

Prospective Pilot-study of Combined Bipolar Radiofrequency Ablation and Application of Bone Cement in Bone Metastases

DIRK PROSCHEK¹, ANDREAS KURTH¹, PETRA PROSCHEK², THOMAS J. VOGL² and MARTIN G. MACK²

¹Department of Orthopaedic and Trauma Surgery, University Hospital Mainz;

²Department of Diagnostic and Interventional Radiology, University of Frankfurt, Germany

Abstract. *Background:* The purpose of this study was to determine the efficacy and safety of radiofrequency ablation (RFA) of bone metastases of breast cancer and to compare RFA alone and RFA with additional bone cement application. The primary objectives were to compare pain reduction and quality of life during long-term follow-up in a prospective pilot study. *Patients and Methods:* Sixteen female patients with painful spinal bone metastases of human breast cancer were included in this prospective pilot study (mean age 59.5 years, range 52 – 69 years). RFA was performed with computed tomographic guidance and under local anesthesia. A bipolar and impedance-controlled radiofrequency system was used. Following RFA, bone cement was injected into the necrosis cavity in half of the patients (n=8). Pain, quality of life and complications were evaluated. Mean follow-up time was 20.4 months (range 8-36). Paired comparison procedures were used for analysis of the results. A review of the literature was carried out. *Results:* In both groups (RFA alone and RFA with additional bone cement application), pain was reduced significantly (mean reduction of pain 51.7%, $p=0.0065$). Quality of life was improved up to 61%. All procedures were performed without side-effects and complications. Imaging showed a complete ablation of the bone tumor in all patients. No local tumor progression was seen. *Conclusion:* RFA is a safe and effective option in the palliative therapy of bone tumors. Application of bone cement into the necrosis cavity has no significant additional effect on the reduction of pain and the improvement in quality of life. In selected cases with big bone defects, combining RFA and bone cement application is a useful option to stabilize the bone.

Correspondence to: Dr. Dirk Proschek, Department of Trauma Surgery, University Hospital Mainz, Langenbeckstrasse 1, 55131 Mainz, Germany. Tel: +49 6131170, Fax: +49 6131176687, e-mail: proschek@unfall.klinik.uni-mainz.de

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Bone metastases are common in many advanced cancer types and are a clinically relevant source of skeletal morbidity. Nearly 30% of all malignant tumors induce bone metastases (1, 2). Most often, the spinal column (80%) and the femur (40%) are affected. In particular breast, lung and bronchus, prostate and kidney cancer types have a high rate for inducing bone metastases. Prostate cancer in male and breast cancer in female are the most common cancer types (1). In the U.S., 33% of the estimated new cases of cancer in males are induced by prostate cancer (230,110 cases of new prostate cancer per year); 32% of the new cases in females are induced by breast cancer (215,990 cases of new breast cancer per year) (1, 2). Sixty to 80% of all patients with breast or prostate cancer develop bone metastases. Pain is the most frequent complication in metastatic bone disease. More than 80% of patients suffer from pain with a reduction of mobility and life quality and therefore have a high risk of concomitant complications. Therapy of bone metastases has three main goals: pain relief, improvement in mobility and quality of life, and improvement of life expectancy. Therapeutic possibilities comprise local strategies like radiation, surgical therapy and systemic therapy. A new and upcoming, minimally invasive therapy option is thermal ablation in bone tumors.

Radiofrequency ablation (RFA) in bone tumors is a promising technique which was first described by Rosenthal *et al.* (3). RFA is used to treat multiple benign and malignant diseases. In particular, liver and lung have become the primary target organs in thermal ablation therapy (4). Due to its high efficacy and safety, RFA has become one of the most accepted techniques in hyperthermal ablation therapy (5-8).

Changes in bone matrix structural factors lead to a microscopic damage of the bone ("micro fractures") and therefore especially to fractured trabeculae (9). Bone also stores energy generated from the stresses of movement with the consequence of pain generated by the micro fractures. The analgesic effect of bone cement application can be explained by the stabilization and immobilization of the fractured bone. Combining RFA and bone cement application might be an improvement in the thermal ablation therapy of bone tumor.

The objective of this prospective pilot study was to assess outcome, efficacy, safety and risks of CT-guided percutaneous radiofrequency ablation of bone tumor and to evaluate the use of an additional application of bone cement after radiofrequency therapy.

