

Combination of Microwave Ablation and Percutaneous Osteoplasty for Treatment of Painful Extraspinal Bone Metastasis

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ABSTRACT

Purpose: To evaluate the efficacy and safety of microwave (MW) ablation combined with percutaneous osteoplasty (POP) on painful extraspinal bone metastases.

Materials and Methods: In this retrospective study, 50 adult patients with 56 extraspinal bone metastasis lesions, who suffered from refractory moderate to severe pain, were treated with MW ablation and POP. Changes in quality of life were evaluated based on the Visual Analog Scale (VAS), daily morphine consumption, and the Oswestry Disability Index (ODI) before and immediately after the procedure and during follow-up times.

Results: Technical success was achieved in all patients. Mean preoperative VAS score and morphine dose were 7.0 ± 2.6 (range, 3–10) and 66.7 ± 33.2 mg (range, 10–120 mg), respectively. Mean postoperative VAS scores and daily morphine doses were as follows: 1 day, 3.5 ± 2.1 and 36.1 ± 25.8 mg ($P < .05$); 1 week, 1.5 ± 1.7 and 12.2 ± 14.8 mg ($P < .001$); 1 month, 0.9 ± 1.4 and 5.7 ± 10.0 mg ($P < .001$); and 3 months, 0.6 ± 1.2 and 4.7 ± 8.4 mg ($P < .001$). A significant decrease in the ODI score was also observed ($P < .05$). Periprocedural death was not observed. A pathologic fracture occurred in 1 (2%) patient with femoral metastasis, and local infection was observed in 2 (4%) patients. Minor cement leakage occurred in 4 (8%) patients with no symptomatic or intra-articular extravasation. No local tumor progression occurred in patients with imaging follow-up.

Conclusions: MW ablation combined with POP is an effective and safe treatment for painful extraspinal bone metastases, which can significantly relieve pain and improve quality of life.

ABBREVIATIONS

MW = microwave, ODI = Oswestry Disability Index, POP = percutaneous osteoplasty, VAS = Visual Analog Scale

Bone metastases are common in patients with advanced cancer, especially breast cancer (1), prostate cancer (2), and lung cancer (3). The spine is the most common site of bone metastasis, followed by the pelvis, ribs, and proximal femur

(4). Complications of bone metastases, including refractory pain, pathologic fractures, and dysmotility, can seriously affect quality of life. Up to 75% of patients with bone metastases have severe pain, and 56%–82.3% of patients are not adequately treated (5). In most cases, the primary goal of treatment is to reduce pain and prevent complications rather than tumor control, especially for patients with limited life expectancy and poor functional status. Minimally invasive treatment is preferred or recommended as a better solution from the Multidisciplinary Oncology Committee. In recent years, imaging-guided percutaneous ablation techniques have been widely used in the treatment of bone metastases, and microwave (MW) ablation offers several potential advantages over other ablation methods (6–10). Osteoplasty can enhance bone stability and has a good effect on preventing and treating osteoporosis and pathologic fractures (11–13). However, there are few reports about the combination of MW ablation and osteoplasty, and there are even

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Table 1. Baseline Characteristics of Study Patients

	Number	Percent (%)
Age (y)		
Mean ± SD (range)	62.3 ± 10.3 (34–79)	
Median	65	
Sex		
Male	26	52.0
Female	24	48.0
Primary tumor		
Lung	27	54.0
Breast	14	28.0
Esophagus	4	8.0
Stomach	3	6.0
Rectum	2	4.0
Location		
Ilium	28	50.0
Femur	10	20.0
Humerus	8	16.0
Pubis	5	10.0
Acetabulum	3	6.0
Tibia	2	4.0
Maximal size of lesion		
>3.5 cm	13	23.2
≤3.5 cm	43	76.8
Lesion nature		
Osteolytic	45	80.4
Osteolytic-osteogenic mixed	11	19.6
Cortical involvement		
No	36	64.3
<30 mm	20	35.7
>30 mm	0	0.0
Mirels score for long bone		
<8	20	100.0
≥8	0	0.0

SD = standard deviation.

fewer reports about the combination of both therapies in extraspinal bone metastases (14–16). Since anatomic locations often confer different challenges to the treating physician, spinal and extraspinal bone metastases are examined separately. In previous reports of MW ablation combined with bone cement in the treatment of extraspinal bone metastases, the series was small and the pain relief was described only in detail. Consequently, the current retrospective study was conducted to present a larger retrospective series to demonstrate the efficacy and safety of this combination therapy on painful extraspinal bone metastases by evaluating pain relief, functional improvement, local tumor control, and complications.

