The Spine Journal 15 (2015) 1832–1840

Basic Science

Helical coil electrode radiofrequency ablation designed for application in osteolytic vertebral tumors—initial evaluation in a porcine model

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Received 23 September 2014; revised 2 March 2015; accepted 17 March 2015

Abstract

BACKGROUND CONTEXT: Radiofrequency ablation (RFA) is emerging as a complementary treatment for vertebral metastases. Traditional RFA induces frictional heating leading to local tissue necrosis but often yields small, incomplete, and inhomogeneous zones of ablation in bone. We have developed a new bone-specific RFA electrode that uses a nontraditional frequency (27.12 MHz) and geometry (helical), exploiting a magnetic field and an electric field to generate larger and more comprehensive treatment zones.

PURPOSE: The purpose of the study was to evaluate the feasibility and safety of the Bone Coil RFA electrode in the spine.

STUDY DESIGN: This is a preclinical in vivo study based on basic science.

METHODS: Under institutional approval, six healthy Yorkshire pigs received a sham and an RF treatment in two adjacent cervical vertebrae. To deploy the Bone Coil RFA device in dense porcine vertebrae, a surgical approach was required; an irrigated coring drill bit created a cylindrical path in the vertebral bodies through which the RFA electrodes were placed. The electronic circuit was completed by four grounding pads. Treatment was delivered for 10 minutes at 20 W (n=1), 25 W (n=1), and 30 W (n=4). To monitor the thermal rise and for safety, fiber-optic probes recorded temperatures in the center of each coil and near the spinal foramen. After the procedure, animals were monitored for 2 weeks. Magnetic resonance imaging (MRI) was completed immediately after treatment and at 14 days. Magnetic resonance image segmentation and histology were used to evaluate the ablation volume.

RESULTS: Comprehensive treatment of the porcine vertebrae was demonstrated by temperature monitoring, MRI, and histology. Large zones of RF ablation were obtained (RF: 3.72 ± 0.73 cm^3 vs. sham: 1.98 ± 0.16 cm^3, $p<.05$), confined within the vertebral body. Internal temperatures were elevated with RF (66.1°C–102.9°C), without temperature rise outside of the vertebrae (38.2°C±1.5°C). Mobility, neurological responses, and behavior were normal, consistent with preprocedural examination. Magnetic resonance imaging best visualized ablation at Day 14. Histology

FDA device/drug status: Investigational (helical coil radiofrequency electrode, Bone Coil).

Author disclosures: ***PSP:*** Nothing to disclose. ***SRD:*** Grant: MaRS Innovation Ref NO. 2011-0 Project No. 2011-0236 (F Canadian Dollar [CAD], Paid directly to institution); Research Support (Investigator Salary, Staff/Materials): Benvenue Medical (D CAD, Paid directly to institution); Grants: Canadian Institutes of Health Research (F CAD, Paid directly to institution), Sunnybrook Foundation (F CAD, Paid directly to institution). ***MKA:*** Nothing to disclose. ***KM:*** Grant: University Health Network (Paid directly to institution). ***CM:*** Grants: Mars Innovation (F CAD, Paid directly to institution), Canadian Institutes of Health Research (F, Paid directly to institution); Sunnybrook Foundation (F, Paid directly to institution), MaRS Innovation (F, Paid directly to institution), NSERC/CHRP (G, Paid directly to institution). ***MS:*** Grant: MaRS Innovation (F CAD, Paid directly to institution); Research Support (Investigator Salary, Staff/Materials): Benvenue Medical (D CAD, Paid directly to institution); Grants: Canadian Institutes of Health Research (F, Paid directly to institution), Ontario Institute for Cancer Research (F, Paid directly to institution). ***CMW:*** Grant: Mars Innovation (subgrant) (E, Paid directly to institution). ***AJMY:*** Grant: Peer-Reviewed Research Grant: MaRS Innovation (F CAD, Paid directly to institution).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

This study was peer reviewed and grant funded (MI POP, $199,900 CAD).

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http://dx.doi.org/10.1016/j.spinee.2015.03.028
1529-9430/

revealed comprehensive homogeneous coagulative necrosis with little peripheral sign of repair.
CONCLUSIONS: The Bone Coil RFA device created large intravertebral ablation volumes with no neurologic sequelae. Radiofrequency thermal ablation (clearly distinguished from the much smaller effects arising from core drilling) corresponded to the homogeneous necrosis visible on histology.