Patients and Methods

Patients. Sixteen female patients with painful spinal metastases of human breast cancer were treated on an outpatient basis under local anesthesia. Eight patients were treated with RFA alone, another eight patients received an additional bone cement application after RFA. Primary indications for therapy were pain (refractory to previous treatment) and improvement of quality of life as well as imminent fracture or instability of the bone due to rapid tumor growth. Before therapy, all patients underwent clinical, radiological and laboratory examinations. X-ray (ap and lateral view), CT and MRI (Siemens TRIO; 3T; T1 and T2 weighted and TIRM sequences) of the spine were carried out before entering the trial and were evaluated by an independent and experienced radiologist. Other inclusion criteria were absence of neurological deficits and an increase of the pain during movement or excessive stress. Exclusion criteria were any vertebral fractures, radicular neurological symptoms, coagulation disturbances, rheumatic diseases, allergy to local anesthesia, pregnancy and any infections (e.g. spondylitis, spondylodiscitis). An informed consent was obtained from all patients enrolled. Before inclusion, a visual analogue scale (VAS) score regarding low back pain was obtained from each patient (10). Pain reduction was evaluated 6 hours after therapy by the physician using the VAS. Additionally the patients themselves used a special diary for the documentation of pain (documentation of pain every hour using the VAS scale). Demographic data and the body mass index were recorded. After therapy, all patients were observed for at least 6 hours on the ward. Another radiological examination (computed tomography) was carried out the day after the intervention. All patients were contacted 1 week and every 6 months after interventional therapy in order to assess the outcome and possible complications.

Study endpoints. Endpoints of this study were the reduction of pain and the improvement in quality of life. Pain was assessed and documented using the VAS (10). Patients were given a special scale, calibrated between 0 (no pain) and 10 (maximum and worst pain). For assessing quality of life, the Oswestry Disability Questionnaire was used (11). On this, general activity, mobility, working sufficiency, sleep and general enjoyment of life were recorded for each patient.

Pre-treatment examination. All patients underwent physical examination before entering treatment. A complete blood count and coagulation laboratory was obtained from each patient at least 24 hours before treatment. Pretreatment radiographics, containing CT scans, MRI and X-ray were evaluated. The maximum tumor diameter was measured. An oncology consultation was carried out and histopathological findings of bone metastases were confirmed in each of the patients.

Radiofrequency ablation. All procedures were performed in a strictly sterile manner in the CT room. All patients were treated under local anesthesia using Mepivacain (0.5% Scandicain; Astra Zeneca, Wedel,

Germany). Intravenous analgesic and sedation therapy consisted of Piriramid (Dipidolor, Janssen-Cilag, Neuss, Germany) and Midazolam (Versed; Roche Pharma, Manati, Puerto Rico) to provide conscious sedation. Patients were positioned (prone position) and the affected bone parts were identified using CT (Siemens Volume Zoom, Erlangen, Germany; Figure 1). Under continuous CT-guidance and after a small skin incision, a vertebroplasty cannula (16 G, Somatex Apart Standard, Somatex Medical Technologies, Teltow, Germany) was used to gain access to the affected bone. The positioning of the instruments was controlled precisely by computed tomography (Figure 2). A 14 G bipolar radiofrequency-applicator (Celon Pro Surge; Celon AG medical instruments, Teltow, Germany) was introduced using the vertebroplasty cannula as a gateway (Figure 3). The length of the radiofrequency applicator depended on tumor size, varying between 20 and 30 mm. Radiofrequency energy was generated by the CelonPOWER System (Celon AG medical instruments). The application power depended on tumor size and was 10 W cm⁻¹ of active length of the electrode. The tip of the electrode was heated depending on tumor size with 10 W cm⁻¹ of tumor size. Tumor coagulation was finished when the continuous energy flow was stopped due to increasing impedance. Postprocedural CT was performed to confirm the lack of soft tissue swelling and hematoma (Figure 3). All patients were discharged after clinical and functional examination.

In half of the patients, an additional application of bone cement was carried out after radiofrequency ablation and under CT guidance. After stopping the tumor coagulation, the RF-applicator was removed, leaving the vertebroplasty cannula in position. The bone cement (SOMATEX Cement, 20 g; Somatex Medical Technologies) was injected using the vertebroplasty cannula (Figure 4) and a cement injection system (Cement Injection System CIS, Somatex Medical Technologies). The procedure was monitored using CT scans. Postprocedural CT included control for correct filling of the necrosis cavity and possible bone cement leakage. Bone cements achieve approximately 90% of their ultimate strength within one hour of injection (12). Therefore all patients could be treated on an outpatient basis and stayed in hospital for at least 6 hours.