MATERIALS AND METHODS

Inclusion and Exclusion Criteria

Cancer patients who met the following criteria were enrolled: 1) focal pain localized to 1 or 2 regions of the

Table 2. Operative Characteristics

Characteristic	MW ablation and POP (n = 56)
Ablation power	
60 W	38 (67.9%)
70 W	28 (32.1%)
Time of MW ablation (min)	
> 3.5 cm	11.5±1.3 (10–14)
≤3.5 cm	6.3±1.9 (3–10)
Cement volume (mL)	
> 3.5 cm	13.9±2.8 (11–19)
≤3.5 cm	5.5±2.4 (2–11)
Follow-up time (months)	
Mean ± SD (range)	4.7 ± 1.4 (3–8)

MW = microwave; POP = percutaneous osteoplasty; SD = standard deviation.

extraspinal bone with imaging confirmation of the presence of bone metastases; 2) intractable pain (Visual Analog Scale [VAS] score ≥4) that was resistant to conventional treatments, including opioids, chemotherapy, and radiotherapy; and 3) high grade of Eastern Cooperative Oncology Group performance status (<3).

Exclusion criteria included: 1) non-correctable coagulation disorder (platelets <50×10⁹/L; international normalized ratio >1.50); 2) uncontrolled infection around the lesions or systemic infections; 3) severely deficient in hepatic, renal, and cardiopulmonary function; and 4) tumors with margins approximating (<1 cm) nerve roots or key vascular structures.

Clinical Data

The institutional ethics committee approved this study. From December 2015 to July 2018, 50 adult patients (26 men and 24 women; mean age, 62 ± 10 years; median, 65 years; range, 34–79 years), with osteolytic or osteolytic-osteogenic mixed extraspinal bone metastases, underwent percutaneous MW ablation and osteoplasty, which were all performed under the guidance of computed tomography (CT) scanning. Of these patients, 88% (44/50) had 1 treated lesion, and 12% (6/50) had 2 treated lesions. The bone metastasis sites included the ilium, acetabulum, pubis, femur, humerus, and tibia. To stratify the risk of pathologic fracture in patients with lesions in long bones, Mirels' scoring system was used, applying criteria of site, degree of pain, lesion characteristics, and size (each scored between 1 and 3) (17). All patients had histopathologic diagnosis and underwent comprehensive imaging scans before the procedure. Baseline characteristics are listed in **Table 1**; operative characteristics are shown in **Table 2**. An interdisciplinary team of radiologists, pain physicians, surgeons, and oncologists evaluated all patients prior to surgery. All patients signed a written informed consent before the procedure.

MW Ablation

Bone MW ablation was performed with the ECO-100A1 MW ablation system (ECO Microwave Electronic

