time for patients to recover from anaesthesia was 2.3 hours (7). Patients were advised to avoid sternous activities for 1 month, if they had lesions in lower limbs (7).

Follow-up:

The mean follow-up period was 8 months (7) & mean time for complete disappearance of pain was 2 to 3 days (7) with first follow up MRI within 24 - 48 h after the procedure and next CT or MRI after 1 month and 1 year.

Complications:

- Major: Any unexpected fracture or large skin burn which requires graft repair (7).
- Minor: Transient paresthesia/erythema/small superficial skin burn surrounding the RF probe or grounding pad (7).

MATERIALS AND METHODS:

At our institution's orthopaedic department, patients who presented with history of non-traumatic pain typically getting worse at night and relieved by taking aspirin with clinical diagnosis of osteoid osteoma are referred for radiological evaluation. The patients graded their pain at day and night on a visual analogue scale with grade 0 – no pain and grade 10 – unbearable pain.

Our study was accepted as ethical according to our institutional Ethical Committee, Govt. Kilpauk Medical College, Chennai -10, Protocol ID no: 04/2015 dated 02.11.2015.

Study design:

Prospective Interventional study.

Study period:

From November 2015 to September 2016.

Study Population:

Study included 16 patients with age group from 8 to 28 years (mean age - 16 years), which includes 14 male patients and 2 female patients.

Criteria for diagnosis of osteoid osteoma:

- Clinical criteria: Patients Presenting with pain getting worse at night and relieved by taking aspirin with visual analog scale grade above 6.
- Radiological criteria: Imaging wise documenting the radiolucent nidus less than 1.5cm with adjacent bony osteosclerosis and cortical thickening on thin slice CT (1 to 3 mm).

INCLUSION CRITERIA:

o Patients who met clinical and radiological criteria.

EXCLUSION CRITERIA:

- Patients who are symptomatically silent.
- o Patients whose primary was already known.
- o Patients with lesions close to neuro vascular bundles i.e within 2cm.
- Non consenting and un co-operative patients.

METHODOLOGY:

All patients included in the study, were diagnosed as osteoid osteoma radiologically and posted for radiofrequency ablation. Day time & night time pain intensity of 16 patients was noted using visual analog scale. The procedure and its alternatives available are thoroughy explained to the patients and their parents and informed written consent was obtained in all cases.

Before the procedure, Hemoglobin, clotting time, bleeding time, prothrombin time and INR were confirmed as normal.

All patients underwent anaesthesia fitness assessment and planned under spinal anaesthesia. Prophylactic antibiotics were administered, prior to the procedure. Radiofrequency ablation machine and all anesthesia equipments are shifted to the room with the CT scanner.

Radiofrequency ablation was done under Spinal anaesthesia (conscious sedation).

Dispersive grounding pads were applied on either side of patient's thighs, in correct alignment with each other and with appropriate skin contact; both of them were kept at almost equal distance from the place of ablation.



Dispersive grounding pads were applied on either side of patient's thighs.

The RFA equipment comprised an STAR med VIVA RF generator (Solutions for Thermo Ablation with RF medical technologies, South Korea), star RF cooled tip electrode with tip exposure 5 -10mm, 11 G COOK bone biopsy needle, a K-wire and a driller.

Coolant Pump and container:

STAR med coolant container has Storage capacity around 3L with two connectors for cool saline input and output. The tubes connects the coolant pump and the electrode. The temperature of coolant (saline) kept below 20°C.

Lesion localization:

The lesions were targeted with the help of a 16 slice MDCT scanner (Toshiba medical systems, Tokyo, Japan) with multi-planar evaluation to assess accurate needle position within the lesion.



RF generator with cooled tip RF probe & Coolant Pump – 1,2 &7. RF power supplied to electrode & targeted tissue, 3&4. Energy in calories 5.

Impedance, 6. Actual amount of current via electrode, 8 &9. Time lap &

Total ablation time,10. Temperature.

PROCEDURE:

- 1. Skin preparation and proper sterilization was done.
- 2. Small skin incision was made using 11' blade.
- 3. 13-Guage bone biopsy needle was introduced into the lesion under CT guidance. And, in patients where there is marked perilesional sclerosis, the tumor was reached through a drill advanced over an appropriate Kirchner guidewire. Biopsy was taken and sent for HPE in formalin.
- 4. Under aseptic precautions, a 350mm long, 15-gauge single cooled tip electrode with exposure tip of 5 -15mm length was then introduced into the centre of osteoid osteoma nidus.
- 5. The electrode was connected to the RF generator and coolant pump with cool saline. so, it reduces impedance and favour ablation without over "burning" the lesional area.
- 6. RF machine settings changed to continuance mode and kept at 20 watts for 6 minutes. The RF output is generated continuously with the setting value.
- 7. The temperature shown in the generator won't reflect the burning temperature. Because, we are ablating with cooled tip electrode connected to coolant pump.so, the observed electrode temperature will be less compared to actual burning temperature.
- 8. Once procedure was over, a small compressive dressing was applied at the percutaneous puncture site.



Osteoid osteoma tibial diaphysis with thick sclerosis – Nidus was reached through K-wire using drill.



Osteoid osteoma tibia diaphysis – RF probe introduced into nidus.



RF generator in continuance mode during ablation.

Post procedure:

The average time for patients to recover from anaesthesia was 4 hours.

Patients were advised to avoid sternous activities for 15 days.

Follow-up:

Post procedure day and night time pain intensity was measured at 1 week and 4 weeks using visual analog scale. Follow up CT/MRI taken at 4 weeks. HPE reports were collected within a week.

Criteria for assessment of success of the procedure:

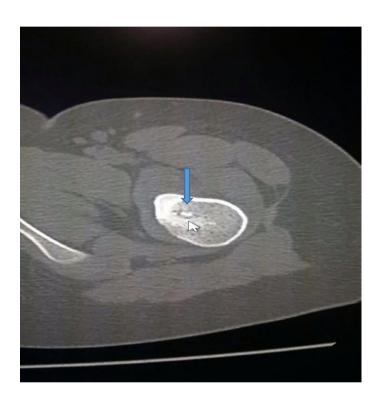
Technically success was considered, when the tip of the electrode was rightly placed into the nidus and the nidus was heated for the appropriate time, at correct parameters.

Clinical success was considered, when patients gets complete relief from pain and getting back to normal activities.

Case 1:

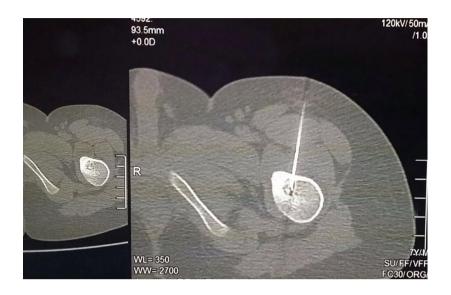
A 17 year old male patient came with typical history of pain in left upper thigh, which is getting worsened at night.