Data analysis. Univariate analysis of independent variables was performed with the *t*-test for independent samples for quantitative variables such as pain, quality of life, age and BMI. All tests were two-sided and a *p*-value <0.05 was considered to be significant. All analyses were conducted with the SPSS statistical software for Windows 14.0 (SPSS, Chicago, IL, USA). The results of this study were compared with the review data found in the literature.

Results

Epidemiology. Sixteen female patients with bone metastases of human breast cancer located in the vertebral body of the lumbar and thoracal spine were treated, with a mean age of 59.5 years, range 52-69 years. Average tumor size was 1.9 cm (range 1.2-3.5 cm). The first 8 of the patients (50%) were treated with RFA alone and the other 8 patients (50%) received RFA and an additional bone cement application. The average follow-up was 20.4 months (range 8-36). None of the patients had a local recurrence during the follow-up.

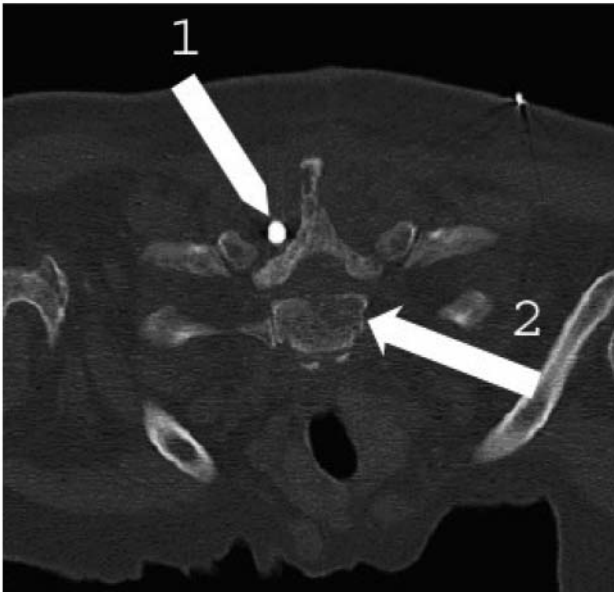


Figure 1. Axial CT scan before therapy showing a metastasis in the second thoracic vertebral body (arrow 2). Arrow 1: part of internal fixation.

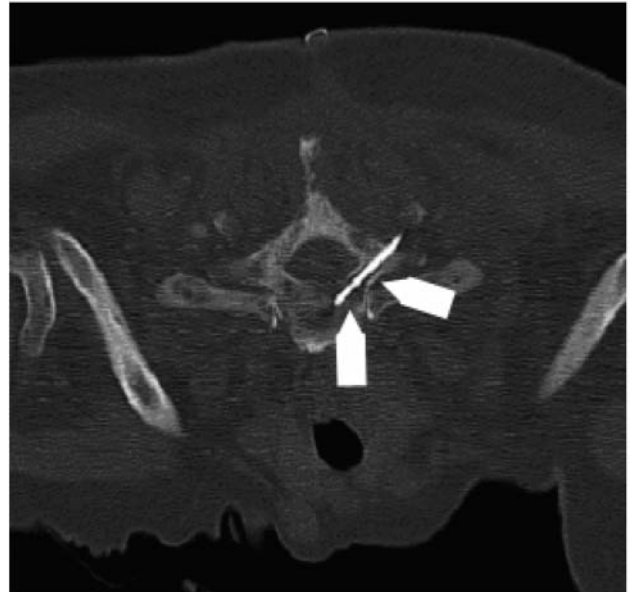


Figure 3. The CT scan showing the positioning of the bipolar radiofrequency probe within the metastasis. The vertebroplasty needle was pulled back in order to allow an unrestricted and unaffected flow of energy between the two electrodes (arrows). Note the insulation between the electrodes of the bipolar radiofrequency probe.



Figure 2. Axial CT scan showing the transpedicular approach to the metastasis in the second thoracic vertebral body using a vertebroplasty needle (arrow).

