

Research Reporting Standards for Image-guided Ablation of Bone and Soft Tissue Tumors



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Abbreviations: BPI = Brief Pain Inventory, LITT = laser-induced interstitial thermotherapy, RF = radiofrequency

IMAGE-guided percutaneous methods of tumor destruction have proven effective for treatment of benign bone tumors as well as for palliation of metastases involving bone and soft tissue beyond the liver and lung. Treatment of primary bone tumors is largely restricted to benign tumors, most notably osteoid osteomas, as a single-modality treatment or as an adjunct to surgical resection (1–4). More recently, image-guided

ablation techniques have proven helpful for palliation of painful metastatic disease involving bone and soft tissue beyond the liver and lung for those patients in whom conventional therapies have failed, including external-beam radiation and narcotic analgesic agents. The purpose of this document from the Society of Interventional Radiology (SIR) is to provide a guideline for reporting clinical studies and research on the

use of ablation methods for the treatment of benign bone tumors and metastases involving bone and soft tissues beyond the liver and lung. The use of these guidelines will allow more meaningful comparison of outcome data and clarify direction for future research.

IMAGE-GUIDED ABLATION OF BENIGN BONE TUMORS

Osteoid osteoma is the most common benign bone tumor, representing approximately 10% of all benign bone tumors. It is a tumor of unknown etiology with no malignant potential that classically affects children and young adults, in an approximately 2:1 male:female ratio. Although these painful tumors may be found in any bone, they tend to affect the appendicular skeleton, with the proximal femur being the most common site (5). The classic presentation is one of dull pain that is worse at night and relieved with aspirin (6). These tumors grow slowly, if at all, and may spontaneously regress.

Treatment options for symptomatic osteoid osteomas that do not regress are divided into three categories: surgical, medical, and percutaneous. The surgical treatment includes en bloc resection or curettage. Intraoperative localization of the nidus can be very challenging, and can result in significant bone resection and possible failure of the nidus re-

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removal in a small percentage of cases. Percutaneous image-guided resection of osteoid osteoma is also possible (7–10). The degree of bone resection also plays a significant role in weight bearing and activity after surgery. Comparative studies between image-guided ablation and surgery show similar effectiveness, with surgery associated with a higher complication rate, longer hospitalization, and longer recovery (3,11).

Medical treatment consists of a variety of nonsteroidal antiinflammatory medications. Although pain relief is frequently obtained, many patients do not wish to continue to receive long-term medications with the acknowledged potential for gastrointestinal, hepatic and renal side effects.

Computed tomography (CT)-guided percutaneous radiofrequency (RF) ablation of osteoid osteoma was reported by Rosenthal et al in 1992 (1). Although the technical aspects of the procedure have changed little, modifications in equipment, including different types of electrodes and other thermal methods have been developed. Since this initial report (1), at least 88 peer-reviewed articles involving more than 1,400 patients (1,466 extraspinal and 30 spinal tumors) have appeared in the literature (2–4,12–15). Primary success rates as high as 97% have been reported, with a 100% secondary success rate (16).

Laser-induced interstitial thermotherapy (LITT) was first reported by Gangi et al in 1997 (17). Since this report (17), there have been at least 17 peer-reviewed articles published involving more than 340 patients (328 extraspinal and 16 spinal tumors) undergoing LITT for the treatment of osteoid osteoma (18–21). The number of LITT-treated osteoid osteoma cases reported in the literature, representing approximately one fifth of the RF ablation cases, suggests this treatment method is less commonly used than RF ablation. Advantages of LITT include a smaller-caliber thermal applicator and magnetic resonance (MR) imaging compatibility. As this technique employs a smaller needle applicator, biopsy of the lesion is usually not possible, although this usually is not necessary as imaging findings are often diagnostic. Primary success rates as high as 98% have been reported, with a 100% secondary success rate (18,22).

Cryoablation has also been used for the treatment of osteoid osteoma, as reported in a case of MR imaging-guided

treatment of an osteoid osteoma in the ischial bone (23). The ability to monitor the ablation zone with CT or MR imaging was reported by the authors to be a potential advantage of cryoablation. Although it was not mentioned by the authors, cryoablation also has the advantage of penetration of the ablation zone into dense bone, which is a normal part of the cortical response to the presence of osteoid osteoma (24). Note that further penetration of the ablation zone into bone may also be a detriment to this therapy, with possible pathologic fracture resulting from weakening of the bone. This ablative technique for osteoid osteoma may benefit from further investigation.

Thermal ablation of osteoid osteoma is the dominant topic in the literature with respect to ablation of primary bone tumors. However, a small number of case reports of other primary bone tumors treated with RF ablation have appeared in the literature (ie, chondroblastoma, chondroma, eosinophilic granuloma, and epithelioid hemangioendothelioma) (25–28).

IMAGE-GUIDED ABLATION OF METASTATIC DISEASE INVOLVING BONE AND SOFT TISSUE BEYOND THE LIVER AND LUNG

Skeletal metastases are a common problem in patients with cancer. Autopsy studies have shown that as many as 85% of patients who die from breast, prostate, and lung cancer have bone metastases at the time of death (29). Complications resulting from skeletal metastases, including pain, fractures, and decreased mobility, can reduce a patient's quality of life and performance status (29,30). In addition, these complications can affect a patient's mood, leading to associated depression and anxiety (29). Current treatment for patients with bone metastases are primarily palliative and include localized therapies (eg, radiation and surgery), systemic therapies (eg, chemotherapy, hormonal therapy, radiopharmaceuticals, and bisphosphonates), and analgesic agents (eg, opioids and nonsteroidal antiinflammatory drugs).

Skeletal metastases that cause pain but that are also at risk for impending fracture may be treated surgically with an intramedullary rod or other internal fixation in an extremity. However, tu-

mors located in the spine and periacetabular regions require greater surgical intervention to effect stabilization. Recently, percutaneous methods have been developed to stabilize these types of tumors through the administration of methyl methacrylate into the tumor, with or without previous treatment with ablative methods (31).

External-beam radiation therapy is the current standard of care for patients with cancer who present with localized bone pain. This treatment results in a reduction in pain for the majority; however, 20%–30% of patients treated with this modality do not experience pain relief, and there may be few additional options (32–37). Unfortunately, patients who have recurrent pain at a metastatic site previously irradiated are often not eligible for further radiation therapy secondary to limitations in normal tissue tolerance. Additionally, metastatic disease in this population is often refractory to standard chemotherapy or hormonal therapy. Surgery, which is usually reserved for impending fracture, is not always an option when patients present with advanced disease and poor functional status. Radiopharmaceuticals, which have known benefit in patients with diffuse painful bony metastases, are not considered standard of care for patients with isolated, painful tumors. For many patients with painful metastatic disease, analgesic agents remain the only alternative treatment option (38). Unfortunately, to obtain sufficient pain control, side effects of these medications such as constipation, nausea, and sedation can be significant.

Because many patients continue to experience pain from metastatic disease despite optimized analgesia and other treatments, RF ablation methods were explored as a potential treatment method and found beneficial for these patients (39–41). Since the first peer-reviewed report of palliation of painful metastatic disease with RF ablation appeared in 2002 (40), at least 25 peer-reviewed manuscripts involving more than 400 patients have appeared in the literature. Subsequently, cryoablation has been used as a treatment method and found to provide similar palliation of painful metastases (24). These reports have established the treatment benefit for patients with benign and metastatic disease involving bone and soft tissue beyond the liver and lung (24,39–45).