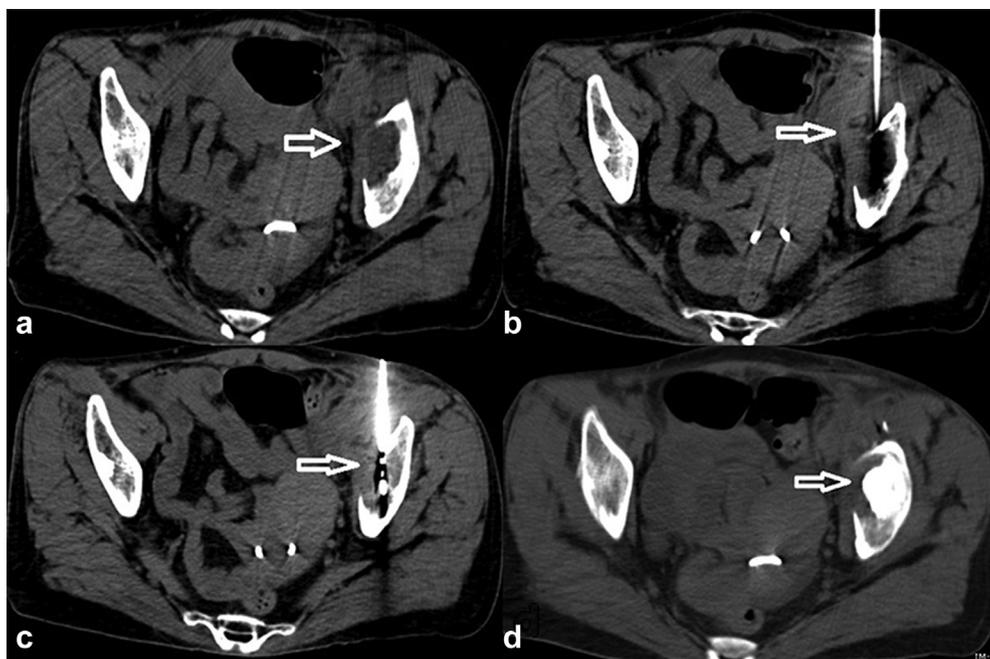


Figure 1. The procedure of MW ablation plus POP for a 62-year-old female with osteolytic metastases (arrow) in the left acetabular. (a) Metastatic lesion (arrow) in the left acetabular (CT scan). (b, c) Radiographs obtained during percutaneous puncture (arrow, b) and MW ablation (arrow, c). (d) After osteoplasty, homogeneous and sufficiently distributed bone cement (arrow) in the lesion location is shown. No evidence of bone cement extravasation was observed.

Institute, Nanjing, China). The microwave emission frequency was 2450 ± 10 MHz, and the output level of adjustable continuous wave ranged between 0 W and 100 W.

Appropriate surgical position was selected according to the lesion and fixed with a vacuum negative pressure pad. To determine the exact location and depth of lesions, a CT scan was performed for each patient (3–5-mm slices, depending on the case). The field was sterilized using povidone iodine, and sterile drapes were applied. For lesions with intact bone cortex, a 10-cm, 11-gauge or 13-gauge bone needle was inserted close to the lesion and advanced to its anterior edge under imaging guidance after administration of local anesthetic (2% lidocaine) along the course of the bone needle. Subsequently, a single 14- or 16-gauge MW ablation antenna was coaxially inserted into the tumor. For lesions with incomplete cortical bone, the microwave antenna was inserted directly into the lesion area. The size of the ablation antenna was determined on the basis of the calculated target lesion size, with the ablation zone calculated as 2 mm beyond the actual size of the target lesion to achieve adequate control. Related studies reported that the mean diameter of MW ablation area is close to 3.5 cm when the output power is 60–80 W (18). When the size of the lesion was more than 3.5 cm, the superposition of 2 or more energies could be accomplished by repositioning the microwave antenna. In this study, ablation power of 60–70 W and ablation time of 3–13 minutes were selected depending on lesion location, size, and adjacent tissue (Table 2, Fig 1a–c, Fig 2a–c).

All procedures were performed as inpatients, and patients were awake during the procedures. Prophylactic antibiotics were not used routinely. High temperature or traction could induce severe pain. Pain was dynamically assessed during the procedure, and the National Cancer Institute's Common Toxicity Criteria were used to report pain (19). Once moderate to severe pain (\geq grade 2) occurred, the procedure was immediately suspended, and morphine injection and diazepam were given. The dose and interval of morphine varied depending on the circumstances of the procedure. For lesions adjacent to soft tissue of the skin, a 2-inch, 25-gauge needle was used to blunt anatomical soft tissue, and ice saline was continuously injected into the gap between the soft tissue and the tumor to provide heat insulation.