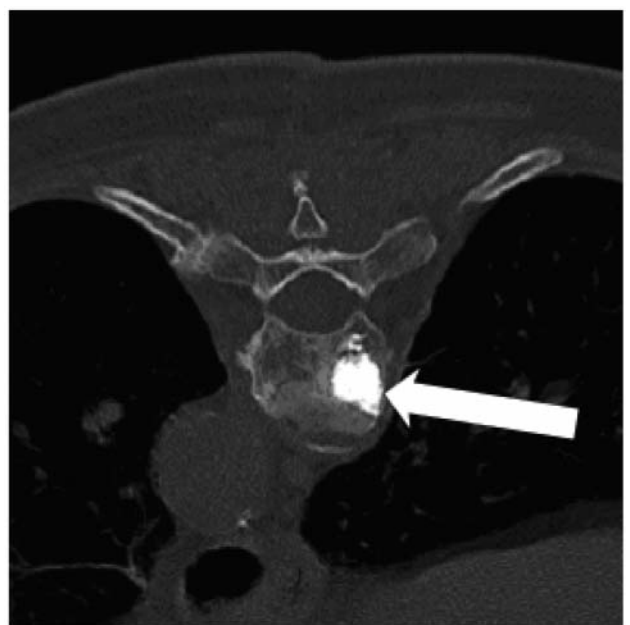


Figure 4. CT scan after RFA and application of bone cement. Note the filling of the necrosis cavity with bone cement.

Group 1: RFA alone. The first eight of the patients were treated with RFA alone and without additional cement application. Mean VAS score before treatment was 7.9 points

(range 6.0-10.0 points; Table I). Mean VAS score after treatment was reduced significantly to 5.5 points (range 3.0-8.0 points; $p=0.018$). Mean VAS score at the end of the

Table I. Comparison of RFA alone and RFA + cement.

Method	Mean VAS (1)	Mean VAS (2)	Mean QoL (1)	Mean QoL (2)
RFA alone	7.9	4.0	64%	33%
RFA + cement	7.6	3.5	66%	35%

(1): Mean VAS score and QoL Oswestry index before therapy; (2): Mean VAS score and QoL Oswestry index at the end of the follow-up.

follow-up was 4.0 points (range 2.0-6.0 points; Table I, $p=0.008$). All patients had a mean reduction of pain of 49.4% with at least 2.5 points decrease in pain and a maximum decrease of 4.5 points; 48.4% of the patients showed an improvement in the quality of life. Mean QoL Oswestry index before treatment was documented at 64% (range 38-84%). After treatment, mean QoL Oswestry index improved significantly to 34% (range 28-38%; $p=0.014$). Three to six months after therapy, quality of life showed no significant change comparing to the results of the QoL-documentation after treatment (mean QoL: 33%; range 23-38%; $p=0.06$). None of the patients had local recurrence.

Group 2: RFA plus cement. Eight of the patients were treated with RFA and an additional cement application. Mean VAS score before treatment was 7.6 points (range 7.0-10.0 points; Table I). Mean VAS score after treatment was reduced significantly to 5.0 points (range 3.0-7.0 points; $p=0.005$). Mean VAS score after completing the follow-up (15-36 months after therapy) was 3.5 points (range 1-5; Table I; $p=0.005$). All patients had a mean reduction of pain of 53.9% with at least 2.5 points decrease in pain and a maximum decrease of 4.5 points; 47.0% of the patients showed an improvement in the quality of life. Mean QoL Oswestry index before treatment was documented at 66% points (range 39-86%). After treatment, mean QoL Oswestry index improved significantly to 36% (range 31-39%; $p=0.003$). Fifteen to 36 months after therapy, quality of life showed only minor differences comparing to the results of the QoL-documentation after treatment (mean QoL: 35%; range 26-38%; $p=0.071$). None of the patients had local recurrence, but three of the patients showed a progress of their primary tumor, which made further therapy necessary and which could not be associated with the therapy of the bone metastases.

Comparing RFA alone and RFA + bone cement. All patients in both groups and independent of the therapy procedure had a significant reduction of pain ($p=0.0065$) and an improvement in quality of life with less interference with daily activities ($p=0.043$). Comparing both groups, there were no statistically significant differences regarding pain

relief ($p=0.074$) or improvement in quality of life ($p=0.917$), indicating that the therapy was equally effective. Additional bone cement application did not improve the pain reduction and quality of life compared to RFA alone (Table I).