His pre-operative VAS was 6 in day and 9 in night time. Patient was subjected to thin slice CT.



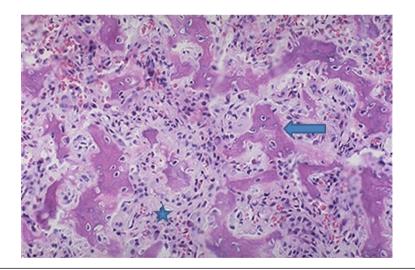
Plain axial CT left upper thigh reveals a well defined cortically placed radiolucent nidus with central calcification and surrounding minimal sclerosis in proximal femoral diaphysis. Nidus size was 7.5mm.

Clinical and radiological criteria was met. So, Planned for RFA under spinal anaesthesia.



During RF procedure with probe tip within the nidus

The lesion was biopsied and sent for HPE and it confirmed the diagnosis as osteoid osteoma.



Biopsy specimen with Hematoxylin and eosin staining showing irregular bony trabeculae with osteoblastic rimming(arrow) embedded in a hypo-cellular fibro-vascular stroma(*).

Patient didn't have any complications. His post op VAS at 1 week was 2 in both day & night time and not had any pain at 4 weeks. Follow up imaging was done at 4 weeks and it showed no evidence of any residual/recurrent nidus.

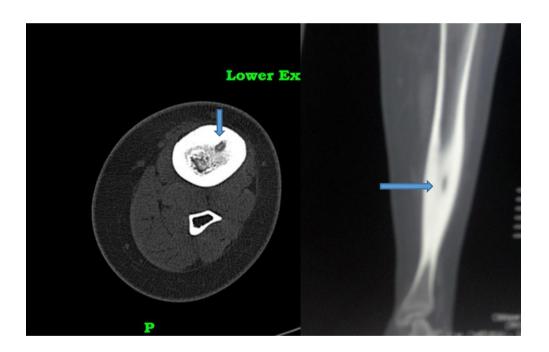


Plain sagittal reformatted CT at 4 weeks shows the needle tract with no evidence of nidus. No residual sclerosis was noted.

Case 2:

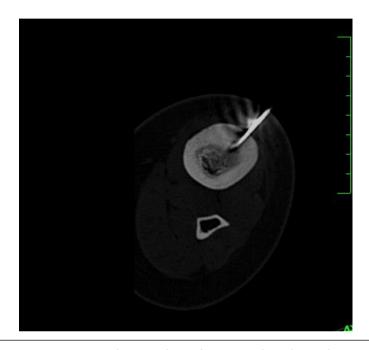
A 14 year old male patient came with typical history of pain in left mid leg, which is getting worsened at night.

His pre-operative VAS was 7 in day and 8 in night time. Patient was subjected to thin slice CT.



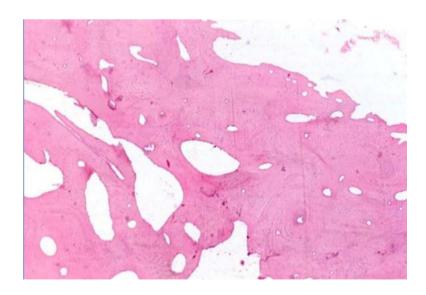
Plain axial and coronal CT left leg reveals a well defined, cortically placed radiolucent nidus with central calcification and surrounding sclerosis in mid tibial diaphysis. Nidus size was 6.2 mm.

Clinical and radiological criteria was met. So, Planned for RFA under spinal anaesthesia.



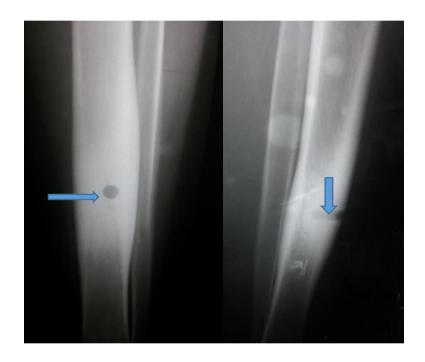
During RF procedure with probe tip within the nidus

The lesion was biopsied and sent for HPE and it came as sclerotic bone.



Biopsy specimen with Hematoxylin and eosin staining showing sclerotic bone. No evidence of osteoblasts.

Patient had mild skin burns, which got healed by its own. His post op VAS at 1 week was 1 in both day & night time and not had any pain at 4 weeks. Follow up imaging was done at 4 weeks and it showed no evidence of any residual/recurrent nidus.

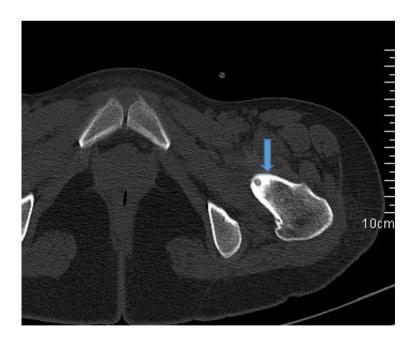


Plain radiograph leg Anteroposterior and lateral view at 4 weeks shows the needle tract with no evidence of nidus. Minimal residual sclerosis was noted.

Case 3:

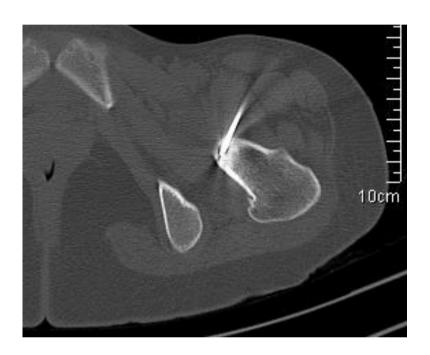
A 17 year old female patient came with typical history of pain in left hip, which is getting worsened at night.

Her pre operative VAS was 7 in day and 9 in night time. Patient was subjected to thin slice CT.



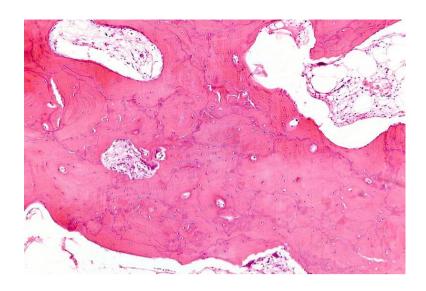
Plain axial CT left hip reveals a well defined, cortically placed radiolucent nidus with central calcification and surrounding minimal sclerosis in femoral neck(epiphysis). Nidus size was 6 mm.

Clinical and radiological criteria was met. So, Planned for RFA under spinal anaesthesia.