The vast majority of reports in the literature are case series from single institutions. Unfortunately, these reports have used a wide variety of study designs and reporting methods that, as a result, limit the understanding of appropriate patient selection, ablation method and technique, and expected treatment outcome.

CURRENT STATUS OF RESEARCH REPORTING FOR IMAGE-GUIDED TUMOR ABLATION

Goldberg and colleagues (46) published an updated consensus report on standardization of terminology and reporting criteria for generic image-guided tumor ablation on behalf of the SIR Technology Assessment Committee and the International Working Group on Image-Guided Tumor Ablation (46). These recommendations have been adopted by the editorial staffs of *Radiology* and the *Journal of Vascular and Interventional Radiology*. As such, investigators involved in image-guided tumor ablation should be familiar with these reporting guidelines and use them for presentations and manuscripts. Ablative methods have become the standard of care for treating osteoid osteoma. However, reports of treatment of other benign bone tumors are limited to case reports and series. Important absences in the current literature are large prospective randomized controlled trials comparing focal ablative therapy versus conventional surgical and nonsurgical standard therapies for treatment of patients with metastatic disease. This report by SIR on research reporting standards provides a guideline for research and reporting on the use of image-guided ablation to treat bone and soft tissue metastases. Additionally these guidelines may be used for research and reporting on the use of image-guided ablation to treat osteoid osteoma and other benign bone tumors.

PATIENT SELECTION

Clinical Criteria for Image-guided Ablation of Benign Bone Tumors

Potential candidates for image-guided ablation of osteoid osteoma include all patients with symptoms that

are not relieved by medical therapy or patients who do not desire long-term medical therapy. As with any potential percutaneous ablation treatment, patient and anatomic criteria should be considered, including accessibility with a percutaneous approach and adjacency of normal structures. Special care should be taken in considering patients with intraarticular tumors, tumors near growth plates, tumors in the hands, and tumors in the spine near neural elements (4).

Clinical Criteria for Image-guided Ablation of Metastatic Disease Involving Bone and Soft Tissue beyond the Liver and Lung

The clinical indication for image-guided ablation of metastatic disease involving bone or soft tissue outside the liver and lung must be clearly specified. Patients with limited metastatic disease involving bone or soft tissue outside the liver and lung who are potential candidates for image-guided ablation fall into four general categories: (i) patients who have limited painful metastatic disease in whom conventional therapies have failed or who have refused conventional therapy, (ii) patients at risk for further morbidity with progression of a metastatic lesion that may be at risk for fracture or invasion of adjacent critical structures, (iii) patients who have limited metastatic disease who are not surgical candidates, and (iv) patients with symptomatic metastatic disease such as hormonally active tumors or hemorrhagic tumors.

Patients in the first category include those who have painful metastatic disease that may be multifocal but has a dominant source of pain limited to one or two locations. Patients are offered focal ablative therapy (eg, RF ablation or cryoablation) for painful metastases in the following settings. First, it is offered when a patient reports moderate or severe pain, typically at least 4 on a scale of 0–10 for worst pain in a 24-hour period. Patients with lower pain scores are typically not offered treatment for palliation of their pain because it is difficult to improve on mild pain and also because this type of pain can usually be adequately managed by oral analgesics. Second, it is offered when a patient's focal pain is limited to one or two sites and the patient's pain is associated with a corresponding abnormality evident

with cross-sectional imaging. Patients with numerous painful tumors are not treated with these techniques because this type of pain is better treated with a systemic, rather than focal, approach. In addition, pain caused by multiple tumors is difficult to adequately localize for directed therapy. Finally, it is offered when treatment of the patient's painful metastatic lesion is amenable to the use of ablative devices. Tumors that are amenable to ablative therapy are most typically osteolytic or mixed osteolytic/osteoblastic in nature or otherwise composed of soft tissue.

Patients in the second category include patients with metastatic disease that would result in increased morbidity if a specific metastatic lesion were to increase in size without treatment. The use of ablative techniques to prevent complications for patients with metastatic disease is warranted if the disease is relatively clinically stable and progression of a specific metastatic lesion may lead to fracture, if one tumor has not responded to chemotherapy while others have regressed, or if there is concern for invasion of an adjacent critical structure such as neural, vascular, bowel, or bladder tissues. Patients at risk for fracture as a result of metastases in axially loaded locations (eg, vertebral bodies or periacetabular region) may benefit from cementoplasty (31). Patients who have pathologic fractures have been treated with both ablation and cementoplasty with pain relief and stabilization of the fracture (47). It is recommended that the use of combination therapies, and the rationale for the use of combination therapy, for the treatment of patients with metastatic disease should be reported.

Patients in the third category include those with disease that is relatively clinically stable and have one or a few metastatic tumors evident on imaging studies that are not candidates for surgery. The use of ablative techniques is indicated in this situation as a method to achieve local control and remission of their disease. In this instance, complete ablation of the targeted lesion is necessary and treatment planning is critical to achieve this goal.

Patients in the fourth category include those with metastatic disease that would benefit from palliation as a result of tumors that release biochemically active hormones such as neuroendocrine tumors or possibly tumors that have

persistent low-grade hemorrhage despite conventional therapy. The uses of ablative techniques are directed toward destruction of neoplastic tissue to achieve control of the patient's symptoms. The goal of the use of ablative therapy should be reported for these patients.

Anatomic Criteria

Anatomic considerations should be taken into account when selecting appropriate tumors for image-guided ablation, including tumor size, proximity to adjacent important neural structures, and proximity to adjacent bowel and bladder. It is recommended that the anatomic considerations that are employed as part of the inclusion or exclusion criteria for a research study or trial should be described. Techniques that are employed to avoid injury or improve safety such as thermocouple deployment or tissue displacement techniques should be described. Guidelines used for treatment decisions based on anatomic considerations (ie, distances for safety margins from critical structures) should be described.

Exclusion Criteria

No rigid exclusion criteria exist for image-guided ablation of osteoid osteoma. Therefore, the decision to treat a tumor in a relatively high-risk area (eg, intraarticular tumors, tumors near growth plates, tumors in the hands, and tumors near neural elements) should be performed based on the operator's experience and possible consultation with orthopedic surgery personnel. The use of tissue displacement techniques such as fluid instillation to increase the margin of safety should be reported. Thermal injury to articular cartilage does not appear to be a factor in the short term, but may manifest itself in long-term evaluation as premature degenerative changes (4). Treatment of tumors near growth plates have the potential to result in thermal injury to the growth plate, with subsequent growth alteration. The tiny nerves of the extremities are not visible on CT and care must be used to avoid injury with image-guided ablation. Safe treatment of osteoid osteomas in the spine near neural elements is based on operator experience with an understanding of the relative protective

effect of intact bone and cerebrospinal fluid insulative effects (4).

