

Safety and efficacy of multilevel vertebroplasty for painful osteolytic spinal metastases: a single-centre experience

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Received: 26 July 2016 / Revised: 3 November 2016 / Accepted: 29 November 2016 / Published online: 14 December 2016
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Abstract

Objective To retrospectively assess the safety and efficacy of percutaneous vertebroplasty (PVP) for painful osteolytic spinal metastases when treating more than three vertebrae per session.

Methods A total of 153 patients with painful osteolytic spinal metastases underwent PVP. Group A patients ($n = 93$) underwent PVP at up to three vertebral levels per session. Group B patients ($n = 60$) underwent PVP at more than three levels in one session. Pain, quality of life (QoL), and mobility were assessed before and after PVP. Minor and major complications were systematically assessed.

Results Both groups experienced significant pain relief and QoL improvement after the intervention ($p < 0.001$). Mobility improvement was observed in both groups, despite worse mobility status before PVP in group B compared with group A. There was no significant difference between the two groups throughout the follow-up period in overall pain relief and improvement in QoL and mobility. There was also no significant difference between groups in minor and major complications.

Conclusions Multilevel vertebroplasty is safe and effective for the treatment of multiple osteolytic spinal metastases. Multilevel PVP relieves pain and improves QoL and mobility.

Key Points

- Percutaneous vertebroplasty is safe and effective for painful osteolytic spinal metastases.
- Multilevel vertebroplasty does not cause more complications than single-level vertebroplasty.
- Multiple spinal metastases patients may regain functional independence after multilevel vertebroplasty.

Keywords Percutaneous vertebroplasty · Pain · Malignant · Multilevel · Spinal neoplasms

Abbreviations

QoL	Quality of life
PVP	Percutaneous vertebroplasty
PMMA	Polymethyl methacrylate
VAS	Visual analogue scale

Introduction

Approximately two-thirds of patients with advanced cancer develop bone metastases, most commonly affecting the spine [1, 2]. Spinal metastases, usually with more than one vertebra involved, may lead to an exacerbation of pain and will finally result in deteriorated quality of life (QoL), mobility, and functional independence [3].

For osteolytic spinal metastases, percutaneous vertebroplasty (PVP) is a less invasive therapeutic option than surgery, providing pain relief and biomechanical stability [4–7]. Many clinicians favour performing PVP at a maximum of three levels per session, considering the potential for complications such as cement leakage, pulmonary cement embolism, and fat embolism [8–10]. However, in patients with multiple vertebrae involved, the reinforcement of a single

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affected vertebra seems insufficient to prevent the progression of spinal deformity or provide stabilisation to an unstable vertebral segment [11], and performing repetitive operations in separate sessions potentially wastes time and money. For these patients, surgical options such as open reduction and internal fixation are rarely performed because of poor bone stock and overall condition [12, 13]. Hence, multilevel vertebroplasty has been adopted by some investigators in recent years [14–16].

As multilevel vertebroplasty has mostly been used to treat osteoporotic vertebral fractures [17, 18], data regarding its safety and efficacy in malignancy are very limited. So this retrospective study aimed to evaluate the safety and efficacy of PVP for painful osteolytic spinal metastases when treating more than three vertebrae per session.

Materials and methods

Patients

This study was approved by the local ethics committee. Due to the retrospective nature of the study, informed consent was waived. Between July 2008 and June 2012, 163 consecutive patients with painful osteolytic spinal metastases underwent PVP. However, ten patients were excluded because of combined treatment of radiofrequency ablation with PVP. The remaining 153 patients (82 males and 71 females) had a mean age of 61.6 ± 7.9 years (range 27–79 years; Table 1). Of these patients, 93 (60.8%) underwent PVP at up to three vertebral levels per session (defined as group A), and 60 (39.2%) underwent PVP at more than three levels per session (defined as group B). The most common primary tumour type was lung cancer, followed by breast and gastric cancer.