During RF procedure with probe tip within the nidus

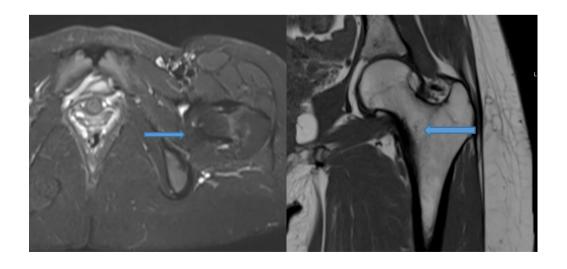
The lesion was biopsied and sent for HPE and it came as sclerotic bone.



Biopsy specimen with Hematoxylin and eosin staining showing sclerotic bone.

No evidence of osteoblasts.

Patient didn't have any complications. Her post op VAS at 1 week was 1 in both day & night time and not had any pain at 4 weeks. Follow up imaging was done at 4 weeks and it showed no evidence of any residual/recurrent nidus.



Axial STIR and coronal T1 MR image at 4 weeks shows no evidence of nidus.

No marrow edema was noted.

Case 4:

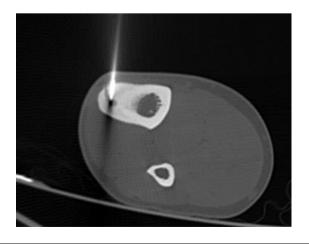
A 25 year old male patient came with typical history of pain in right mid leg, which is getting worsened at night.

His pre operative VAS was 7 in day and 8 in night time. Patient was subjected to thin slice CT, radiograph and bone scintigraphy.



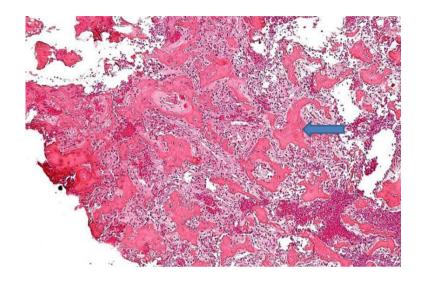
Plain AP radiograph, Axial CT and scintigraphy: right mid leg reveals a well defined, cortically placed radiolucent nidus with no central calcification and surrounding sclerosis with double density sign (scintigraphy) in mid tibial shaft Nidus size was 8mm.

Clinical and radiological criteria was met. So, Planned for RFA under spinal anaesthesia.



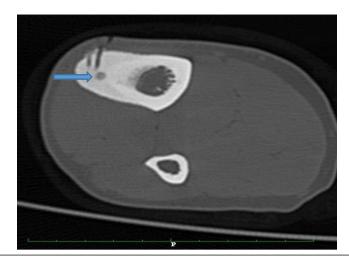
During RF procedure with probe tip within the nidus

The lesion was biopsied and sent for HPE and it confirmed the diagnosis as osteoid osteoma.



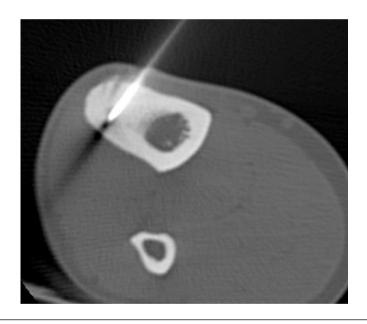
Biopsy specimen with Hematoxylin and eosin staining showing Immature trabeculae(arrow) enveloped by prominent osteoblasts / clasts.

Patient had mild skin burns, which got healed by its own. His post op VAS at 1 week was 5 in day & 7 in night time and had persistence of pain at 4 weeks. Follow up imaging was done at 4 weeks and it showed evidence of residual nidus.

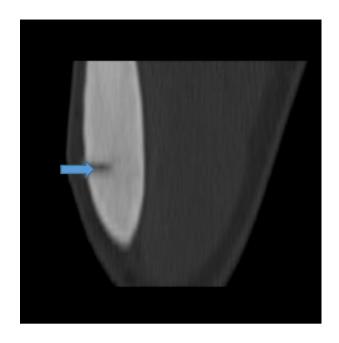


Plain axial CT at 4 weeks shows the needle tract with evidence of residual nidus.

Planned for 2nd RFA under spinal anaesthesia.



During 2nd RF procedure with probe tip within the nidus



Plain sagittal reformatted CT at 4 weeks after 2nd RFA shows the needle tract with no evidence of nidus. No residual sclerosis was noted.

STATISTICAL ANALYSIS & RESULTS

The collected data were analysed with IBM.SPSS statistics software 23.0 Version.

To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables.

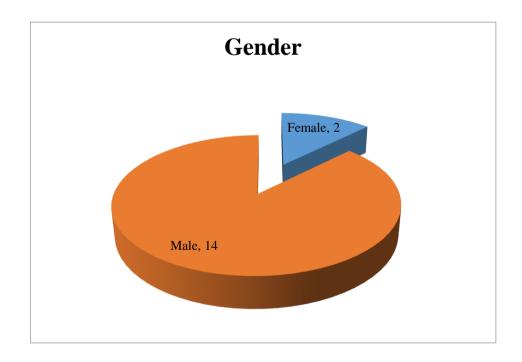
To find the significant difference between the bivariate samples in Paired groups (Pre & Post) Wilcoxon signed rank test was used.

For the multivariate analysis in the repeated measures (Pre, Week1&Week4) the Friedman test was used.

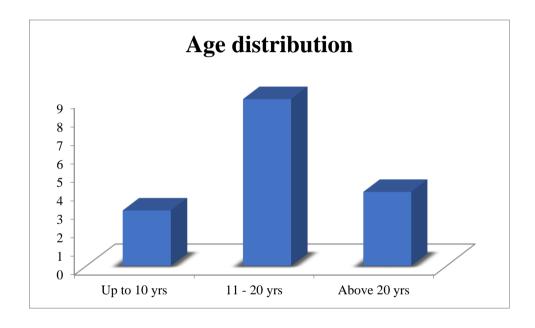
To find the significance in categorical data Chi-Square test was used. In all the above statistical tools the probability value .05 is considered as significant level.

