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Feasibility of Thermal Ablation of Lytic Vertebral Metastases with Radiofrequency Current

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Radiofrequency ablation (RFA) is presented as a novel method to treat lytic metastases to the spine, which can present a difficult therapeutic dilemma. As a feasibility study, the short series by Grönemeyer et al¹ is only the first clinical step in the definition of indications and in the validation of a treatment. Although much of the initial work on image-guided RFA of neoplasms is quite promising, it is still early in the evaluation process, with few long-term studies having been reported, even for the most common indication, which is unresectable liver tumors.

The authors make no broad claims about efficacy, without further investigations. The evaluation of a new treatment indication should be methodical, controlled, and randomized, whenever ethically possible. In this study, the authors have set the stage for further study and are to be commended for taking the first important, and sometimes risky, leap into the clinical world. However, the basic science, animal studies, and clinical experience with bone and nerve ganglion RFA suggest that this might be a safe and successful therapy for certain patients with spine metastases and no other options.

This work expands on the basic animal and thermometry studies performed by Dupuy et al.² RFA that heats tissue to 45°C is cytotoxic to the spinal cord and peripheral nerves, which is a vital point.²⁻⁴ Accessory thermistors could have been placed to measure temperature slightly away from the thermal lesions or near the thecal sac or the peripheral nerves. We have done this to decrease risk of nerve damage in RFAs near sciatic, axillary, ulnar, and other peripheral nerves (unpublished data, Wood BJ, 2002). Maintaining temperatures below 45°C in adjacent nerve tissue for short periods should prevent unwanted nerve damage.

The study makes no distinction between cortical and cancellous bone, both of which have less heat conductivity than soft tissue.² Cortical bone insulates and protects the spinal canal, but an absent or lytic posterior vertebral body cortex or a widened neural foramen could present added risk for thermal damage to nerves. Adjacent vascular structures or vascular tumors may also significantly change the thermal distribution. There is actually little published information regarding the differences in thermal and electrical conductivities of different tissues at high temperatures. There remains a lot to learn from a basic physics and heat transfer perspective, and RFA is not yet completely predictable.

Several study design weaknesses deserve further discussion. The confounding factor of the four vertebroplasties dilutes the results somewhat because it is hard to separate the treatment

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effects of each therapy. No rationale is given for performing vertebroplasty 3 to 7 days after RFA. We have performed RFA immediately before vertebroplasty in the same setting, to treat pain as well as to possibly increase the amount of cement deposition, although this is speculative (unpublished data, Wood BJ, Watson V, 2001). There is selection bias inherent to the inclusion and exclusion criteria given for the 10 patients selected from the 21 patients referred with unresectable spine metastases. Did a third party determine the presence of high risk of neurologic deficits or increased risk of fractures? These risks were inclusion criteria, not exclusion criteria. A more uniform and lower-risk patient population, without these features, might have proved a more defensible result. The spectrum of treated tumor histology is also broad. This study does not mention that there are few data on the differing dielectrics of tumor tissues. Even simple tissue vascularity has broad implications on thermal and electrical conductivity and on resulting thermal lesion profiles. A difference of several degrees near a temperature-sensitive nerve could damage the nerve.

Was the study approved by an investigational review board? This is a controversial issue because three RFA systems are United States Food and Drug Administration 510K-cleared for “soft tissue ablation,” and lytic metastases might be considered soft tissue. (This study was not conducted in the United States and was therefore not subject to Food and Drug Administration regulations.) The authors did not use sedation, which is a variation to standard RFA. This was for the sake of an accurate neurologic examination during the RFA. They state that the electrodes can be comfortably placed. However, in our experience, the application of alternating current is met with moderate to severe pain in most patients who are lightly sedated. The authors call RFA treatment pain “very moderate local pain.”¹ What does the “very” mean here? Is this worse than moderate? Did they ask the patients at the time of the RFA?