Patients may be excluded from focal ablative therapy for metastatic disease involving bone or soft tissue metastases outside the liver and lung for three primary reasons: (i) because successful treatment would require treatment of a portion of the tumor located within approximately 1 cm of the spinal cord, major motor nerve, brain, artery of Adamkiewicz, bowel, or bladder. This margin of safety is a general guideline for the deployment of the ablative device adjacent to these critical structures. In practice, the nearest proximity of the ablative device to critical structures is dependent on visibility of the ablation margin, use of thermal protection devices, monitoring of temperatures and neural structures, and experience of the interventional oncologist (ii) when patients present with numerous painful tumors. However, many patients will have multiple metastatic sites of disease and it is not unusual for only one or two of the sites to cause moderate to severe pain. In these cases, the tumor(s) responsible for moderate to severe pain might be ablated for palliation (iii) when patients present with predominately osteoblastic disease. Treatment of osteoblastic tumors is technically possible with the use of bone biopsy techniques or with a bone drill to provide access to the affected area and to provide a path for deployment of the ablative device. However, these are infrequently performed because of the often-difficult access through sclerotic bone with hand-driven bone biopsy devices (a drill minimizes this issue) and because sclerotic metastases are often multifocal when present. Although cryoablation will effectively treat intact or sclerotic bone, RF ablation energy is poorly delivered into sclerotic or otherwise intact bone (48).

Recommendations

The clinical indication for image-guided ablation and evaluated endpoints of the study must be clearly specified. For patients treated for palliation of painful disease, the pain score before treatment, on a 0–10 scale, must be recorded. Pain medication use should be documented, and preferably reported using a standard conversion of opioid analgesia to morphine equivalents (49,50). For patients treated for metastatic disease at risk for increased mor-

bidity such as fracture, or for progression that would involve a critical structure, the intent of the therapy should be described. For patients with limited metastatic disease with the goal of obtaining complete local control and remission, the treatment strategy should be described. Anatomic location and description of all tumors must be reported. Study inclusion and exclusion criteria and the methods used to assign treatments to subjects must be described.

PRETREATMENT EVALUATION

Demographics and Risk Factors

Evaluation of patients for consideration of image-guided ablation must include assessment of demographics (ie, age, sex, and ethnicity). Patients with cardiac pacemakers require additional planning before the use of RF ablation (and possibly microwave and irreversible electroporation systems) but not cryoablation or laser, and may require temporary continuous pacing operation without sensing of the device or monitoring of the patient by a technician as a result of possible electromagnetic interference during the ablation procedure (51). Patients with mechanical cardiac valves require conversion from warfarin to unfractionated or low molecular weight heparin for the image-guided ablation procedure, followed by resumption of oral anticoagulation.

Osteoid osteomas are usually solitary and sporadic, and therefore recognized risk factors are not widely described in the medical literature (52). Presumed or suspected risk factors should be documented nonetheless. Finally, the presence and nature of previous osteoid osteoma therapy, either surgical or percutaneous, should be described.

Comorbidities/Performance Status

Osteoid osteomas typically affect patients during the second and third decades of life (52). As such, these young individuals generally lack significant comorbid medical conditions. Regardless, the presence of concurrent illness, particularly congenital and acquired cardiovascular and respiratory disease, which may introduce a high risk of general anesthesia, surgical therapy, and postablative complications, should be reported.

Table 1
Eastern Cooperative Oncology Group/Zubrod Performance Status Scale

Score	Definition
0	Asymptomatic and fully active; no restrictions
1	Symptomatic; fully ambulatory; restricted in physical strenuous activity
2	Symptomatic; unable to carry out any work activities; ambulatory; capable of self-care; <50% waking hours spent out of bed
3	Symptomatic; limited self-care; confined to bed or chair >50% of time
4	Completely disabled; no self-care; totally confined to bed or chair

Other musculoskeletal abnormalities should be documented if present.

In most cases, patients with osteoid osteomas describe severe localized pain present for duration of weeks to years, and the severity of which is increased at night and relieved by use of nonsteroidal antiinflammatory drugs (52). As such, the presence, location, severity, duration, and temporal nature of patient symptoms should be reported, particularly if refractory to conservative medical management. Aggravating or alleviating factors should also be noted. Depending on their location, osteoid osteomas may result in physically evident musculoskeletal abnormalities. Any spinal deformities resulting from vertebral osteoid osteomas or joint abnormalities, such as pain, soft tissue swelling, joint effusion, and decreased range of motion, resulting from intraarticular tumors should be described. Secondary physical manifestations of disease, including osteoarthritis, limb length discrepancy, gait abnormality or limp, and muscle atrophy should be reported.

In consideration of treatment of patients with metastatic disease, the patient's performance status should be reported according to Eastern Cooperative Oncology Group/World Health Organization/Zubrod or Karnofsky scoring systems (53,54) (Table 1). Further consideration of treatment includes rate of disease progression, as an estimated life expectancy of at least 2 months is generally necessary to obtain benefit from the therapy. Other evaluations include comorbid medical renal or renovascular disease, coronary artery disease, and chronic obstructive pulmonary disease.

Other Therapies

Patients treated for metastatic disease involving bone or in the soft tissues outside the liver and lung often receive

other therapies before consideration of treatment with image-guided ablation. Reporting completed and ongoing chemotherapy, hormonal therapy, targeted molecular therapy, or bisphosphonate therapy, as well as previous radiation therapy, is necessary for evaluation of the effectiveness of these image-guided ablation therapies.

Relative Contraindications

Contraindications to percutaneous image-guided ablation of benign and metastatic disease include technical, anatomic, clinical, and operator considerations. Close proximity of tumors to neurovascular or dural structures, particularly in spinal tumors and tumors located in the small bones of the hand, may preclude image-guided ablation therapy. Guidelines employed for the use of image-guided ablation adjacent to critical structures such as neural tissues or in a periarticular location should be reported.

Imaging Correlation

Image-guided ablation of benign bone tumors.—Description of the particular radiographic elements of imaging diagnosis of osteoid osteoma is imperative, principally because percutaneous ablative therapy of osteoid osteoma may be pursued based on imaging alone and without a tissue diagnosis. Radiographic diagnosis of osteoid osteomas should include a detailed description of tumor location. Tumors may be cortical (ie, diaphyseal or metaphyseal), medullary, or intraarticular. The presence of cortical thickening, periosteal reaction, and reactive bony sclerosis should be noted and described. A radiolucent nidus represents the imaging hallmark of osteoid osteomas, and may contain focal areas of internal mineralization. The nidus is generally solitary (but may be paired), and is radiographically

evident in approximately 85% of cases (55). Nidus presence, number, and size should be reported.

Although radiography may be diagnostic of osteoid osteoma, CT scans should be obtained before percutaneous image-guided ablation to definitively delineate the tumor nidus. Furthermore, CT allows for distinction of osteoid osteoma from imaging mimics, including bone (ie, Brodie) abscess, stress fracture, and subchondral cyst (ie, "geode"), for which alternative therapies or no treatment are required. Contrast enhancement of the vascular nidus on dynamic contrast-enhanced CT should be described. In contradistinction, bone abscesses, stress fracture, and subchondral cysts show no contrast enhancement. Although it is less useful for nidus identification, MR imaging may reveal bone marrow and soft tissue edema, which should be reported when this imaging study is obtained.

Finally, correlation of radiographic and cross-sectional imaging with other imaging studies, such as technetium Tc 99m bone scan, should be reported in the case of atypical osteoid osteoma location or radiographically unapparent tumors. Tumor characteristics on vascular, blood pool, and delayed phases of imaging should be described. Correlation of clinical findings of osteoid osteoma with confirmatory radiologic imaging should be reported.

Image-guided ablation of metastatic disease involving bone and soft tissue beyond the liver and lung.—Effective palliative treatment of patients with metastatic disease requires correlation of the patients' focal pain with a corresponding abnormality evident with cross-sectional imaging. As part of this correlation, it is critically important to physically examine each patient before the image-guided ablation treatment to determine if the patient's pain corresponds to an identifiable lesion on CT, MR imaging, or ultrasound (US) imaging. Correlation of clinical findings of metastatic disease with confirmatory radiologic imaging should be reported.