Age & Gender distribution of osteoid osteoma in tables and diagrams:

sex					
				Valid	Cumulativ
		Frequency	Percent	Percent	e Percent
Valid	Female	2	12.5	12.5	12.5
	Male	14	87.5	87.5	100.0
	Total	16	100.0	100.0	

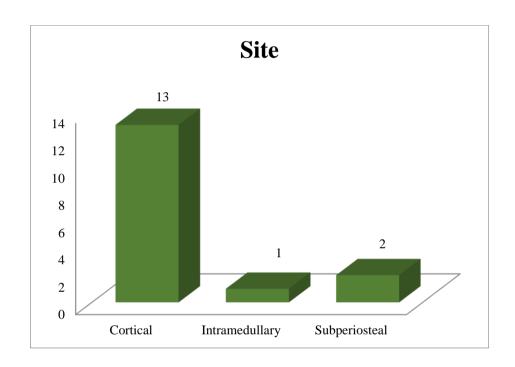


Age	Distribution
<10 years	3
10– 20 years	9
>20 years	4

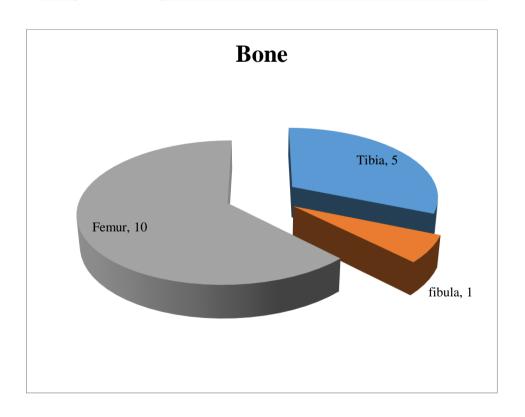


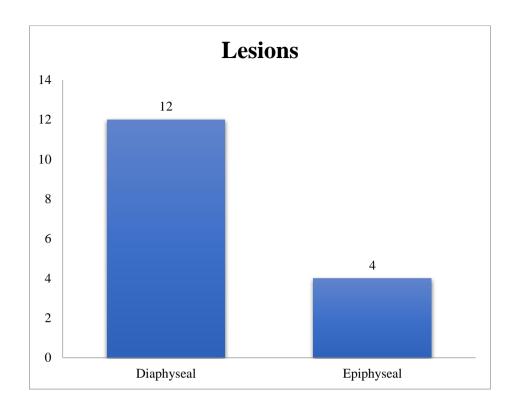
Distribution of osteoid osteoma according to the Site of Origin in bar diagram and frequency tables:

site(transverse)						
Frequency Percent Percent e Percent						
Valid	Cortical	13	81.3	81.3	81.3	
	Intramedul lary	1	6.3	6.3	87.5	
	Subperios teal	2	12.5	12.5	100.0	
	Total	16	100.0	100.0		



	bone & location(longitudinal)				
		Frequenc y	Percent	Valid Percent	Cumulativ e Percent
Valid	femur - distal diaphysis	1	6.3	6.3	6.3
	femur - epimetap hysis	1	6.3	6.3	12.5
	femur – epiphysis	2	12.5	12.5	25.0
	femur – meta diaphysis	1	6.3	6.3	31.3
	femur – mid diaphysis	1	6.3	6.3	37.5
fem pro	femur – proximal diaphysis	3	18.8	18.8	56.3
	femur – proximal diaphysis	1	6.3	6.3	62.5
	fibula- distal diaphysis	1	6.3	6.3	68.8
	tibia - epiphysis	1	6.3	6.3	75.0
	tibia - mid diaphysis	3	18.8	18.8	93.8
	tibia - middiaph ysis	1	6.3	6.3	100.0
	Total	16	100.0	100.0	





Comparison of pre procedure day & night VAS with post procedure day & night VAS at 1 week and 4 weeks:

NPar Tests:

Wilcoxon Signed Ranks Test:

Ranks

		N	Mean Rank	Sum of Ranks
Pre op VAS night - Pre op	Negative Ranks	0 ^a	.00	.00
VAS day	Positive Ranks	16 ^b	8.50	136.00
	Ties	0 ^c		
	Total	16		
post op vas at 1 week	Negative Ranks	0 ^d	.00	.00
Night - post op vas at 1 week day	Positive Ranks	4 ^e	2.50	10.00
week day	Ties	12 ^f		
	Total	16		
post op vas at 4 weeks	Negative Ranks	0 ^g	.00	.00
night - post op vas at 4 weeks day	Positive Ranks	1 ^h	1.00	1.00
	Ties	15 ⁱ		
	Total	16		

- a. Pre op VAS night < Pre op VAS day
- b. Pre op VAS night > Pre op VAS day
- c. Pre op VAS night = Pre op VAS day
- d. post op vas at 1 week Night < post op vas at 1 week day
- e. post op vas at 1 week Night > post op vas at 1 week day
- f. post op vas at 1 week Night = post op vas at 1 week day
- g. post op vas at 4 weeks night < post op vas at 4 weeks day
- h. post op vas at 4 weeks night > post op vas at 4 weeks day
- i. post op vas at 4 weeks night = post op vas at 4 weeks day

Test Statistics ^a					
	Z	Asymp. Sig. (2- tailed)			
Pre op VAS night - Pre op VAS day	-3.624 ^b	.000			
post op vas at 1 week Night - post op vas at 1 week day	-1.890 ^b	.059			
post op vas at 4 weeks night - post op vas at 4 weeks day	-1.000 ^b	.317			
a. Wilcoxon Signed Ranks Test					
b. Based on negative ranks.					

In comparison, Pre-operative VAS values between daytime and night time, the difference was statistically significant (Z value = -3.624 and p value = <.05).

NPar Tests:

Friedman Test:

Ranks		Ranks	1
	Mean Rank		Mean Rank
Pre op VAS day	3.00	Pre op VAS night	3.00
post op vas at 1 week day	1.97	post op vas at 1	1.97
post op vas at 4 weeks dav	1.03	week Night post op vas at 4	1.03

Multivariate analysis using friedman test, reveals stastically significant p values(< .05) between Day Pre op VAS, Post op VAS at 1 week and at weeks. Similar values were obtained for night VAS multivariate analysis too. Assessing the difference between the bivariate samples in Paired groups (Pre & Post):

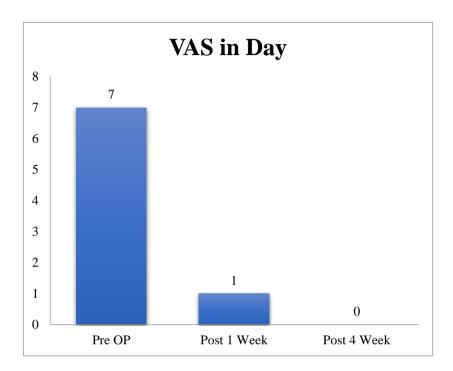
Test Statistics ^a						
	Z	Asymp. Sig. (2- tailed)				
post op vas at 1 week day - Pre op VAS day	-3.588 ^b	.000				
post op vas at 4 weeks day - Pre op VAS day	-3.601 ^b	.000				
post op vas at 4 weeks day - post op vas at 1 week day	-3.771 ^b	.000				
a. Wilcoxon Signed Ranks Test						
b. Based on posit	b. Based on positive ranks.					

All three paired comparisons in day time i.e Pre op VAS vs Post op VAS at 1 week, Pre op VAS vs Post op VAS at 4 weeks and Post op VAS at 1 week vs Post op VAS at 4 weeks were found to be stastically significant (P value < .05).