The techniques and the geometry of the thermal lesion are unspecified and incomplete. The authors state, “depending on the tumor’s distance to the spinal cord, the power output was slowly increased,” without defining that distance.¹ In fact, these results are not reproducible, because needle location, ramping time, stopping points, cooling times, and dielectric measurements, such as impedance, are all unspecified. No imaging outcomes criteria are defined, and the methods are not reproducible without more information. For example, the authors produced thermal lesions up to 9 cm in diameter but repositioned the probe (and changed the location of the resulting 3-cm thermal lesion) only two to three times.¹ Computer modeling of overlapping thermal spheres suggests that a 3-cm probe could yield only a 3.75-cm-diameter sphere without untreated tumor gaps, even with six perfectly overlapped RFA sessions.⁵ The authors claim 9 cm thermal lesions with 2–3 spheres, which is mathematically impossible without gaps of untreated intervening tumor. How close to the margin of the tumor did they go, and how close was this to major nerves?

There are several inaccuracies in this study that need clarification. The 50-W generator (Rita Medical Systems Inc., Mountain View, CA) has been replaced by a 150-W variety, and the 3-cm probe has been replaced by a 5-cm probe, and even more recently a 7-cm, tree-shape probe. Other systems have 200 W. The low-wattage system used in this study may fortuitously make complications less likely in the spine, where temperature and thermal lesion volume should not be maximized, because of proximity of nerves. Also, at least three different systems are actually marketed for tumor RFA, not two, as stated. One is water cooled (Radionics, Inc, Burlington, MA), one is coaxial and temperature controlled (RITA Medical Systems Inc.), and the last is coaxial and impedance controlled (Radiotherapeutics Corp., Mountain View, CA). The study states that the expandable system used here has the advantage of delivering a precise and controlled thermal lesion. The converse could also be stated; the nondeployable water-cooled system could allow more precise and controlled RFA without deployment of hooks in three dimensions, potentially into sensitive structures (Fig. 1). Monitoring the three-dimensional simultaneous deployment of the hooks can also be difficult. The water-cooled

system also has the advantage of being a smaller 17.5-gauge needle instead of a 14- or 15-gauge needle, as is the case with the coaxial systems.

It cannot be overemphasized that RFA has a steep learning curve. The techniques and principles prerequisite to successful and safe RFA should be mastered elsewhere in the body, such as in the liver and in nonspinal bones (well away from nerves and other collateral structures). RFA relies on technology that is recently in constant evolution. Operator experience may not have yet caught up with the rapid deployment of RFA systems in the community. Also, by the time an RFA study reaches press, there are often more recent models or advancements that render the conclusions somewhat obsolete. This complicates interpretation of results and also complicates randomization against other competing therapies. Controlling a study also may present ethical dilemmas. For example, in light of this study, would it now be unethical to have a control group and withhold spinal RFA from a patient without other options who might benefit from this treatment? When in doubt, early involvement of the ethics board or investigational review board is wise.

The pain and quality-of-life outcomes measures in this study are pragmatic and useful, and RFA is likely an effective treatment for recalcitrant pain in certain settings, such as vertebral metastases without other conventional treatment options. In this rapidly changing clinical atmosphere, the time for scientific questions and answers is now. The opportunity to design and implement quality RFA studies will diminish in the near future, if clinical practice outpaces basic science background and scientific proof. The authors have opened this brief window for study. I hope that interested surgeons, interventional radiologists, oncologists, and engineers rise to the task, before spinal RFA becomes more widespread clinical practice simply by default.

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FIGURE 1.

Alternative method of radiofrequency thermal ablation of a spinal tumor using the water-cooled system, which uses a smaller needle (17.5 G) but does not have as many thermistors as the coaxial system used in the Grönemeyer et al¹ study. The needle was placed through a 6.5-French catheter such that the length of the active, uninsulated tip could be modified to change the size and the shape of the thermal lesion. (RFA was performed in conjunction with Dr. Vance Watson, Georgetown University, Washington, DC.)