Percutaneous Osteoplasty

Poly(methyl methacrylate) (Haraeus Medical GmbH, Wehrheim, Germany) was applied for the bone cement injection. Immediately after the MW ablation procedure, several 1-ml syringes were used to extract the paste cement and then placed in ice brine prepared in advance. Bone cement was injected into the position of the ablative lesion slowly, in batches and in small amounts through a bone puncture needle. CT scans were performed immediately after each 1-ml injection to observe the filling and flow direction of bone cement. The volume of cement injected varied significantly according to the tumor size and the location of the injection (Table 2, Fig 1d, Fig 2d, e). The mean volume of bone cement injected per lesion

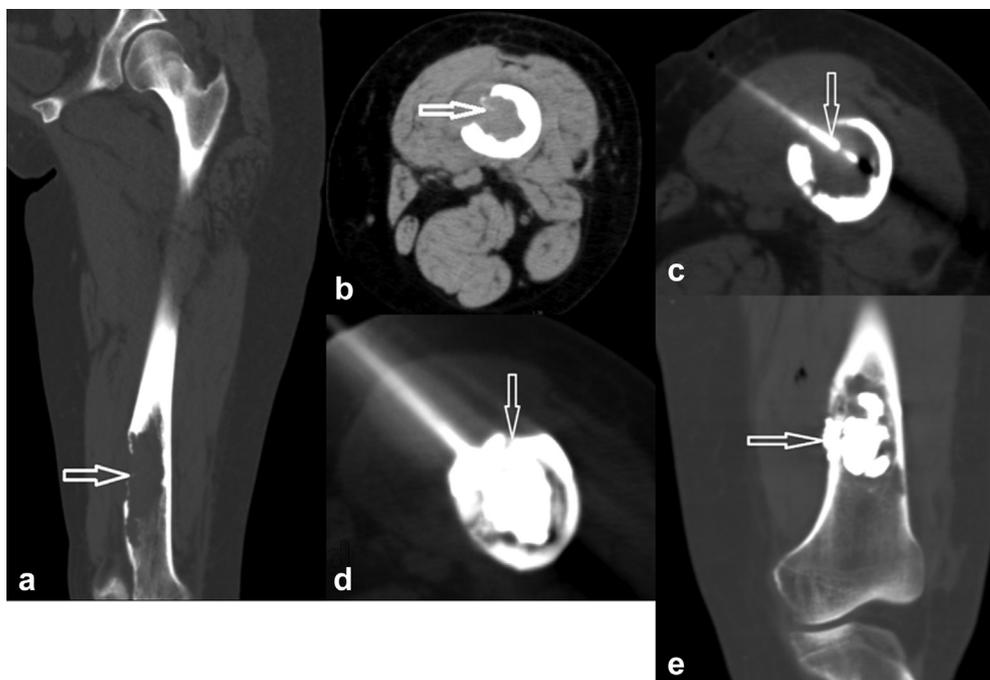


Figure 2. The procedure of MW ablation plus POP for a 53-year-old female with left femoral osteolytic metastasis. (a, b) Metastatic lesion (arrow) in the left femur (x-ray; CT scan). (c) A microwave antenna (arrow) was inserted into the lesion location. (d) Fifteen ml of bone cement (arrow) was injected into the lesion. (e) Bone cement uniformly distributed (arrow) at the lesion location.

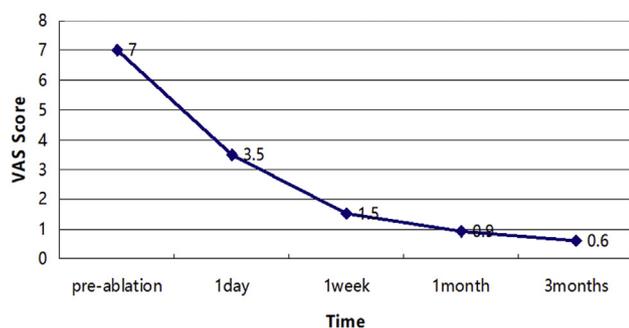


Figure 3. VAS score before and after the procedure.

location was 7.4 ± 4.4 mL (range, 3–19 mL). Once the cement had solidified, the bone needle was immediately extracted. Then, final CT was done to ensure adequate filling of cement in the lesion location and to exclude any undesirable leakage of cement.