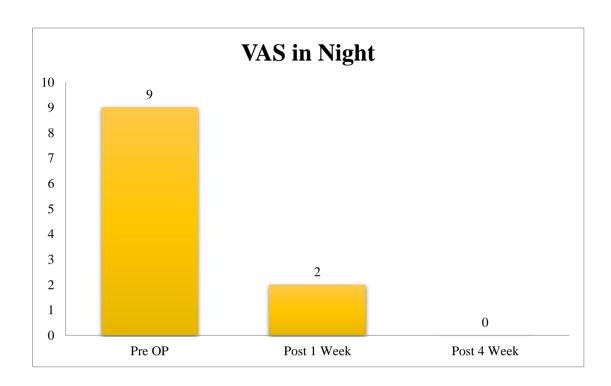
Test Statistics ^a					
	Z	Asymp. Sig. (2- tailed)			
post op vas at 1 week Night - Pre op VAS night	-3.584 ^b	.000			
post op vas at 4 weeks night - Pre op VAS night	-3.630 ^b	.000			
post op vas at 4 weeks night - post op vas at 1 week Night	-3.578 ^b	.000			
a. Wilcoxon Signed Ranks Test					
b. Based on positive ranks.					

All three paired comparisons in night time i.e Pre op VAS vs Post op VAS at 1 week, Pre op VAS vs Post op VAS at 4 weeks and Post op VAS at 1 week vs Post op VAS at 4 weeks were found to be stastically significant (P value < .05).

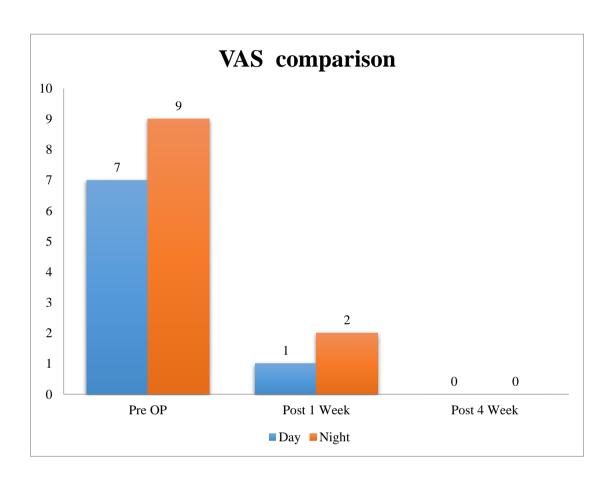
Descriptives:



Day	Pre op	Post op 1 week	Post op 4 weeks
VAS	7	1	0



Night	Pre op	Post op 1 week	Post op 4 weeks
VAS	9	2	0



VAS	Pre op	Post op 1 week	Post op 4 weeks
Day	7	1	0
Night	9	2	0

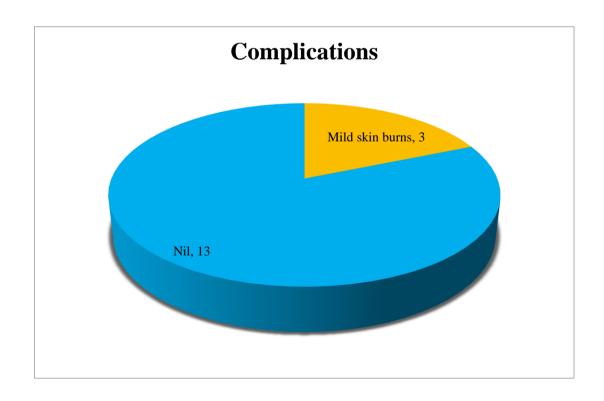
The median Pre op VAS day time was 7 and median pre op VAS night time was 9.

The median post op VAS day time at 1 week was 1 and median post op VAS night time at 1 week was 2.

The median post op VAS day/night time at 4 weeks was 0.

COMPLICATIONS:

complications						
				Valid	Cumulativ	
		Frequency	Percent	Percent	e Percent	
Valid	Mild skin	3	18.8	18.8	18.8	
	burns					
	Nil	13	81.3	81.3	100.0	
	Total	16	100.0	100.0		

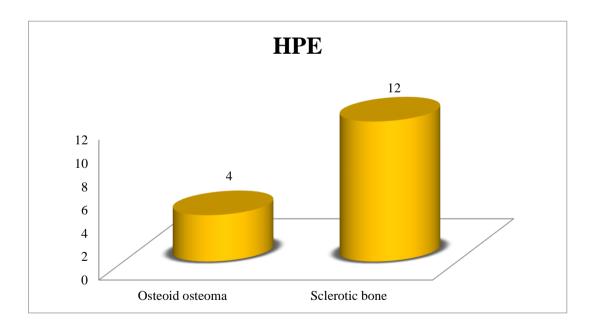


No major complications was observed. Three patients had mild skin burns of less than 10 mm in RF probe insertion site, which got healed without having any secondary infection.

Histopathological examination:

HPE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	osteoid osteoma	4	25.0	25.0	25.0
	sclerotic bone	12	75.0	75.0	100.0
	Total	16	100.0	100.0	



4 out of 16 patients HPE reports came as osteoid osteoma. Rest of the patients reports came as sclerotic bone.

Comparison between nidus size and histopathological report yield:

Cross tabs:

HPE * nidus size(mm) Crosstabulation

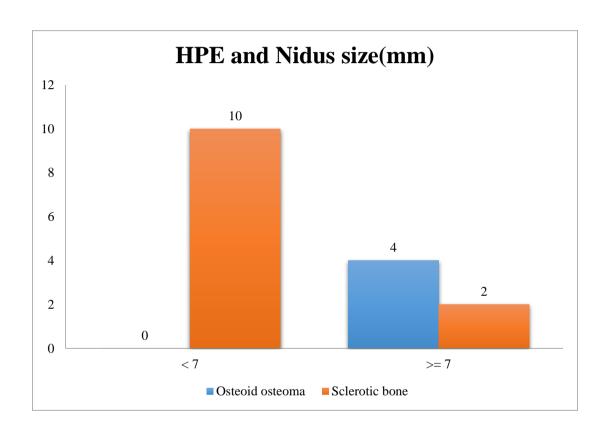
Count

		nidus siz		
		< 7	>= 7	Total
HPE	osteoid osteoma	0	4	4
	sclerotic bone	10	2	12
Total		10	6	16