Recommendations

Correlation of clinical symptoms and complete description of the particular elements of imaging diagnosis of osteoid osteoma is imperative, as percutaneous ablative therapy of osteoid osteoma may be pursued

- 1) Please rate your pain by circling the one number that best describes your pain at its **worst** in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain									Pain as bad as you can imagine	

- 2) Please rate your pain by circling the one number that best describes your pain at its **least** in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain									Pain as bad as you can imagine	

- 3) Please rate your pain by circling the one number that best describes your pain on the average in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain									Pain as bad as you can imagine	

- 4) Please rate your pain by circling the one number that tells how much pain you have **right now**.

0	1	2	3	4	5	6	7	8	9	10
No Pain									Pain as bad as you can imagine	

Figure. BPI Short Form questionnaire.

based on imaging alone and without a tissue diagnosis before treatment. Reporting the imaging methods used and the process for correlation of the imaging findings with the patients' focal pain is necessary. Characterization of the patient cohort with respect to demographics, risk factors, comorbidities, and performance status allows comparison across different studies, and must be reported. Reporting the patient's previous treatments and corresponding time interval to image-guided ablation is an important variable to separate treatment response to therapy.

TUMOR CHARACTERISTICS

Tumor size should be recorded as the maximal unidimensional tumor diameter as seen on CT, MR, or US imaging. When a more detailed assessment of tumor size is recorded, the dimensions in three orthogonal axes should be recorded. Tumor volume may be estimated from the orthogonal diameters, or measurement of tumor volume is possible using volume-rendering software. The basis for recording tumor size and the method of volume estimation, if employed, should be specified.

The anatomic location of the tumor should be reported, including whether contained within a particular bone, abutting the bone with or without periosteal reaction, or located in the soft tissues such as intraperitoneal fat, intramuscular, subcutaneous tissues, or dermis. If contained within a bone, the relative location, such as medullary or cortical, should be reported. Other anatomic locations such as adjacent to joints or other functional bony landmarks should be reported.

Tumor proximity to a major motor nerve can result in suboptimal treatment in order to avoid injury. In ad-

5) What treatments or medications are you receiving for your pain?

6) In the past 24 hours, how much **relief** have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete relief

7) Please circle the one number that describes how, during the past 24 hours, **pain has interfered** with your:

A. General activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Figure. (continued)

dition, close proximity to bowel and bladder and dermis may require adjunctive techniques to prevent off-target injury of adjacent normal structures during the ablation procedure. Consequently, anatomic location of all treated tumors must be reported and adjunctive techniques described.

Biopsy

Because the clinical and imaging features of osteoid osteoma have high diagnostic accuracy (56), and because non-diagnostic biopsy findings are common in osteoid osteoma (57), tumors with characteristic clinical presentation and radiologic characteristics may be treated

without histologic confirmation. When biopsy is performed, results must be reported. Instances in which biopsy is not performed must be specifically described. Additionally, these tumors and procedures must be included in outcome measure analysis.

Before treatment of patients with metastatic disease with image-guided

D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

Figure. (continued)

therapies, it is important to have histologically or cytologically documented solid tumor metastasis. If the nature of the metastatic disease has been previously documented through biopsy, the lesion to be treated does not require further documentation. When necessary, a biopsy should be performed before ablation to prove malignancy. The biopsy can be performed in a separate setting or just before the introduction of the applicator. A specific histologic cell type should be obtained, as a number of different tumors can metastasize to bone and soft tissue sites, and some may respond to local therapies (eg, radiation and surgery), systemic therapies (eg, chemotherapy, hormonal therapy, radiopharmaceuticals, or bisphosphonates) and analgesics (eg, opioids and nonsteroidal antiinflammatory drugs), whereas others may not.

Recommendations

A detailed description of tumor characteristics must be provided, including histologic type, size, and an anatomic description. When biopsy is performed, the results must be reported. When biopsy is not performed, the rationale for this must be described, including the basis for the assumed histologic type of the treated tumors.

TREATMENT DESCRIPTION

Method of Targeting and Monitoring

Placement of devices for image-guided ablation of metastases involving bone and soft tissue metas-

tases may be performed with multiple methods including US, CT, or MR guidance, and possibly fusion of these imaging methods with one another or with other cross-sectional imaging data such as positron emission tomography/CT. The imaging method for guidance and targeting must be described. Monitoring of image-guided ablation can be done with these same methods dependent on the ablation device or system. The imaging method used for monitoring of ablation should be described with the imaging parameters used. A description of the endpoints used to define the length of time used for ablation should be provided. The imaging method or treatment parameters used to estimate or determine the treatment margin must be reported.

Table 2
Classification of Complications of Ablation of Bone and Soft Tissue

Complication	Class
Abscess	Infectious/inflammatory
Allergy/anaphylactoid reaction	Contrast agent-related
Angina/coronary ischemia	Cardiac
Death related to procedure	Death
Death unrelated to procedure (30-d mortality)	Death
Hypotension	Cardiac
Hematoma bleeding at ablation site	Vascular
Hematoma bleeding puncture site	Vascular
Idiosyncratic reaction	Medication-related
Myocardial infarction	Cardiac
Nerve Injury	Neurologic
Pleural effusion	Respiratory/pulmonary
Pneumothorax	Respiratory/pulmonary
Pulmonary embolism	Vascular
Respiratory failure	Respiratory/pulmonary
Sepsis	Infectious/inflammatory
Skin burn	Device-related
Stroke	Neurologic
Tumor seeding	General nonvascular
Unintended perforation of hollow viscus	General nonvascular
Vagal reaction	Cardiac

Ablation Description

As specified in the SIR Technology Assessment Committee and International Working Group on Image-Guided Tumor Ablation reporting standard guidelines (46), a description must be given of the ablation device (energy source and applicator) and treatment protocol used for image-guided ablation. The details of a manufacturer's recommended treatment protocol or the precise details and specific modification of the protocol used by the operator must be stated. The duration and method of the energy application must be recorded. For RF ablation, this includes the energy modulation used (eg, target temperature, impedance-based, pulsed), the number of overlapping ablations, the number of ablation sessions, and the treatment endpoint (eg, time, target temperature, maximum impedance) and number of electrodes. For RF ablation, details as to whether the electrode used was a single-tip, cluster, or multitined electrode must also be given, as well as the length of the active electrode, number of deployed tines, or number of electrodes used for the treatment. A distinction between bipolar and monopolar devices must be specified. When multitined expandable electrode systems are used for RF ablation, or multiple electrodes

are placed for use with a switching generator, the electrode position(s) before the application of RF energy should be verified with a scan volume through the treatment region. The number of grounding pads, skin positioning, and skin preparation must be stated.

For cryoablation and microwave, the probe manufacturer, probe size and configuration, number of probes, and probe positioning (including maximum and minimum interprobe spacing) should be stated. The duration of active freezing, duration of active and/or passive thawing, and the number of freeze/thaw cycles must be recorded. The imaging method and frequency of monitoring ice ball formation must be provided. When thermocouples are used, the number, positioning, and minimum temperatures reached must be stated. The cryoprobe placement location with respect to the boundaries of the tumor and adjacent critical structures should be described.

These same guidelines are used for reporting studies that employ other ablation modalities such as microwave, laser interstitial thermal therapy, high-intensity focused US, and irreversible electroporation. As such, descriptions should include the type of applicator or energy source used, with treatment parameters reported.

