CLINICAL STUDY

Safety and Clinical Outcomes of Percutaneous Radiofrequency Ablation for Intermediate and Large Bone Tumors Using a Multiple-Electrode Switching System: A Phase II Clinical Study

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ABSTRACT

Purpose: To evaluate the safety and clinical outcomes of radiofrequency (RF) ablation using a multiple-electrode switching system in patients with bone tumors > 3 cm.

Materials and Methods: This prospective study enrolled 20 subjects (15 men, 5 women; mean age 70.0 y ± 7.4 [SD]; range, 60–80 y) with malignant unresectable bone tumors. The maximum mean tumor diameter was 5.5 cm ± 2.0 (range, 3.1–10.0 cm). Two to three RF electrodes were placed into each bone tumor. Real-time CT fluoroscopic guidance was used with a multiple-electrode switching system. The primary endpoint was safety, as evaluated by Common Terminology Criteria for Adverse Events, until 12 months after bone RF ablation. As secondary endpoints, pain relief was evaluated by visual analog scale (VAS) scores before and 1 week after RF ablation; tumor response, by contrast-enhanced magnetic resonance imaging studies until 4 weeks after bone RF ablation; and survival, by Kaplan-Meier method.

Results: No adverse event was found in 19 of 20 patients (95%). Grade 2 fever occurred in 1 patient (5%; 1/20). VAS scores decreased by ≥ 2 in 11 of 13 patients (84.6%) who had painful bone tumors. Tumor response (complete or partial response) was achieved in 16 of 18 patients (88.9%) who underwent follow-up imaging studies. The 1-year overall survival rate was 60.9%, and the median survival time was 14.1 months.

Conclusions: Bone RF ablation using this system is safe and achieves local tumor control and pain relief in patients with large bone tumors.

ABBREVIATIONS

RF = radiofrequency, VAS = visual analog scale

Bone is the third most common site for cancer after the liver and lung. Metastatic bone tumor is the most frequent bone malignancy. Postmortem studies showed that up to 80% of patients dying of cancers have metastatic bone disease (1–4). Multicenter prospective studies showed that radiofrequency (RF) ablation is a useful therapeutic option to relieve pain not only for patients with metastatic bone tumors but also for patients with multiple myeloma, bone sarcoma, and osteoid osteoma (5–15). Few studies assessed local tumor control after bone RF ablation (16). Although the prognosis of patients with metastatic bone metastasis and recurrent sarcoma is influenced by the primary malignancy, complete tumor removal gives patients the chance of a cure (17–20). However, most patients are not surgical candidates because of multiple lesions and risk of postoperative dysfunction as well as comorbid

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diseases. When the tumor is small, the probability exists that bone tumors are ablated completely by RF ablation (9,15). Larger tumors are more likely to recur with recurrent pain (9).

A multiple-electrode switching system that enables simultaneous use of up to three RF electrodes and that sequentially switches RF power between electrodes was introduced to increase the ablative zone (21–24). RF ablation using a multiple-electrode switching system enables creation of large coagulation necrosis adapted to the shape of the bone tumor. Complete necrosis of large bone tumors might result in a better prognosis and quality of life. This prospective study was undertaken to evaluate the safety and clinical outcomes of RF ablation using a multiple-electrode switching system in patients with bone tumors $>$ 3 cm.

MATERIALS AND METHODS

Study Design and Eligibility

This prospective single-arm, nonrandomized, phase II single-center study evaluated the safety and outcome of RF ablation for large bone malignancies using a multiple-electrode switching system. The study was approved by the institutional review board. Written informed consent was obtained from all patients. This study is registered under Clinical Trials Registry No. 000002514 (www.umin.ac.jp/ctr/index.htm).

Inclusion criteria of the study were the following: malignant unresectable bone tumors 3.1–10 cm, regardless of the presence or absence of pain; age $\geq$ 20 years old; Eastern Cooperative Oncology Group performance status of 0, 1, 2, or 3 (25); and life expectancy of $\geq$ 1 month. Patients with multiple symptomatic bone tumors were excluded. Other exclusion criteria were abnormal coagulability as defined by a platelet count of $\leq 50 \times 10^3/\mu L$ and an international normalized ratio $>$ 1.5.

Between September 2009 and January 2012, bone RF ablation was performed in 32 consecutive patients; 20 patients (62.5%; 20 of 32) were enrolled in this study (Fig 1). Five patients were excluded because they had tumors $\leq$ 3 cm. Seven patients were excluded because they had multiple painful bone tumors. Patients included 15 men and 5 women with a mean age of 70.0 years $\pm$ 7.4 (range, 60–80 y). The mean maximum tumor diameter was 5.5 cm $\pm$ 2.0 (range, 3.1–10.0 cm). Nine patients (45%) had intermediate-sized (3.1–5 cm) bone tumors. The other 11 patients (55%) had large (5.1–10 cm) tumors. Patient and tumor characteristics are listed in the Table. The mean follow-up period was 16.3 months (range, 1.4–37.5 mo). During that time, 13 patients (65%; 13 of 20) had painful bone tumors; the other seven patients (35%; 7 of 20) had painless tumors. All patients had bone metastases. Percutaneous bone biopsy was performed in two patients (10%; 2 of 20). The diagnosis of bone metastasis was established based on radiologic findings in other patients.

Routine physical examination, laboratory tests, bone radiography, and whole-body computed tomography (CT) or magnetic resonance (MR) imaging studies without and with contrast enhancement were conducted within 4 weeks before bone RF ablation (Fig 2a). The

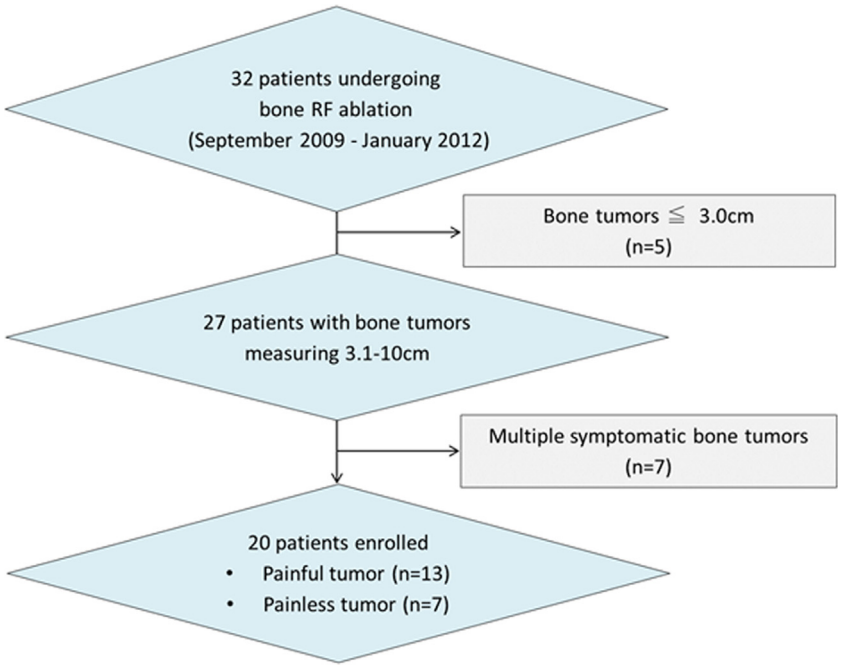

Figure 1. Algorithm for patient selection.