Follow-up Schedule

Considering that quick pain relief remains the highest priority for patients with intractable pain, and patients have a short life expectancy, the clinical follow-up period of this study was 3 months, which is sufficient to demonstrate the efficacy of MW ablation combined with percutaneous osteoplasty (POP). After the procedure, VAS scale, morphine dosage, postoperative side effects, and complications were recorded daily. All patients were followed-up weekly in the pain clinic or by telephone interviews, and they were asked to return for CT scans of

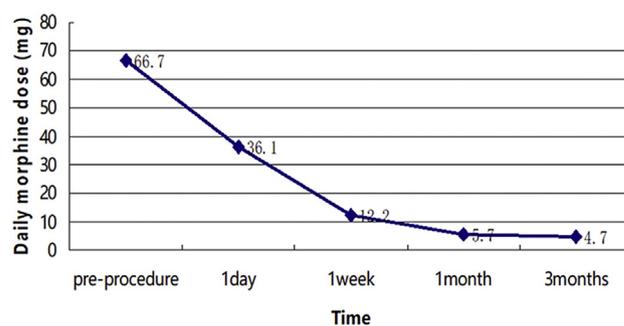


Figure 4. Daily morphine dose before and after the procedure.

the involved area in 1 week, 1 month, and 3 months after the procedure.

Outcome Assessment

Patients were asked to rank their pain from 0 to 10 (where 10 indicated the strongest pain ever experienced and 0 indicated absence of pain) using a VAS before and 24 hours, 1 week, 1 month, and 3 months after the procedure (20). The daily opioid consumption was calculated as morphine sulfate equivalence. The degree of disability was assessed using the Oswestry Disability Index (ODI) (18), including the intensity of pain, self-care, lifting, walking, sitting, standing, disturbing sleep, sex life, and tourism. Follow-up imaging was performed based on patient symptoms or discretion of the oncologist. Local tumor progression was defined as growth of the osteolytic defect or soft tissue component of the tumor (21).

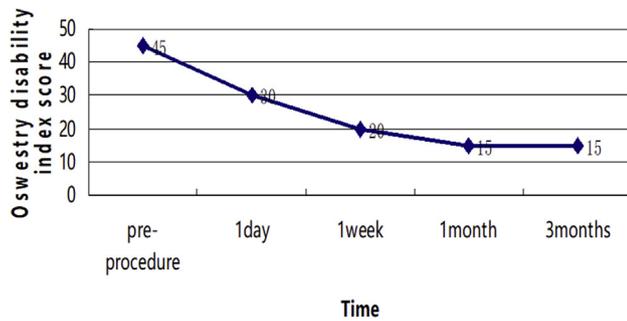


Figure 5. ODI score before and after the procedure.

Assessment of Complications

Complications were assessed according to the standards drafted by the International Working Group on Image-Guided Tumor Ablation in 2005 (22). Major complications were defined as clinical symptoms during or after ablation that may be life threatening, resulting in substantial damage and dysfunction and requiring hospitalization or prolonged hospitalization. Minor complications were defined as follows: self-limiting complications without sequelae and requiring only a short hospital stay for observation or treatment. Side effects referred to pain, post-ablation syndrome, and asymptomatic minor bleeding or fluid accumulation on CT.

Statistical Methods

Statistical analysis was done using SPSS Statistics version 22 software (IBM Corp, Armonk, New York). Numerical data were expressed as mean and standard deviation or median and range as appropriate. The paired Student *t*-test was applied to evaluate the VAS scale and the dose of morphine before and after the procedure. All tests were 2 tailed, and a *P* value less than .05 was considered significant.

RESULTS

In this study, MW ablation combined with POP was successfully performed on 56 osteolytic or osteolytic-osteogenic mixed extraspinal bone metastases in 50 cancer patients. Technical success was defined as the ability to achieve complete ablation at the interface between soft tissue and bone and adequate filling of the cement. All patients were successfully followed-up for at least 3 months.