All patients had clinical and imaging evidence of osteolytic spinal metastases, and the diagnosis of primary cancer had been made using standard clinical criteria. In addition, a biopsy of the spine confirming metastatic bone disease was performed in 83 patients before PVP. Before each PVP procedure, patients underwent a thorough clinical examination, evaluation of cardiopulmonary function, and imaging studies. Imaging studies included multiplanar reconstruction computed tomography (CT) and magnetic resonance imaging (MRI, including T1W, T2W, and short TI inversion recovery sequences) of the involved vertebrae, bone scan, or positron emission tomography.

The clinical indications for PVP were in accordance with the Cardiovascular and Interventional Radiological Society of Europe quality assurance guidelines [19] and the Society of Interventional Radiology quality improvement guidelines [20], and they included the following: (1) excruciating pain in patients with adverse effects to opioid analgesics or opioid tolerance; (2) intractable pain refractory to chemotherapy and/

Table 1 Baseline characteristics of the two groups

Characteristics	Group A (<i>n</i> = 93)	Group B (<i>n</i> = 60)	<i>P</i> value
Male/female	51/42	31/29	0.701
Age (years)	63.7 ± 8.3	58.3 ± 9.1	0.328
Primary malignancy			
Lung cancer	49	30	
Breast cancer	18	13	
Gastric cancer	8	7	
Musculoskeletal sarcoma	4	3	
Liver cancer	3	1	
Colorectal cancer	2	1	
Bladder cancer	2	0	
Prostate cancer	2	0	
Nasopharyngeal cancer	1	1	
Renal cancer	1	1	
Glioblastoma	1	0	
Thyroid cancer	1	1	
Submandibular gland carcinoma	0	1	
Unknown origin	1	1	

Unless otherwise stated, data are numbers of patients

or radiation therapy; (3) painful vertebrae with extensive invasion secondary to malignant tumour. PVP was performed at vertebral levels on which local percussion over the posterior elements elicited pain, and osteolytic metastases at these levels were verified on imaging studies. If CT or MRI showed that more than 60% of the longitudinal or cross section of a painful vertebra was affected by an osteolytic lesion, irrespective of fracture presence, the vertebra was deemed at high risk of collapse and was reinforced by vertebroplasty. Before PVP, indications were confirmed by an interdisciplinary team of medical oncologists, interventional radiologists, and orthopaedists.

Relative contraindications to PVP included radiculopathy, extension of the tumour into the spinal canal, and collapse of the posterior vertebral body wall. Severe cardiopulmonary comorbidity, asymptomatic vertebral fracture with low risk for biomechanical instability and collapse, active infections, uncorrectable coagulopathy, and allergy to bone cement were regarded as absolute contraindications.

PVP procedure

All procedures were performed by two experienced interventional radiologists with 15 and 10 years of experience in spinal intervention, respectively. For cervical vertebral bodies, an anterolateral approach was generally used with the patient lying in a supine position. For thoracic, lumbar, and sacral vertebrae, procedures were performed with the patient in a prone position. After administration of

local anaesthetic (2% lidocaine), small skin incisions were made, through which 11- or 13-gauge needles with obturators (Murphy M2, Cook, Bloomington, Indiana) were inserted and driven under biplanar fluoroscopic guidance. When the needle tip reached the anterior one-third of the vertebral body or the centre of the osteolysis, opacified polymethyl methacrylate (PMMA) with 30% barium sulphate by weight (SpinePlex, Stryker, Kalamazoo, MI, USA) was injected through the needles into the vertebral body under continuous fluoroscopic monitoring. The maximal volume of injected cement was limited to 4 ml per cervical, thoracic, and sacral vertebra and 6 ml per lumbar vertebra. If any cement leakage was detected, the injection was immediately stopped by depressurising the application system. If the unilateral approach resulted in unsatisfactory filling, a bipedicular approach was used. For cases in which two or more lesions were treated per session, the lesion with major cortical destruction was treated last because of the relatively higher risk of cement leakage. A CT scan of the treated vertebrae was immediately performed to assess the cement distribution and check for cement leakage.

To avoid patients having to be readmitted to manage potential complications following PVP, patients were routinely admitted to hospital for 2–3 days of observation after the procedure. Patients then received medical treatments at the discretion of the treating physician.