Adjunctive Techniques

Adjunctive techniques are commonly used to displace normal critical structures away from the expected ablation region (58). When RF ablation is employed, this may involve the instillation of sterile water, or more commonly a nonionic solution such as dextrose in water, to form a boundary or buffer zone between the target tissue and the adjacent normal structure (59–62). Deliberate injection of inert gas, such as carbon dioxide, into the epidural space is another adjunctive technique described for treating masses surrounding the spinal cord (22). This technique involves percutaneous instillation of gas into the epidural space, which acts as an insulator without producing injury to the spinal cord. Other techniques such as placement of a balloon between the tumor and the gastrointestinal tract have been described to protect adjacent bowel from injury (63). Similarly, ionic solutions, gas, or balloons may be used with cryoablation to avoid nontarget tissue injury. Similarly, injection of fluid can also be performed to raise the dermis away from a relatively superficial tumor. Thermocouples may be placed adjacent to critical structures to accurately monitor temperature changes in these regions. When used, these techniques must be reported.

Anesthesia and Hemodynamic Monitoring

Image-guided ablation of benign and metastatic tumors involving bone and metastatic soft tissue tumors may be performed with the use of general anesthesia or moderate sedation. The method of anesthesia or type of sedation must be recorded. All patients require hemodynamic monitoring in compliance with national hospital accreditation standards and local institutional standards. When an ablation is performed in the region of an adrenal gland, it is necessary to monitor blood pressure continuously through the use of a radial arterial catheter to recognize and treat a rapid increase in blood pressure resulting from ablation of adrenal tissue (64). Use of these additional forms of hemodynamic monitoring should be reported.

In general, cryoablation does not cause an increase in pain during or after the procedure. However, heat-based

Table 3
SIR Definitions of Complications

Minor complications
No therapy, no consequence
Nominal therapy, no consequence
Includes overnight admission for observation only
Major complications
Require therapy, minor hospitalization (<48 h)
Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 h)
Result in permanent adverse sequelae
Result in death

methods can often cause increased pain and moderate sedation with local or regional blocks or possibly general anesthesia may be required to allow complete treatment of the target lesion. When moderate sedation is used, airway evaluation before and throughout the procedure is necessary because some patients will be in a prone position during the procedure. Any regional blocks performed, including epidural or spinal anesthesia, as well as local anesthetic treatments, should be reported.

Recommendations

The imaging method of treatment targeting (US, CT, MR imaging) must be provided. A description of the ablation electrodes and energy source must be stated, along with the treatment algorithm. When adjunctive percutaneous techniques are used for the protection of adjacent viscera from perforation or injury to adjacent vital structures from thermal injury, sufficient detail must be provided to enable another operator to perform the same maneuver. The type of anesthesia used and hemodynamic monitoring must be provided.

POSTTREATMENT IMAGING

There are no established standards for posttreatment imaging of osteoid osteoma. Therefore, the decision to image after treatment should be determined on a case-by-case basis. If posttreatment imaging is performed, the rationale and comparison with pretreatment imaging should be reported. For patients with

Table 4
Recommendations for Reporting Standards

Procedure	Required	Recommended
Evaluation before ablation		
Population demographics	X	
Risk factors and comorbidities	X	
Purpose of treatment	X	
Duration and severity of symptoms	X	
Baseline evaluation (clinical/imaging/laboratory)	X	
Anatomic location of tumor	X	
Tumor staging	X	
Biopsy	X	
Study design		
Inclusion criteria	X	
Exclusion criteria	X	
Method of treatment assignment	X	
Prior and concomitant treatments	X	
Functional status and quality of life		X
Ablation description		
Ablation device description	X	
Treatment endpoint	X	
Energy and duration of ablation	X	
Number of ablation zones	X	
Method of targeting and monitoring	X	
Adjunctive techniques	X	
Anesthesia/sedation	X	
Hospital days	X	
Evaluation after ablation		
Definition of technical/anatomic success	X	
Assessment of safety and complications	X	
Immediate complications/24 h	X	
30 d complications	X	
Late complications	X	
Assessment of treatment efficacy/effectiveness	X	
Primary outcome measure	X	
Follow-up imaging at regular intervals	X	
Follow-up of clinical status	X	
Survival		X
Disease-free survival		X
Quality of life assessment		X
Uniform duration of follow-up	X	
Need for additional ablation/surgery/other	X	
Comparison between treatment groups		
Study design	X	
Statistical analysis	X	
Intent to treat/per-protocol analysis	X	
Sample size/power	X	
Costs and cost effectiveness		X
IRB approval	X	
Sponsorship/funding/role of sponsor	X	
Participating centers	X	
Conclusions/limitations	X	

Note.—IRB – institutional review board.

metastatic disease, the need for post-treatment imaging is based on the indications for treatment.

Frequency of Imaging

The necessary frequency of imaging after image-guided ablation is related to

the natural history of the underlying primary neoplasm and metastases, which can vary widely as to rates of progression. For patients treated with the goal of local control and disease remission, the patient should undergo a contrast-enhanced CT or MR imaging examination after treatment and ap-

proximately 4 weeks after the treatment to document the presence or absence of viable tumor. Depending on the patient's symptoms, it may be appropriate to perform CT or MR imaging at 3–6-month intervals after an early scan has been obtained. Positron emission tomography/CT imaging may also be employed if appropriate based on tumor histology and clinical indication. The frequency of follow-up imaging remains to be defined from a cost-effectiveness standpoint. For the purpose of study design, all patients within a study ideally should undergo imaging with the same frequency.

Follow-up Clinical Status

Evaluation of each patient's clinical status should be performed with at least the same frequency as follow-up imaging. These assessments should record the patients' general medical condition including clinical and functional status. The clinical response and functional status are the most relevant posttreatment issues with osteoid osteoma. Pain relief, such as measured by the Brief Pain Inventory (BPI; further described later), and analgesia use should be documented. Interference with activities of daily living and changes after treatment should be reported. Physical examination findings, eg, muscle atrophy, should be documented and compared with pretreatment findings. Any late complications possibly related to image-guided ablation, including fracture, infection, nerve damage, transient bowel or bladder incontinence, and skin burn should be reported.

Follow-up Functional Status

The potential benefit of image-guided ablation in the treatment of patients with metastases involving bone and soft tissue sites needs to be defined in the context of an individual patient's functional status. Each patient's functional status should be recorded during every follow-up encounter according to the same grading system used in the pretreatment evaluation.

Duration of Follow-up

Initial follow-up for osteoid osteoma is usually performed at 30 days after treatment. Additional follow-up should then be performed on a case-by-case ba-

sis. If additional follow-up is required because of recurrent symptoms or treatment side effects, this should be reported. If retreatment is required because of recurrent symptoms, this should be reported.

In order for ablation methods to become further established as a palliative therapy for the treatment of patients with metastases involving the bone and soft tissue locations, reports of patient response need to be comparable to those of other proven local and systemic therapies. Therefore, follow-up duration should be for a period of time that is similar to previous studies involving surgery, radiation, and other proven palliative therapies. This duration should be consistent for all treated patients and ideally be a minimum of 6 months to 2 years, depending on tumor type and patient population. This approach will allow valid comparisons with these other therapies.