Pain Relief

Compared to the preoperative VAS score (7.0 ± 2.6 ; range, 3–10), the postoperative VAS scale decreased significantly after 1 day (3.5 ± 2.1 , $P < .05$), 1 week (1.5 ± 1.7 , $P < .001$), 1 month (0.9 ± 1.4 , $P < .001$), and 3 months (0.6 ± 1.2 , $P < .001$) (Fig 3). Moreover, a similar significant decrease in the daily morphine consumption was observed. The daily preoperative morphine dose was 66.7 ± 33.2 mg (range, 10–120 mg). The daily postoperative

Table 3. Side Effects and Complications

	Number	Percent (%)
Side effects		
Pain (grade 2–3)	13	23.2
Post-ablation syndromes	5	10.0
Complications		
Pathologic fracture (SIR classification D)	1	2.0
Mild skin infection (SIR classification B)	2	4.0
Minor cement leakage (SIR classification A)	4	8.0

morphine doses were as follows: 1 day, 36.1 ± 25.8 mg ($P < .05$); 1 week, 12.2 ± 14.8 mg ($P < .001$); 1 month, 5.7 ± 10.0 mg ($P < .001$); and 3 months, 4.7 ± 8.4 mg ($P < .001$) (Fig 4).

Degree of Disability

Compared to pre-operation, the ODI score decreased significantly 1 day, 1 week, 1 month, and 3 months after the procedure (Fig 5). Of the 50 patients, 29 had limited walking ability determined by the ODI score before treatment. At the 3-month follow-up, walking ability was improved in 21 of the 29 patients (72%).

Local Tumor Progression

Follow-up imaging at 1 week, 1 month, and 3 months after the procedure was available in all patients. None of the patients experienced local tumor progression during the follow-up period.

Side Effects and Complications

Pain was the most common side effect during the procedures (Table 3). Patients experienced moderate pain (grade 2) in 8 sessions and severe pain (grade 3) in 5 sessions, and morphine sulfate and diazepam were used to treat pain. Four patients experienced pain aggravation up to 6–24 hours after the procedure, and the pain gradually reduced within 1 week. Post-ablation syndromes were exhibited in 5 patients with low fever and general malaise, and the syndrome persisted for 3–5 days.

Complications occurring during the procedure were graded using Society of Interventional Radiology (SIR) criteria (23) (Table 3). One patient (2%) with femoral metastasis developed a pathologic fracture 2 months after the procedure (SIR classification D). Cannulated screws were placed with surgical assistance due to increased pain and mobility disorders in the patient. With a follow-up of 3 months, the fracture healed, and the patient had normal lower extremity motor function without pain. Mild skin infection at the puncture site was observed in 2 patients (4%) (SIR classification B). Both patients were given oral antibiotics and recovered within 5 days. Minor cement

leakage (<1 mL) showed up on CT scans 1 week after the procedure in 4 patients (8%), resulting in no associated symptoms (SIR classification A). Skin burns, nerve injury, bone cement embolism, and periprocedural death were not observed.

DISCUSSION

Most patients with bone metastases have a late-onset limited life expectancy and poor functional status. Therefore, the main goal of treatment is to reduce pain and prevent pathologic fractures. Imaging-guided ablation techniques have potential advantages in the treatment of bone metastases, including low operating costs, real-time imaging guidance, synergy with other treatments, reproducibility, and short operating time (6–10,14–16). Given the significant effect in reducing pain, ablation therapy has been included in clinical guidelines for bone metastases (24). The effect of ablation in reducing pain is attributable to the following mechanisms: destruction of pain nerve fibers in the periosteum and bone cortex with reduced pain transmission; reduction in the size of tumor with reduced transmission of pain via the nerve endings; and decreased osteoclastic activity and coagulative necrosis of the tumor cells with a resultant decrease in the production of nerve-stimulating cytokines, such as interleukins and α -tumor necrosis factor (25).