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

Introduction

Bone metastases frequently occur in patients with advanced cancer and present treatment challenges that may require a multidisciplinary strategy [1]. In the skeleton, cancer spreads most commonly to the spine [2,3] with metastases representing more than 90% of the tumors of the vertebrae [4]. When left untreated, bone metastases can lead to skeletal-related events including pain, hypercalcemia, and pathologic fractures [2,5,6]. The use of radiofrequency ablation (RFA) in the management of vertebral metastases is increasing [7–12]. In patients with painful metastasis in whom other methods have been inadequate or contraindicated, minimally invasive RFA provides an attractive alternative [13]. The clinical goal of RFA in vertebral metastases is primarily pain reduction and tumor shrinkage before stabilization [1,10,14]. Conventional radiofrequency ablation electrodes, generally developed and optimized for use in soft tissues, are integrated into a straight needle. Radiofrequency devices with retractable curved electrodes (multitined electrodes) in an umbrella-shaped geometry have also been developed in an attempt to create larger lesions than those generated using a monopolar straight needle. These devices operate in a frequency range of 450 to 600 kHz [15]. At these frequencies, the electric field generated by the devices is localized to the immediate vicinity of the device [16]. This will in turn excite the nearby ions within the tissue, causing ionic movement, heat generation, and conduction. Conventional ablation electrodes therefore depend on heat conduction within the target tissue, which is reliant on the thermal properties of the tissue [17]. Bone has a low thermal conduction coefficient [18]; therefore, comprehensive ablation of a sizable tumor in bone without charring and carbonization remains a clinical challenge [19]. The other limitation of conventional RFA devices is their susceptibility to local blood flow, which carries heat away from the treatment site and limits the size of coagulation in highly vascularised tissues.

Recently, a new RFA device design has been developed, which incorporates a helical coil geometry and operates at a frequency of 27.12 MHz [20]. The combination of the geometry and frequency in this design allows for induction of magnetic and electric fields inside the coil. Unlike conventional RFA technology that operates in the kilohertz range (which heavily relies on thermal conduction), the helical coil electrode design exploits both magnetic and electric fields leading to a uniform power deposition inside the coil, irrespective of the tissue thermal conduction properties. As a result, a larger, more uniform, and comprehensive ablation zone may be produced that has the potential to address more extensive metastatic lesions. The performance of this technology has been demonstrated in phantoms and liver tissues [20–22] and is currently being evaluated in a Phase I clinical trial. To apply this technology to bone, it was necessary to redesign the helical RF coil geometry to enable its use within the metastatic spine. The electrode coil and introducer were modified in terms of size and stiffness to enable deployment and ablation within bone tissue.

This work demonstrates the safety and efficacy of this novel Bone Coil ablation electrode in an in vivo porcine vertebral model. The results of the Bone Coil ablation are compared with a conventional needle electrode designed for use in bone [23]. It was hypothesized that the electromagnetic fields produced by the novel ablation device design can be used to safely create larger lesions in a bony environment than conventional RFA technology.

Materials and methods

Experimental design

Institutional approval was obtained for all the animal procedures. A healthy vertebral pig model was used because of its similarity to the human vertebrae in terms of size and geometry. Furthermore, a healthy pig model was used as there is no readily available in vivo preclinical vertebral tumor model of a suitable scale for device testing. Six Yorkshire pigs (40–50 kg) received both a sham (n=6, RF ablation electrode placement only, and generator not turned on) and a radiofrequency treatment (n=6), respectively, in two adjacent cervical levels (e.g., C4 and C5) accessed surgically. The outcome parameters included temperature in the center of ablation zone and adjacent to spinal foramen, neurologic status of the animals, dimensions of the treatment zone (based on MRI and histologic analysis of the excised vertebrae), and histologic evidence of ablation. Zones of ablation were compared with the results from a previous study using a similar healthy porcine vertebral model and a bone-targeted needle ablation electrode [23].

RF ablation device

Previous RF coil electrode development for soft-tissue tumor ablation [20] guided the current novel coil design for osseous applications. Refinement of the ablation electrode design and heating protocol was carried out in gel phantoms, muscle