Follow-up and data collection

A database was designed to retrospectively collect clinical and technical information on patients who underwent PVP. Data on sex, age, primary malignancy, number of treated vertebrae, the level of each treated vertebra, approach technique, amount of PMMA injected per vertebra, duration of the procedure, clinical outcomes, and complications were collected and checked by two of the authors (J.J.Z. and Y.J.S.). Clinical outcomes included the following items:

1. Visual analogue scale (VAS) pain scores, with 0 representing no pain and 10 representing the maximum pain intensity imaginable;
2. Karnofsky Performance Scale (KPS) scores of patient well-being;
3. Mobility scale where 0 represented no limitation, 1 represented limitation without the need for orthopaedic aids, 2 represented limitation necessitating orthopaedic aids, and 3 represented an inability to stand [6].

Clinical outcomes were assessed before intervention and at 24 h, 1 month, 3 months, and 6 months after intervention. Any potential complications following PVP, such as bleeding, haematoma, infection, local cement leakage, radiculopathy,

pulmonary cement embolism, fat embolism, and cardiogenic shock were recorded. Complications were classified as major (requiring extra care) or minor (not requiring extra care) according to clinical significance [20]. Efficacy and safety data were collected from questionnaire responses and clinical charts based on entries made during return visitation or repeat hospitalisation. Missing data were collected from patients by telephone.

Statistical analysis

Data analysis was performed using commercially available software (Statistical Package for the Social Sciences, version 15.0, SPSS, Inc., Chicago, IL, USA). A p value < 0.05 was considered significant. Continuous variables were presented as mean \pm SD. Qualitative variables were expressed as absolute and relative frequencies. The Wilcoxon rank sum test was used to compare VAS pain scores, KPS scores, and mobility scale scores before and after PVP. The Mann-Whitney U test was used to further evaluate the differences between group A and B regarding VAS, KPS, mobility scale scores, volume of PMMA injected, and duration of the procedure. The χ^2 or Fisher's exact test was used to compare proportions.

Results

A total of 191 vertebrae were treated in group A, and 284 vertebrae were treated in group B. The total 475 treated vertebrae included 38 cervical vertebrae, 233 thoracic vertebrae, 171 lumbar vertebrae, and 33 sacral vertebrae. All lesions were treated in the first session (one level, $n = 28$; two levels, $n = 32$; three levels, $n = 33$; four levels, $n = 29$; five levels, $n = 21$; six levels, $n = 8$; seven levels, $n = 1$; eight levels, $n = 1$); no patient needed further intervention by a second vertebroplasty during the 6-month study period. Pathologic fractures were detected in 43 of 191 treated vertebrae in group A and 72 of 284 treated vertebrae in group B, with no significant difference between groups in rate of fracture ($p = 0.479$). A unilateral approach was used in most treated vertebrae ($n = 452$, 95.2%), including 177 vertebrae in group A and 275 vertebrae in group B. The mean procedure time was significantly shorter in group A (1 ± 0.3 h) compared with that in group B (1.5 ± 0.4 h; $p < 0.001$). The mean amount of PMMA injected per vertebra in group A was 4.0 ± 0.7 ml, which was not significantly different from the amount injected in group B (3.8 ± 0.9 ml; $p > 0.05$). The mean follow-up period was 15 ± 8 months (range 8–43 months) in group A and 12 ± 6 months (range 5–28 months) in group B. Follow-up for 6 months was completed for 152 of the initial 153 patients, as 1 patient from group B died of complications from lung cancer 5 months after PVP.

Efficacy

The VAS pain scores in groups A and B are presented in Table 2. The mean VAS scores before PVP were 7.5 ± 1.3 in group A and 7.8 ± 1.6 in group B. After PVP, the mean VAS scores in group A significantly decreased to 3.1 ± 1.5 at 24 h, 2.3 ± 1.1 at 1 month, 2.0 ± 0.7 at 3 months, and 3.3 ± 1.0 at 6 months ($p < 0.001$). Similarly, the mean VAS scores in group B significantly decreased to 3.3 ± 1.3 at 24 h, 2.1 ± 1.2 at 1 month, 1.9 ± 0.8 at 3 months, and 3.0 ± 1.4 at 6 months ($p < 0.001$). Complete or partial pain relief (VAS-measured pain reduction $>50\%$) was achieved in 84 of 93 patients (90.3%) from group A and in 53 of 60 patients (88.3%) from group B at 24 h after PVP, with no significant difference between groups ($p = 0.695$). At 6 months after PVP, 78 of 93 patients (83.9%) in group A and 50 of 59 patients (84.7%) in group B still had complete or partial pain relief ($p = 0.885$).