Recommendations

Imaging after image-guided ablation performed for local control must be performed at a regular frequency with CT, MR or positron emission tomography/CT imaging. Clinical factors may influence the choice of imaging (eg, pacemaker precluding MR imaging or contrast agent allergy or renal insufficiency precluding CT); otherwise, within a clinical trial, imaging modality use should be uniform among follow-up imaging data. Standardized definitions of residual disease must be used according to recent recommendations (46). The clinical status and functional status of patients after image-guided ablation should be evaluated during each follow-up encounter. The results of imaging and clinical follow-up must be reported. The duration of follow-up should be sufficient to detect progression of disease.

ANALYSIS OF OUTCOMES

Reporting Measures

Evaluation of response to therapy following treatment of patients with painful metastases involving bone or soft tissues outside the liver and lung is primarily based on symptomatic relief of pain. Although there are several measures used for pain response, the most commonly used for evaluation of pain

in patients with cancer, and the most validated for evaluation of response to focal therapy, is the BPI. The BPI has been validated in 25 different languages and used in more than 100 different clinical studies (65) (Figure). Recently, a consensus panel in pain research assessed the state of the science surrounding evaluations of the efficacy and effectiveness of treatments (66). This group, referred to as the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials, recommended the BPI as a core outcome measure in clinical trials of chronic pain treatments.

In the BPI, a validated standardized numeric scale is used to evaluate pain response in patients with cancer. Patients are asked to rate their worst, least, and average pain in the past 24 hours, with allowed responses ranging from 0 to 10 (0, no pain; 10, pain as bad as you can imagine). Relief of pain secondary to the RF ablation procedure or to pain medications is scored on a scale of 0% (ie, no relief) to 100% (ie, complete relief). Pain interference with daily living is evaluated with questions concerning general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life, also on a 0–10 scale (0, no interference; 10, completely interferes). Although pain is scored on a 0–10 point scale, the response of patients is often trichotomized into broad categories of mild (ie, score of 0–4), moderate (ie, 5–6), and severe (ie, 7–10) for the purposes of determining clinical intervention (67).

Opioid and nonopioid analgesic agent use is an additional standard measure of patient response to therapy. Pretreatment and posttreatment pain medications over a 24-hour period before treatment should be recorded to establish a baseline preprocedure medication usage for each patient. All analgesics should be converted into standard morphine equivalent doses using previously published and validated conversion tables (49). Total analgesic requirements for a period of 24 hours can be collected at different time intervals after the procedure for comparison versus pretreatment analgesic use as an objective measure of procedure-related changes in pain.

Reporting of response to therapy should use a validated visual analog scale, with the BPI or equivalent used as

the recommended instrument. In addition, the patients' pretreatment responses should be reported along with the posttreatment responses and the time interval between patients' reported responses during follow-up. Patients' analgesic use, converted to morphine equivalent dose, when collected, should also be reported.

Intent-to-treat Analysis

Patients who are included in studies of ablation of benign bone tumors or metastatic disease involving bone or soft tissue outside the liver and lung should be considered to have undergone ablation treatment if this was the intended treatment after registration to the study. For example, if a patient develops peritumoral hemorrhage and increased pain during insertion of a cryoprobe, which then precludes completion of the procedure, the patient should still be included as a patient in the cryoablation treatment arm during subsequent outcome analyses. The use of intent-to-treat analysis and the treatment assignment for each patient should be reported and the success of the procedure(s) should be evaluated against this intent-to-treat plan.

Survival Analysis

For patients with metastatic disease who are treated with the intent of complete local control, an important measure of the outcome of these treatments is disease-free survival. Studies reporting survival data should use the Kaplan-Meier technique. The Kaplan-Meier method calculates survival based on time from treatment to the actual time of the failure or censoring event. When appropriate, intergroup comparisons of survival estimates should be performed with an appropriate non-parametric technique, such as the log-rank test.

Stratification

In order to allow comparison of similar subgroups of patients in a randomized clinical trial, it is important to provide a mechanism to distribute similar numbers of these patients in different treatment arms. These subgroup analyses can provide an understanding of the relative benefit of a treatment (or potentially increased risk) to specific patients,

tumor histology, tumor size, and location in the body. In addition, in the analysis of data in single-arm clinical trials, these same subgroup analyses may provide additional understanding of the types of patients, tumors, and locations that benefit from treatment compared with those that may not derive the same level of benefit.

Meaningful stratification variables include comorbid conditions, history of treatments of the target tumor including radiation therapy, tumor histology, tumor size, and location. Treatment-related differences such as treatment time, the use of adjunctive therapies, and completeness of therapy may be important. When a clinical trial involves stratification or if the analysis was performed using stratified variables, the variables identified and the technique of analysis should be presented. The measures of statistical significance should be stated.

Comparison of Ablation with Other Treatments

RF ablation for the treatment of osteoid osteomas is the accepted gold standard therapy. The use of ablation methods for palliation of patients with metastatic disease is currently used primarily following failure of conventional therapies, when surgery is not a good option, or if the patient elects ablation treatment. For ablation treatment methods for palliation of patients with painful metastatic disease to become a first-line therapy, it is necessary to conduct a prospective randomized clinical trial to compare ablation with the gold standard treatment. The patient cohort, treatment methods, and stratification methods should be reported. Whenever possible, these randomized trials should incorporate the economic evaluation of image-guided ablation compared with the alternative treatment. Comparison of different ablation techniques is likely not possible, but if performed, blinded studies regarding the type of ablation therapy employed for treatment (eg, RF ablation vs cryoablation) may not be possible. If conducted, follow-up imaging can be evaluated in a core laboratory with observers blinded to therapy.

Recommendations

Measurement of pain relief and quality of life should be performed using the

BPI, a previously validated instrument for oncology patients. Opioid analgesic agent use changes after therapy should be converted to morphine equivalent dosage for comparison of different analgesic agents. If reporting a clinical trial with two treatment arms, an initial intent-to-treat basis should be used for evaluating patient outcomes after randomization. Disease-free interval and overall survival after treatment should be determined with the Kaplan-Meier method. Stratification methods should be specified for clinical trial inclusion criteria as well as for analysis of retrospective data. When possible, comparison with other treatments, including both nonsurgical and surgical methods, is optimal, rather than single-arm studies or retrospective case series of patients treated only with ablation.

COMPLICATIONS

All complications of the ablation treatment must be reported, including those that are definitely related and those that do not appear to be related to the procedure. Recognized and/or potential complications of bone and soft tissue image-guided ablation are given in **Table 2**. Complications should be reported at standard intervals, such as 24 hours and 30 days. Complications that occur within 30 days of the treatment are presumed to be procedure-related. Complications beyond 30 days may be procedure-related and, if considered related to the procedure, also need to be reported. The classification system used by SIR for grading complications and by the National Cancer Institute in the Common Terminology Criteria for Adverse Events (currently version 3) must be used, and the method for grading adverse events should be stated in the report (**Table 3**) (68,69).

COSTS AND COST EFFECTIVENESS

When reporting costs of bone and soft tissue ablation, authors should report the costs associated with the procedure (eg, devices, imaging guidance and monitoring, anesthesia, and hospital stay) and, if directly related to the procedure, subsequent costs that may have resulted from the imaging follow-up to detect residual or recurrent disease and possible retreatment. When this is related to the quality-adjusted life years to determine cost effec-

tiveness these costs are then summed for the study patient cohort to give the cumulative numerator of cost. The denominator of cost effectiveness is the number of quality-adjusted life years for the study population. The cost effectiveness is then the ratio of the cumulative cost divided by quality-adjusted life years, or cost per quality-adjusted life year. These cost-effectiveness data are critical to allow comparison of image-guided ablation with other therapies.