Review of the literature. Only four studies with 68 patients presenting a combined therapy of RFA and application of bone cement were found in the literature. No studies comparing both therapies with each other are available. Nakatsuka *et al.* treated 17 patients with RFA and additional bone cement application (13). A significant reduction of pain was documented: 86.9% (VAS score before treatment: 8.4, after treatment: 1.1). Toyota *et al.* treated 17 patients with painful bone metastases and demonstrated a pain score reduction (VAS) from 6.4 to 2.4 and an analgesic reduction in 41% of the patients (14). All other studies also showed a significant reduction of pain without major complications (28, 29).

Discussion

Critical evaluation of RFA. RFA is a minimal invasive tumor ablation therapy with promising results. Indications for therapy have been recently discussed (19). Bone metastases are considered to be advanced tumor disease and limit the therapy options of the patients. Surgical treatment is often not possible or indicated due to the localization and size of metastases. Bone metastases result in increasing pain and restricted quality of life. In these cases, and additionally due to possible compression of neuronal structures, RFA is indicated. Several studies analyzing the value of RFA for the treatment of bone tumors have been published. Goetz *et al.* treated 43 patients with painful bone metastases in a multicenter trial (20) where 95% of the patients showed a significant reduction of pain (VAS before treatment: 7.9; VAS 24 weeks after treatment: 1.4). Major complications occurred in 6.9% of cases. However, most of the studies found in the literature treated patients with osteoid osteoma (21-23).

All of the patients in the present cohort suffered from progressive pain, a loss of mobility and impairment of their daily activities. After RFA, they showed a significant reduction of pain (51.7% pain reduction) and an improvement in quality of life (47.7% improvement). Reviewing the literature RFA provided a significant pain relief and a significant improvement of the quality of life in all studies (19, 24, 25).

Critical evaluation of RFA + bone cement application. Currently there are no significant and randomized data available in the literature. Apart from several case reports (15-18, 27), some retrospective studies evaluating pain reduction showed a feasibility of RFA in combination with bone cement

injection with a significant reduction of pain and decrease in the VAS score (13, 14, 28, 29). However, the results of these studies are similar to studies concerning RFA alone. Actually it is not clear whether there is a significant benefit in using additional bone cement injection. Prospective and randomized controlled trials are lacking. In cases of large metastases and imminent fracture of the bone segment, cement application stabilizes the bone and prevents further fracture in the treated area. A critical evaluation of additional bone cement application is necessary. The results showed that there was a significant reduction of pain after therapy (mean 51.7%) in both groups. However, this is independent of using RFA alone or RFA with bone cement application, and there was no statistical difference regarding the outcome of pain reduction and the improvement in quality of life.

In other treatment options such as vertebroplasty, the analgesic effect of bone cement application can be explained by the stabilization and immobilization of the macro and micro fractures (9). Polymerization heat might be another important factor in the reduction of pain. However statements about the effect of heat from methylmethacrylate to destroy nerves have largely been dropped. Two arguments have been discussed lately: the pain fibers in the vertebrae can be found mainly in the periosteum of each vertebra, while bone cement is typically injected more into the middle of the vertebral body; and that a certain high degree of temperature and a certain time maintaining this temperature is necessary to kill a nerve. Polymerization heat of bone cement is not high enough and does not last long enough to destroy the pain fibers (21, 26).

In cases of treating bone metastases with RFA before application of bone cement, the extensive impact of the radiofrequency heat destroys the inner architecture of the bone including trabecular structures and pain fibers. Therefore, additional bone cement application has only a minor influence on pain reduction since RFA itself is responsible for the destruction of pain fibers. The additional bone cement application stabilizes the affected bone structure. It prevents further destruction or fracture of the treated bone after RFA, especially in large vertebral body metastases with a large necrosis cavity. In selected cases, additional application of bone cement into the necrosis cavity after RFA is useful.

RFA is a safe and minimally invasive tumor ablation therapy which rapidly reduces pain and improves quality of life in patients with bone metastasis of human breast cancer. The results of this pilot study show that additional bone cement application has only minor influence on pain reduction. But it is a useful therapy option in selected cases with large metastases or instable bone situations, where a reliable stabilization of the bone is necessary. Prospective randomized controlled trials with a larger study population are necessary to evaluate the use of an additional bone cement application after RFA in painful bone metastases.

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