	(Chi-Square	Tests		
	Value	df	Asymp. Sig. (2- sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi- Square	8.889ª	1	.003		
Continuity Correction ^b	5.689	1	.017		
Likelihood Ratio	10.357	1	.001		
Fisher's Exact Test				.008	.008
N of Valid Cases	16				

a. 3 cells (75.0%) have expected count less than 5. The minimum expected

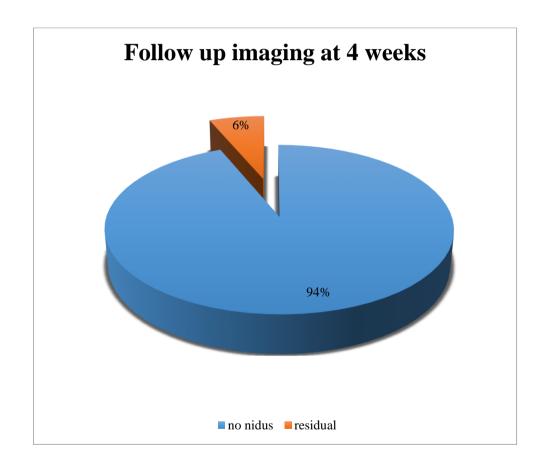
b. Computed only for a 2x2 table



6 patients had nidus size more than or equal to 7 mm and 4 out of 6 patients HPE turned positive for osteoid osteoma. Whereas, 10 patients had nidus size less than 7mm and their HPE reports came as sclerotic bone. This was statistically significant with P value < .05 using fisher's exact test.

Follow up imaging at 4 weeks:

follow up imaging at 4 weeks										
		Frequency	Percent	Valid Percent	Cumulativ e Percent					
Valid	4mm - residual	1	6.3	6.3	6.3					
	no nidus seen	15	93.8	93.8	100.0					
	Total	16	100.0	100.0						



At 4 weeks follow up imaging using either radiograph or CT/MRI, one patient had residual nidus of size 4mm. Patient underwent second RFA and his treatment completed successfully.

DISCUSSION

A study by Karagoz et al., in 2016 the mean age among 18 patients was 17.4 years. In our study, the mean age was 16 years and no significant difference obtained (6).

In our study, the mean nidus size was 6.6mm, whereas in karagoz et al., study the mean nidus size was 8.06 mm.

In our study with 16 patients, most common bone involved was femur (n= 10), followed by tibia (n =5) and fibula(n=1). Commonest location in bone was cortical (n=13), subperiosteal (n =2) and intramedullary (n= 1). Among all, four patients had lesions in epiphysis. These observations are similar to results of several studies. But, we haven't lesions in less common sites like spine and upper extremities.

A study by Jahanbakhsh et al., in 2011 showed similar results. In their study of 44 patients, most common bone involved was femur followed by tibia and phalanx. Commonest location in bone was cortical followed by intramedullary and then sub-periosteal (5).

Kransdorf et al., in 1991(14) and Papathanassiou et al., in 2008(15) observed that more than 50% osteoid osteomas occurs in femur or tibia. They also observed 67% of femoral lesions are either inter trochanteric

or intra-capsular location. In our study 93% lesions were in femur or tibia and out of 10 femoral cases, only 40% were seen in intertrochanteric/intra capsular location.

The RF machine, we used was STAR med VIVA RF generator (Solutions for Thermo Ablation with RF medical technologies, South korea), STAR RF cooled tip electrode with coolant pump. The advantage of this system was minimal tissue charring/ over cooking, due to usage of cooled tip probe connected to cooled saline. Although it also works based on impedance, the input we are giving here was Watts, not the temperature. The machine inherently designed in such a way, when temperature goes beyond 99°C it automatically turns off, and prevents over cooking.

A study by Dicaprio et al., in 2007(2) and Santiago et al., in 2009(7), used RITA and Radionics RF machines with dry tip electrode with input given was temperature (90°C for 6 minutes). It ablates nidus at higher temperature, So, adjacent tissues also burns in few occasions and it has higher chance for over cooking of nidus.

As like our study, most of the studies (1,2) uses single rod electrode for ablation of osteoid osteoma. So, these rods can be easily

introduced via drilled hole. Unipolar tip electrode cooks in cylindrical fashion with rounded border.

In our study with 16 patients, pre treatment median VAS was 7 and post treatment median VAS at one week was 1 for day time and pre treatment median VAS was 9 and post treatment median VAS at one week was 1 for night time. The VAS reduction for both day and night time was statistically significant.

Several supportive studies to our results includes De Palma et al., reported in their study with 20 patients, night time mean VAS as 8.5 pre and 0.5 after treatment and day time mean VAS as 5.95 pre and 0.9 after treatment (6,49). Karagoz E. et al., reported in their study with 18 patients, night time median VAS as 9 pre and 0 after treatment and day time median VAS as 7 pre and 0 after treatment (6).

Morassi et al., in 2014 evaluated 11 patients and they observed the significant reduction in visual analog score in pre and post procedure evaluation i.e from 8.6 to 0. And, our study too reveals significant reduction in visual analog score i.e from 8 to 1(52).

In a study by Rehnitz et al., (50) which included 72 patients and another study by Cantwell et al., (53) showed no correlation between

nidus size and VAS. Age, gender and nidus size not affected the clinical success in Rosenthal et al., study in 2003(38). Compared to all these studies our study, not shown any correlation between age, sex, nidus size with VAS score or Clinical outcome.

Patients getting complete relief from pain following treatment ranges between 1 day to 2 weeks. A study by Vanderschueren et al., in 2002 which included 54 patients reveals 87% patients got completely relieved from pain on day 1. Whereas,13% patients recovered at two weeks (54). Another study in 2001 by Lindner et al., reported that complete relief of pain was obtained at the end of 1 week (55). Whereas, Karagoz et al., (6) reported between 3 to 10 days. In our study sparing, one patient with residual lesion, rest all relieved from pain in between 8 to 9 days.

In our study with 16 patients, 15 out of 16 patients got primary technical and clinical success i.e 93.8% and second time RF had 100% technical and clinical success. The problem we encountered in that one case was high impedance probably, because of large size drill compared to electrode size. So, technically not able to achieve adequate ablation, that was needed to cook the nidus (7).

However, the success rates of our study was comparable with several other studies like Cantwell CP et al., in 2004 and Yang et al., in 2007 observed technical success, near 100% and clinical success of 76 to 100% and after second Radio Frequency ablation the success rate was near 100%(41,56).

A study by Rehintz et al., in 2013 which included 72 patients showed 99% primary clinical success rate and 100% secondary success rate (50). Another similar results i.e 100% technical success, 94% Primary success and 100% secondary success rate was obtained in study by Karagoz et al., in 2016(6).

Jankharia et al., study in 2009 which included 40 Patients, showed 100% technical success with 2 patients had recurrence at 5th and 8th month. So, the primary success rate was around 95% and after 2nd RFA the success rate was 100% (7).