CONCLUSIONS

The use of ablative methods is the standard of care for most patients with osteoid osteoma. Use of these methods for other benign bone tumors is an alternative therapy for treatment. The use of ablative techniques for patients with bone and soft tissue tumors outside of the liver and lung is becoming an established minimally invasive therapy for many patients in whom conventional therapy fails or who are poor surgical candidates. In order to continue to gain further acceptance clinically, the use of image-guided percutaneous ablation must be supported by well conducted single-arm prospective trials or as part of randomized prospective trials when compared with other modalities. It is also necessary that early-phase clinical trials are conducted with standardized research approaches so that it is possible to transition to the more costly but definitive randomized controlled trials. The goal of this document is to provide recommended definitions to enable uniform construction and reporting of these trials. A summary of recommendations and requirements is provided in **Table 4**.

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References

- Rosenthal DI, Alexander A, Rosenberg AE, Springfield D. Ablation of osteoid osteomas with a percutaneously placed electrode: a new procedure. *Radiology* 1992; 183:29–33.
- Rosenthal DI, Springfield DS, Gebhardt MC, Rosenberg AE, Mankin HJ. Osteoid osteoma: percutaneous radio-frequency ablation. *Radiology* 1995; 197:451–454.
- Rosenthal DI, Hornicek FJ, Wolfe MW, Jennings LC, Gebhardt MC, Mankin HJ. Percutaneous radiofrequency coagulation of osteoid osteoma compared with operative treatment. *J Bone Joint Surg Am* 1998; 80:815–821.
- Rosenthal DI, Hornicek FJ, Torriani M, Gebhardt MC, Mankin HJ. Osteoid osteoma: percutaneous treatment with radiofrequency energy. *Radiology* 2003; 229:171–175.
- Bloem JL, Kroon HM. Osseous lesions. *Radiol Clin North Am* 1993; 31:261–278.
- Barei DP, Moreau G, Scarborough MT, Neel MD. Percutaneous radiofrequency ablation of osteoid osteoma. *Clin Orthop Relat Res* 2000;115–124.
- Voto SJ, Cook AJ, Weiner DS, Ewing JW, Arrington LE. Treatment of osteoid osteoma by computed tomography guided excision in the pediatric patient. *J Pediatr Orthop* 1990; 10:510–513.
- Assoun J, Railhac JJ, Bonneville P, et al. Osteoid osteoma: percutaneous resection with CT guidance. *Radiology* 1993; 188:541–547.
- Labbe JL, Clement JL, Duparc B, Poey C, Railhac JJ. Percutaneous extraction of vertebral osteoid osteoma under computed tomography guidance. *Eur Spine J* 1995; 4:368–371.
- Poey C, Clement JL, Baunin C, et al. Percutaneous extraction of an osteoid osteoma of the lumbar spine under CT guidance. *J Comput Assist Tomogr* 1991; 15:1056–1058.
- Lindner NJ, Scarborough M, Ciccarelli JM, Enneking WF. CT-controlled thermocoagulation of osteoid osteoma in comparison with traditional methods. *Z Orthop Ihre Grenzgeb* 1997; 135:522–527. [German]
- Gebhardt MC, Rosenthal DI, Arnell PM. Case records of the Massachusetts General Hospital. Case 8-2005. A 10-year-old boy with pain in the right thigh. *N Engl J Med* 2005; 352:1122–1129.
- Rosenthal DI. Percutaneous radiofrequency treatment of osteoid osteomas. *Semin Musculoskelet Radiol* 1997; 1:265–272.
- Rosenthal DI. Radiofrequency treatment. *Orthop Clin North Am* 2006; 37:475–484, viii.
- Rosenthal DI, Hornicek FJ, Wolfe MW, Jennings LC, Gebhardt MC, Mankin HJ. Decreasing length of hospital stay in treatment of osteoid osteoma. *Clin Orthop Relat Res* 1999;186–191.
- Martel J, Bueno A, Ortiz E. Percutaneous radiofrequency treatment of osteoid osteoma using cool-tip electrodes. *Eur J Radiol* 2005; 56:403–408.
- Gangi A, Dietemann JL, Gasser B, et al. Interstitial laser photocoagulation of osteoid osteomas with use of CT guidance. *Radiology* 1997; 203:843–848.
- Gangi A, Alizadeh H, Wong L, Buy X, Dietemann JL, Roy C. Osteoid osteoma: percutaneous laser ablation and follow-up in 114 patients. *Radiology* 2007; 242:293–301.
- Gangi A, Dietemann JL, Gasser B, et al. Interventional radiology with laser in bone and joint. *Radiol Clin North Am* 1998; 36:547–557.
- Gangi A, Dietemann JL, Guth S, et al. Percutaneous laser photocoagulation of spinal osteoid osteomas under CT guidance. *AJNR Am J Neuroradiol* 1998; 19:1955–1958.
- Moser T, Buy X, Goyault G, Tok CH, Irani F, Gangi A. Image-guided ablation of bone tumors: review of current techniques. *J Radiol* 2008; 89:461–471.
- Moser T, Giacomelli MC, Clavert JM, Buy X, Dietemann JL, Gangi A. Image-guided laser ablation of osteoid osteoma in pediatric patients. *J Pediatr Orthop* 2008; 28:265–270.
- Skjeldal S, Lilleas F, Folleras G, et al. Real time MRI-guided excision and cryo-treatment of osteoid osteoma in os ischii—a case report. *Acta Orthop Scand* 2000; 71:637–638.
- Callstrom MR, Atwell TD, Charboneau JW, et al. Painful metastases involving bone: percutaneous image-guided cryoablation—prospective trial interim analysis. *Radiology* 2006; 241:572–580.
- Christie-Large M, Evans N, Davies AM, James SL. Radiofrequency ablation of chondroblastoma: procedure technique, clinical and MR imaging follow up of four cases. *Skeletal Radiol* 2008; 37:1011–1017.
- Ramnath RR, Rosenthal DI, Cates J, Gebhardt M, Quinn RH. Intracortical chondroma simulating osteoid osteoma treated by radiofrequency. *Skeletal Radiol* 2002; 31:597–602.
- Munk PL, Malfair D, Rashid F, Torreggiani WC. Radiofrequency ablation of solitary eosinophilic granuloma of bone. *AJR Am J Roentgenol* 2008; 191(suppl):W320.

