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Basic Science

Evaluation of a bipolar-cooled radiofrequency device for ablation of bone metastases: preclinical assessment in porcine vertebrae

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Abstract

BACKGROUND CONTEXT: Cancer spread to the spine affects bone stability and can lead to pathologic fracture and neurologic impairment. Radiofrequency ablation (RFA) recently has gained popularity in treating skeletal tumors. Conventional RFA devices use a monopolar design, which limits the ability to comprehensively treat large tumors in bony tissues and may pose risks to adjacent critical normal neurologic tissues when applied to vertebrae. New bipolar-cooled radiofrequency (BCRF) may generate larger controlled lesions without the same degree of risk to adjacent structures.

PURPOSE: The purpose of this study was to evaluate the feasibility, efficacy, and safety of RFA with the use of a new bone-specific, BCRF probe in a porcine vertebral model and to evaluate the ability of magnetic resonance (MR) imaging to represent histologic outcomes of RFA treatment.

STUDY DESIGN: Basic science: preclinical in vivo study.

METHODS: RFA was evaluated in three noncontiguous lumbar vertebrae in six Yorkshire pigs (25–30 kg). Via a transpedicular approach for probe placement, two vertebrae received BCRF treatment and one vertebrae served as a sham control. MR imaging and neurological assessments were conducted pre- and posttreatment as well as immediately before animal sacrifice (n=3 at day 0, n=3 at day 14). MR ablation zones were compared with hematoxylin and eosin–stained histological sections.

RESULTS: With BCRF, large reproducible zones of ablation were achieved, confined within the vertebrae, without damage to adjacent tissues or the spinal cord. All animals demonstrated normal consistent neurologic behavior pre- and posttreatment. External tissue temperatures around targeted vertebrae were not increased. MR imaging after 14 days was more effective in demonstrating ablation effects than images on day 0, with radiologic findings most apparent on T2-weighted sequences. Histologic analysis of samples corresponded well to the zones of ablation observed on MR images (R=0.9, p<.01).

FDA device/drug status: Approved (Bipolar Cooled Radiofrequency Probe (OsteoCool), Baylis Medical Company).

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CONCLUSIONS: The study demonstrated feasibility, safety, and effectiveness of BCRF ablation of vertebral bone. This motivates ongoing preclinical evaluation in diseased models to further explore the potential for its use in clinical treatment of metastatic vertebrae.

Keywords: Bone cancer; Bone metastases; Radiofrequency ablation; Minimally invasive; Porcine; Preclinical; Tumor

Introduction

Bone metastases are unfortunate and frequent consequences of malignant tumors that affect more than 85% of patients with cancer [1]. The most common site for skeletal metastasis is the spine [2,3]. Spread within the skeleton can cause considerable morbidity, including bony pain, hypercalcemia, pathologic fracture, spinal cord and nerve root compression, and bone marrow aplasia. Collectively these complications are referred to as ‘‘skeletal-related events’’ [2,4,5]. Patients suffering from bone metastasis generally experience a skeletal-related event every 3–6 months [6].

Currently, multiple therapeutic approaches, including radiotherapy, surgical resection, and bisphosphonate therapy, are implemented in the treatment of skeletal metastases. However, these modalities have limitations that include tissue tolerance and toxicities associated with radiotherapy; relative patient health and long recovery times for surgical procedures; and complications such as femoral stress fractures, osteonecrosis of the jaw, and renal issues associated with bisphosphonate therapy [1]. These constraints render adjunctive local minimally invasive therapies as attractive alternatives. Vertebroplasty and Kyphoplasty have gained recent interest as a local minimally invasive spinal therapy to stabilize metastatically involved vertebrae. The ability to cannulate targeted vertebrae via the use of a bone trochar provides an additional opportunity to deliver a bone-specific RFA probe to biologically ablate tumor tissue before the stabilization afforded by the injection of polymethyl methacrylate. This multimodality approach is clinically attractive for its potential to both biologically and mechanically treat metastatically involved vertebrae [7].

Radiofrequency ablation (RFA) is a local minimally invasive therapy, most commonly used to treat primary bone (ie, osteoid osteoma) and soft tissue cancers. The available technology uses a monopolar, single or multiple, probe design whereby the electric current originating from a radiofrequency (RF) generator is emitted through the probe into the neighboring tissues. The ionic current induces frictional heat production, generating a zone of thermal ablation. The electrical circuit is completed via a grounding pad, often placed on the thigh of the patient. This common setup has a major drawback for bone applications, as the osseous tissue has semiinsulative electrical and thermal properties [8]. Completing the electrical circuit from the probe to the grounding pad using the common monopolar setup frequently limits the zone of ablation. Incomplete ablation results in tumor residue leading to greater recurrence rates and associated pain [9]. In addition, extension of the heat towards the grounding pad may result in unwanted damage of neighboring structures. Finally, bone marrow within trabecular structures may act as a heat sink, further impeding ionic flux between contacts, which produces a lesion that is smaller than planned.

As such, the ability of RFA to treat large structural bone lesions has been limited. Current monopolar RF may also introduce safety concerns when one is treating metastases adjacent to the spinal cord or nerves [10], because it is possible to pass current through these critical structures and unintentionally injure these tissues. Conventional bipolar devices do not require the use of a grounding pad but rely on electrodes at the end of the two probes that must be meticulously placed adjacent to one another to achieve successful treatment. This requires high levels of operator dexterity, and can lead to variation in the treatment's effect.

To address these limitations for large structural bone applications, a novel, bipolar-cooled radiofrequency (BCRF) device was developed (OsteoCool; Baylis Medical Company, Mississauga, ON, Canada) that incorporates the active and grounding electrodes on the tip of a single probe, eliminating the need for a grounding pad or a second probe. The bipolar nature of the system was designed to compensate for the thermal and electrical insulating properties of the bone. The internal cooling of the device minimizes tissue desiccation and charring at the probe tip, allowing for formation of larger heat lesions. The purpose of this study was to evaluate the feasibility, efficacy, and safety of this new BCRF probe with the use of a porcine vertebral model and also to evaluate the ability of MR imaging to represent histologic outcomes of RFA treatment.

Materials and methods

Experimental design

Ethics approval was obtained for the porcine RFA study from the institutional animal care committee. Six Yorkshire pigs (weighing 25–30 kg; University of Guelph, Guelph, ON), were randomly divided in two groups. A total of three vertebral levels were analyzed from each of six pigs. The effect of RFA on the vertebral bone was evaluated at two