In 2009, A study by Fernando et al., out of 15 patients 14 patients (93%) had clinical success rate. However, one patient with tibial osteoid osteoma had recurrence and the nidus was removed via open surgery (1).

In our study, we had 3 patients with mild skin burns with no major complications. All three had lesions in mid tibial shaft and distance between lesions and skin was less than 1 cm.so, the skin burns might have occurred due to some transient contact between electrode tip and skin while ablating. However, all three skin burns healed after topical application. None of the patients, had any other complications.

A study by Jankharia et al., in 2009(7) Out of 40 patients, one patient had skin burn of around 6mm near probe insertion site in mid arm i.e diaphysis of humerus and the nidus was 1.7cm away from skin surface. They also experienced one more complication, a small bony chip fracture occurred in entry site. Since, it is a sclerotic bone it can be negligible and patient was advised for few weeks of rest.

Goetz et al., in 2004(10) and Callstrom et al., in 2006(48) observed certain complications like damage to neurovascular bundles, pathological fractures, muscle and skin burns turning into abscess in entry path. They also stated about burns occurring near grounding pads site.

Another observation was made by Tins et al., (57) in 2006, while ablating intra articular osteoid osteomas in weight bearing joints: lower

extremities, their occurred damage to cartilage which in turn leads to some disability. They also added that few of the patients experienced mechanical weakening of bone.

Motamedi D et al. in 2009(51) and Vanderschueren et al., in 2002(54) said superficial thermo-coagulation sometimes lead into skin burns.

Rosenthal et al., in 2003(38) and Lindner et al., in 2001(55) observed in their study, Radio Frequency Ablation complications like neural injury occurs when the lesions stay closer to nerves i.e within 1 cm, particularly while ablating spinal and hand osteoid osteomas.

Gangi et al., in 2007(58) stated that osteoid osteomas located within 8mm from skin surface should be treated with other modality rather than percutaneous Radio Frequency Ablation due to its complications like skin burns and tissue necrosis.

In our study, we found that the lesions with nidus size less than 7mm (10 patients) HPE reveals only sclerotic bone. Whereas, if nidus size exceeds 7mm (4 out of 6 patients) then, HPE came as osteoid osteoma with possible explanation that the smaller nidus might have been destroyed while drilling itself.

LIMITATIONS OF THE STUDY

- Smaller sample size.
- We haven't done, RFA in other less common sites of osteoid osteoma like spine, ribs, hands and feet. So, the Success rate in those sites was not assessed.
- Average follow up period in our study was, only 2 to 3 months which was not adequate. Because, most of the recurrences occur in between 3 to 6 only (45).

CONCLUSION

- Radio Frequency Ablation is a safe, quick, minimally invasive and extremely effective method in osteoid osteoma management.
- ii. We have been able to achieve a high technical and clinical success rate, with less morbidity & complications.
- iii. Computed Tomography Guided Radio Frequency Ablation should be the method of choice for treating osteoid osteomas.

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ABBREVIATIONS

RFA – RadioFrequency Ablation

CT – Computed Tomography

MRI – Magnetic Resonance Imaging

US - UltraSound

MDCT – Multi Detector Computed Tomography

T1WI – T1 Weighted Imaging

T2WI – T2 Weighted Imaging

STIR – Short Tau Inversion Recovery

CECT – Contrast Enhanced Computed Tomography

FDG PET - FluoroDeoxyGlucose Positron Emission Tomography

AP – Antero Posterior

RF - Radio Frequency

COX – Cyclo Oxygenase

PGE₂ – ProstaGlandin E₂

NSAID'S - Non Steroidal Anti Inflammatory Drugs

HPE – HistoPathological Examination

KVP – KiloVoltage Peak

MAS – Milliampere Seconds

VAS – Visual Analog Scale

K wire – Kirschner wire

G – Gauge

STAR med – Solution for Tomo Ablation with RF Medical

technologies

VIVA – Variable Insulation Vari-sized Ablation

RITA – RF Interstitial Tissue Ablation

PATIENT INFORMATION SHEET

Investigator:

Name of Participant:

Title: Image guided RadioFrequency Ablation of Bone Tumours

You (your son/daughter) are invited to take part in this research/ study /procedures. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

You(your son/daughter)are being asked to participate in this study being conducted in Govt. Kilpauk Medical College & Hospital.

Osteoid osteoma is a extremely painful benign bone lesion typically smaller than 1.5cm, with pain getting worsened in night and relieved by salicylates which has predilection for young boys. Image guided radiofrequency ablation is the current treatment modality of choice in treating osteoid osteoma with 95 to 100% cure rate

Our study is focused in evaluating the technical and therapeutic efficacy of radiofrequency ablation in osteoid osteoma in our hospital, to assess the technical limitations and post procedural complications.

Study Procedures

First you will be subjected to imaging using Multi Detector CT in which your lesion site will be imaged. A series of planning images are performed, with the lesion to be ablated planned on the computer terminal and then marked on your skin. Spinal anaesthesia will be given. Then, skin preparation will be done. Using driller right path to lesion will be created. Followed by a biopsy from lesion then, Radio Frequency generator will be turned on and connected with coolant and RF electrode. Under CT guidance the lesion will be ablated. The whole procedure will take around 90 minutes The specimen obtained is sent for histopathological examination.

After 24 hours rest ,you can limit your activities for 2 weeks. You may have to come to the hospital (study site) for examination and investigations apart from your scheduled visits, if required.

Women of Childbearing Potential

You must not participate if you are pregnant, breast feeding a child, or if you are of child bearing potential and not practicing two forms of effective methods of contraception.

Possible Risks to you(your son/daughter):

Risks of this procedure is rare and includes

Skin burns:most of these are minor. However, it rarely needs antibiotic support and wound closure.

Bleeding: this is also rare and common in patients with bleeding disorders.

Nerve damage: When lesions lie close to neuro vascular bundles.

Possible benefits to other people

The result of the research may provide benefits to the society in terms of advancement of medical knowledge and/or therapeutic benefits to future patients

Confidentiality of the information obtained from you (your son/daughter)

You(your son/daughter) have the right to confidentiality regarding the privacy of your(your son/daughter)medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you(your son/daughter) will be allowing the research team investigators, other study personnel, sponsors, IEC and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your(your son/daughter)identity.

How will your decision to not participate in the study affect you(your son/daughter)?

Your decisions to not participate in this research study will not affect your(your son/daughter)medical care or your relationship with investigator or the institution.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons.

However, it advisable that you talk to the research team prior to stopping the treatment.