28. Rosenthal DI, Treat ME, Mankin HJ, Rosenberg AE, Jennings CL. Treatment of epithelioid hemangioendothelioma of bone using a novel combined approach. *Skeletal Radiol* 2001; 30:219–222.
29. Nielsen OS, Munro AJ, Tannock IF. Bone metastases: pathophysiology and management policy. *J Clin Oncol* 1991; 9:509–524.
30. Mercadante S. Malignant bone pain: pathophysiology and treatment. *Pain* 1997; 1–18.
31. Hoffmann RT, Jakobs TF, Trumm C, Weber C, Helmlinger TK, Reiser MF. Radiofrequency ablation in combination with osteoplasty in the treatment of painful metastatic bone disease. *J Vasc Interv Radiol* 2008; 19:419–425.
32. Massie MJ, Holland JC. The cancer patient with pain: psychiatric complications and their management. *J Pain Symptom Manage* 1992; 7:99–109.
33. Spiegel D, Sands S, Koopman C. Pain and depression in patients with cancer. *Cancer* 1994; 74:2570–2578.
34. Jeremic B, Shibamoto Y, Acimovic L, et al. A randomized trial of three single-dose radiation therapy regimens in the treatment of metastatic bone pain. *Int J Radiat Oncol Biol Phys* 1998; 42:161–167.
35. Price P, Hoskin PJ, Easton D, Austin D, Palmer SG, Yarnold JR. Prospective randomised trial of single and multifraction radiotherapy schedules in the treatment of painful bony metastases. *Radiation Oncol* 1986; 69:247–255.
36. Cole DJ. A randomized trial of a single treatment versus conventional fractionation in the palliative radiotherapy of painful bone metastases. *Clin Oncol (R Coll Radiol)* 1989; 1:59–62.
37. Gaze MN, Kelly CG, Kerr GR, et al. Pain relief and quality of life following radiotherapy for bone metastases: a randomised trial of two fractionation schedules. *Radiation Oncol* 1997; 45:109–116.
38. Hara S. Opioids for metastatic bone pain. *Oncology* 2008; 74(suppl 1):52–54.
39. Dupuy DE. Minimally invasive therapies in the treatment of bone malignancies. *Crit Rev* 1998; 75:161–171.
40. Callstrom MR, Charboneau JW, Goetz MP, et al. Painful metastases involving bone: feasibility of percutaneous CT- and US-guided radio-frequency ablation. *Radiology* 2002; 224:87–97.
41. Goetz MP, Callstrom MR, Charboneau JW, et al. Percutaneous image-guided radiofrequency ablation of painful metastases involving bone: a multicenter study. *J Clin Oncol* 2004; 22:300–306.
42. Callstrom MR, Charboneau JW. Percutaneous ablation: safe, effective treatment of bone tumors. *Oncology (Williston Park)* 2005; 19:22–26.
43. Callstrom MR, Charboneau JW, Goetz MP, et al. Image-guided ablation of painful metastatic bone tumors: a new and effective approach to a difficult problem. *Skeletal Radiol* 2006; 35:1–15.
44. Dupuy DE. Tumor ablation: treatment and palliation using image-guided therapy. *Oncology (Williston Park)* 2005; 19:4–5.
45. Dupuy DE, Safran H, Mayo-Smith WW, Goldberg SN. Radiofrequency ablation of painful osseous metastatic disease (abstr.). *Radiology* 1998; 209(suppl):389.
46. Goldberg SN, Grassi CJ, Cardella JF, et al. Image-guided tumor ablation: standardization of terminology and reporting criteria. *J Vasc Interv Radiol* 2005; 16:765–778.
47. Hierholzer J, Anselmetti G, Fuchs H, Depriester C, Koch K, Pappert D. Percutaneous osteoplasty as a treatment for painful malignant bone lesions of the pelvis and femur. *J Vasc Interv Radiol* 2003; 14:773–777.
48. Dupuy DE, Hong R, Oliver B, Goldberg SN. Radiofrequency ablation of spinal tumors: temperature distribution in the spinal canal. *AJR Am J Roentgenol* 2000; 175:1263–1266.
49. Pereira J, Lawlor P, Vigano A, Dorgan M, Bruera E. Equianalgesic dose ratios for opioids: a critical review and proposals for long-term dosing. *J Pain Symptom Manage* 2001; 22:672–687.
50. Global RPh. The Clinician's Ultimate Reference. Available at <http://www.globalrph.com/narcoticonv.htm>. Accessed June 1, 2009.
51. American Society of Anesthesiologists. Practice advisory for the perioperative management of patients with cardiac rhythm management devices: pacemakers and implantable cardioverter-defibrillators: a report by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Rhythm Management Devices. *Anesthesiology* 2005; 103:186–198.
52. Lee EH, Shafi M, Hui JH. Osteoid osteoma: a current review. *J Pediatr Orthop* 2006; 26:695–700.
53. Oken MM, Creech RH, Tormey DC, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol* 1982; 5:649–655.
54. Schag CC, Heinrich RL, Ganz PA. Karnofsky performance status revisited: reliability, validity, and guidelines. *J Clin Oncol* 1984; 2:187–193.
55. Yildiz Y, Bayraktar K, Altay M, Saglik Y. Osteoid osteoma: the results of surgical treatment. *Int Orthop* 2001; 25:119–122.
56. Campanacci M, Ruggieri P, Gasbarrini A, Ferraro A, Campanacci L. Osteoid osteoma. Direct visual identification and intralesional excision of the nidus with minimal removal of bone. *J Bone Joint Surg Br* 1999; 81:814–820.
57. Sim FH, Dahlin CD, Beabout JW. Osteoid-osteoma: diagnostic problems. *J Bone Joint Surg Am* 1975; 57:154–159.
58. Kam AW, Littrup PJ, Walther MM, Hvizda J, Wood BJ. Thermal protection during percutaneous thermal ablation of renal cell carcinoma. *J Vasc Interv Radiol* 2004; 15:753–758.
59. Farrell MA, Charboneau JW, Callstrom MR, Reading CC, Engen DE, Blute ML. Paraneoplastic water instillation: a technique to prevent bowel injury during percutaneous renal radiofrequency ablation. *AJR Am J Roentgenol* 2003; 181:1315–1317.
60. Kim YS, Rhim H, Paik SS. Radiofrequency ablation of the liver in a rabbit model: creation of artificial ascites to minimize collateral thermal injury to the diaphragm and stomach. *J Vasc Interv Radiol* 2006; 17:541–547.
61. Park BK, Kim SH, Byun JY, Kim YS, Kwon GY, Jang IS. CT-guided instillation of 5% dextrose in water into the anterior pararenal space before renal radiofrequency ablation in a porcine model: positive and negative effects. *J Vasc Interv Radiol* 2007; 18:1561–1569.
62. Wah TM, Koenig P, Irving HC, Gervais DA, Mueller PR. Radiofrequency ablation of a central renal tumor: protection of the collecting system with a retrograde cold dextrose pyeloperfusion technique. *J Vasc Interv Radiol* 2005; 16:1551–1555.
63. Yamakado K, Nakatsuka A, Akeboshi M, Takeda K. Percutaneous radiofrequency ablation of liver neoplasms adjacent to the gastrointestinal tract after balloon catheter interposition. *J Vasc Interv Radiol* 2003; 14:1183–1186.
64. Atwell TD, Wass CT, Charboneau JW, Callstrom MR, Farrell MA, Sengupta S. Malignant hypertension during cryoablation of an adrenal gland tumor. *J Vasc Interv Radiol* 2006; 17:573–575.
65. Mendoza T, Mayne T, Rublee D, Cleeland C. Reliability and validity of a modified Brief Pain Inventory short form in patients with osteoarthritis. *Eur J Pain* 2006; 10:353–361.
66. Turk DC, Dworkin RH, Burke LB, et al. Developing patient-reported outcome measures for pain clinical trials: IMMPACT recommendations. *Pain* 2006; 125:208–215.
67. Serlin RC, Mendoza TR, Nakamura Y, Edwards KR, Cleeland CS. When is cancer pain mild, moderate or severe? Grading pain severity by its interference with function. *Pain* 1995; 61:277–284.
68. Sacks D, McClenny TE, Cardella JF, Lewis CA. Society of Interventional Radiology clinical practice guidelines. *J Vasc Interv Radiol* 2003; 14(suppl):S199–S202.
69. Common Terminology Criteria for Adverse Events v 3.0 (CTCAE). Available at <http://ctep.cancer.gov/forms/CTCAEv3.pdf>. Accessed February 10, 2009.