Microwave ablation is more effective in ablation of high-impedance tissues like bone because poor thermal conduction in bone is a limiting factor in radiofrequency ablation. The relative permeability and low conduction of osseous tissue help microwaves penetrate deeper and make microwaves more effective in thermal ablation compared to radiofrequency ablation (26). Osteonecrosis and osteoporosis can occur after bone ablation in the weight-bearing area. Cement formation can increase bone stability and reduce the occurrence of pathologic fractures. In addition, it also reduces pain and controls tumor progression (11–13,27). Bone cement can be injected with poly(methyl methacrylate) alone or in combination with other instruments (screw, metal, or polyether ether ketone implants). Masala et al (28) concluded earlier that the combined effects of ablation and bone cementing can be superimposed on each other and have synergistic effects. Halpin et al (29) confirmed the results in their study: the use of ablation before cement injection has the advantage of decreasing tumor cell spread either mechanically through the formation of an ablation-shell barrier or through embolization of necrotic tumor cells; ablation may result in thrombosis of the venous plexus, which should decrease the risk of cement extravasation.

To date, few studies have reported the safety and efficacy of MW ablation combined with POP in the treatment of painful extrapural bone metastases, and the results are exciting (14,16). Pusceddu et al (14) reported 35 patients with 37 metastatic bone lesions (including extrapural metastases in 25 patients) who underwent MW ablation combined with cementoplasty. The mean reduction in the VAS

score was 84%, 90%, 90% at week 1, month 1, and month 6, respectively. Improved walking ability occurred in 100% and 98% of cases, and no major complications were observed. Wei et al (16) reported MW ablation and osteoplasty of 33 painful extrapural bone metastases in 26 lung cancer patients. Technical success and pain relief were achieved in all patients. Complications were observed in 8 patients (28%). In the current study, a larger number of extrapural bone metastases were treated with CT-guided MW ablation and POP. Compared to pre-operation, VAS score and morphine dose were significantly reduced during follow-up, which is similar to the results described by Wei et al. Regarding functional evaluation, the ODI score was also significantly decreased in this study, and walking ability was improved in 21 of the 29 patients with limited walking ability. No patients showed evidence of local tumor progression in the treated sites during 3 months of follow-up. In the previous study, Wei et al did not report on functional evaluation and tumor control.

Regarding the safety of this combination treatment, side effects were described in more detail, and complications were graded in the study, compared to previous studies. No periprocedural death was observed in the study. Pathologic fracture was observed in 1 patient with femoral metastasis (Mirels score <8; cortical involvement <30 mm). The strength of poly(methyl methacrylate) has poor performance in the peripheral skeleton where rotational and shearing forces are applied, and especially in weight-bearing locations (30,31). According to the Mirels scoring system, in cases of a lesion scoring ≥ 8 , prophylactic fixation is indicated (32,33). Moreover, according to literature studies and reviews, the risk of pathologic fracture after cementoplasty seems to be higher for cortical involvement greater than 30 mm (34). Mild skin infection was observed in 2 patients. To reduce the occurrence of local infection, the principle of aseptic operation must be strictly followed, and prophylactic antibiotics are required in the case of larger lesions and longer ablation time. In this series, patients experienced 4 minimal asymptomatic leaks (8%) and no symptomatic cement leak. Cement extravasation rates after osteoplasty vary in the literature and may be influenced by the presence of cortical defects and the sensitivity of the imaging modality used to guide the procedure and to detect extravasation (35). The advantages of combined MW ablation and cementoplasty result from optimal cement distribution into the ablated tissue and bone stabilization in a single session. Cavitation after ablation of the osteolytic lesion promotes cement distribution, and thrombosis of the venous plexus decreases the risk of cement extravasation (14).

The current study is limited by its retrospective nature and heterogeneous cohort of primary tumor histologies. There was no comparison arm of patients undergoing no treatment, MW ablation alone, or percutaneous osteoplasty alone. Thus, assessment of the true benefit of MW ablation combined with POP is unreliable. Pain scales were obtained by patient self-reports, which were unreliable for comparison. Some of the post-procedural assessments were performed

via telephone rather than in person. Future studies with extended clinical follow-up periods are needed, although these studies would be limited by the short life expectancy of these patients.

In conclusion, the results of this study showed the effectiveness, safety, and feasibility of performing both therapies in a single session, with very good results regarding midterm outcome. Patients with short life expectancy who are suffering from painful extraspinal bone metastases could quickly benefit from the combination of MW ablation and POP, which may have a synergistic effect on pain relief and can enhance bone stability.

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