PROFORMA

STUDY TITLE:

"IMAGE GUIDED RADIOFREQUENCY ABLATION OF BONE TUMOURS"

S.No:							
Name:							
Age/Sex:							
Address with Contact No:							
Presenting Complaints and History:							
Imaging: s size)	site(transve	erse & long	itudinal lo	cation, bone	e involved,	, nidus	
Complicat	ions:						
HPE:							
Follow up	imaging a	t 4 weeks:	(nidus see	n or not)			
VAS	Pre op		Post op a	t 1 week	Post op at	t 4 weeks	
	Day	Night	Day	Night	Day	Night	
Grade							

Signature of Investigator Signature of the Participant

Witness:

PATIENT INFORMED CONSENT FORM

Title of the study: "Image guided radiofrequency ablation of bone tumours".

Name of the Participant:

Name of the Principal (Co-Investigator):

.Name of the Institution:

Age/sex:

Documentation of the informed consent:

I have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age (Father/Mother in case of age less than 18 years) and, exercising my free power of choice, hereby give my consent to be included (to include my son/daughter) as a participant.

- 1. I have read and understood this consent form and the information provided to me.
- 2. I have had the consent document explained to me.
- 3. I have been explained about the nature of the study.
- 4. I have been explained about my rights and responsibilities by the investigator.
- 5. I have been advised about the risks associated with my(my son/daughter) participation in this study.*
- 7. I agree to cooperate with the investigator and I will inform him/her immediately if I (my son/daughter)suffer unusual symptoms. *
- 8. I have(my son/daughter) not participated in any research study within the past month(s). *
- 9. I am aware of the fact that I(my son/daughter) can opt out of the study at any time without having to give any reason and this will not affect my (son/daughter) future treatment in this hospital. *

- 11. I am also aware that the investigator may terminate my(son/daughter)participation in the study at any time, for any reason, without my consent. *
- 12. I hereby give permission to the investigators to release the information obtained from me(my son/daughter) as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC.
- 13. I have understand that my(son/daughter) identity will be kept confidential if my data are publicly presented
- 14. I have had my questions answered to my satisfaction.
- 15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and	d signature /	' thumb	impression	of the	participant:

Name Signature

Name and Signature/thumb impression of the participant's Parent:

Name Signature

Date

Date

Name and Signature of the investigator or his representative obtaining consent:

Name Signature

Date



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UNAGE GUIDED JABOOUREQUENCY ABLATION OF BUNE TUNIOURS

INTERIOR CHIEF

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INSTITUTIONAL ETHICAL COMMITTEE GOVT.KILPAUK MEDICAL COLLEGE, CHENNAI-10 Protocol ID. No. 04/2015 Dt: 02.11.2015 CERTIFICATE OF APPROVAL

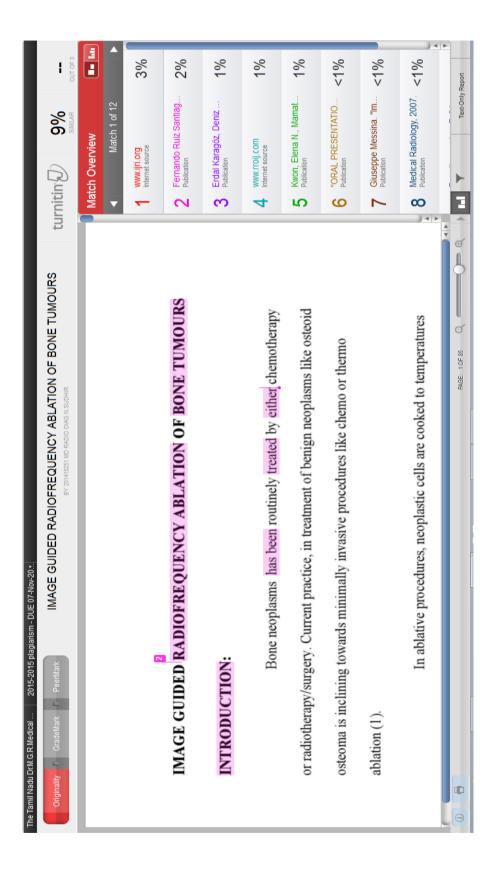
The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "Image Guided Radio Frequency Ablation of bone tumours" - For Project Work submitted by Dr. N. Sudhir, M.D. Radiology Postgraduate, Govt. Kilpauk Medical College, Chennai.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

Govt.Kilpauk Medical College, Chennai – 10.

Stiller



s. no	name	age	sei		e op 'AS	site (trans)	bone & location(long)	nidus size (mm)	complicat ions	HPE		op vas week		op vas weeks	follow up imaging at 4 weeks
				day	night						day	Night	day	night	nidus(mm)
1	Amrit das	25	m	7	9	cortical	tibia - mid diaphysis	8	mild skin burns	osteoid osteoma	5	7	5	7	4mm - residual
2	Sailesh	13	_ m	6	9	intramedullary	femur - distal diaphysis	10	nil	osteoid osteoma	1	2	0	0	no nidus seen
3	Deepan	9	m	7	8	cortical	femur - meta diaphysis	5	nil	sclerotic bone	1	1	0	0	no nidus seen
4	Prabhakaran	19	m	6	9	cortical	femur - proximal diaphysis	7	nil mild skin	sclerotic bone	1	1	0	0	no nidus seen
5	Joseph Daniel	14	m	7	8	cortical	tibia - mid diaphysis	6.2	burns	sclerotic bone sclerotic	1	1	0	0	no nidus seen
6	Jeya indhu	17	f	7	9	cortical	femur - epiphysis femur - proximal	6	nil	bone	1	1	0	0	no nidus seen
7	Lakshmanan Thangavel	28	m	6	8	cortical	diaphysis	8	nil	osteoma sclerotic	1	1	0	0	no nidus seen
8	prabhakar	21	m	7	9	subperiosteal	fernur - epiphysis	6	nil	bone sclerotic	1	1	0	0	no nidus seen
9	Arun aravind	13	m	6	9	cortical	tibia - epiphysis	5	nil	bone sclerotic	1	1	0	0	no nidus seen
10	Chandran	22	m	7	9	subperiosteal	femur - mid diaphysis	7	nil 	bone sclerotic	1	1	0	0	no nidus seen
11	Rakib Balaraman	11	m	7	9	cortical	femur - epimetaphysis tibia -middiaphysis	6.5 6	nil mild skin burns	bone sclerotic bone	 	1	0	0	no nidus seen
13	Santhosh	17		6	9	cortical	femur -proximal diaphysis	7.5	nil	osteoid osteoma	2	2	0	0	no nidus seen
14	Dhinesh kumar	9	m	7	9	cortical	tibia - mid diaphysis	5.5	nil	sclerotic bone	1	1	0	0	no nidus seen
15	Vimala	14	f	6	8	cortical	femur - proximal diaphysis	5.8	nil	sclerotic bone	1	2	0	0	no nidus seen
16	Gopalakrishna n	8	m	7	9	cortical	fibula- distal diaphysis	6	nil	sclerotic bone	1	2	0	0	no nidus seen