The KPS scores in groups A and B are presented in Table 3. The mean KPS scores in group A increased significantly from 67.9 ± 9.1 before PVP to 79.2 ± 6.9 at 24 h, 81.7 ± 8.6 at 1 month, 83.9 ± 5.2 at 3 months, and 80.1 ± 9.2 at 6 months after PVP ($p < 0.001$). Similarly, the mean KPS scores in group B increased significantly from 65.7 ± 9.8 before PVP to 77.8 ± 5.9 at 24 h, 82.6 ± 6.5 at 1 month, 80.9 ± 7.8 at 3 months, and 82.1 ± 4.9 at 6 months after PVP ($p < 0.001$). No significant difference in mean KPS score was observed between the two groups at any time point during follow-up (Table 3).

The mobility scale scores in groups A and B are presented in Table 4. The mobility scale scores 24 h before PVP were significantly decreased at 24 h, 1 month, 3 months, and 6 months after PVP in both groups ($p < 0.001$), indicating a substantial mobility improvement (Table 4). It is notable that although patients in group B had worse mobilisation status compared with group A before PVP ($p < 0.05$), the mobility scale scores after PVP were similar in both groups during the 6-month follow-up ($p > 0.05$).

Safety

CT detected local cement leakages after PVP in 119 of 475 treated vertebrae, corresponding to a leakage rate of

Table 2 Changes in visual analogue scale (VAS) pain scores during the 6-month follow-up period

Group	24 h before	24 h after	1 month after	3 months after	6 months after
A	7.5 ± 1.3	3.1 ± 1.5^a	2.3 ± 1.1^a	2.0 ± 0.7^a	3.3 ± 1.0^a
B	7.8 ± 1.6	3.3 ± 1.3^a	2.1 ± 1.2^a	1.9 ± 0.8^a	3.0 ± 1.4^a
<i>P</i> ^b	0.159	0.323	0.296	0.677	0.128

^a $P < 0.001$ compared with baseline value

^b P value for comparisons between A and B

Table 3 Changes in Karnofsky Performance Scale (KPS) scores during the 6-month follow-up period

Group	24 h before	24 h after	1 month after	3 months after	6 months after
A	67.9 ± 9.1	79.2 ± 6.9^a	81.7 ± 8.6^a	83.9 ± 5.2^a	80.1 ± 9.2^a
B	65.7 ± 9.8	77.8 ± 5.9^a	82.6 ± 6.5^a	80.9 ± 7.8^a	82.1 ± 4.9^a
<i>P</i> ^b	0.264	0.285	0.597	0.163	0.386

^a $P < 0.001$ compared with baseline value

^b P value for comparisons between A and B

25.1% per vertebral level. Most cement leakages were within the adjacent intervertebral discs ($n = 39$, 8.2%), followed by leakages into the surrounding paravertebral tissue ($n = 31$, 6.5%) and the epidural space ($n = 28$, 5.9%); leakage into the venous plexus occurred in 18 (3.8%) vertebrae, and puncture trajectory leakages were detected in 3 (0.6%) vertebrae. None of the patients with vascular or nonvascular cement leakages developed any clinical or neurological symptoms. Group A experienced 45 leakages and group B experienced 74 leakages, indicating similar leakage rates of 23.6% and 26.1% per level, respectively ($p = 0.538$). The cement leakage rate per level for unilateral vertebroplasty (25%) was similar to that for bilateral vertebroplasty (26.1%; $p > 0.05$). Two cases (2.2%) in group A and one case (1.7%) in group B presented with haematoma at the puncture site, all of which resolved spontaneously within 1 week. One patient (1.1%) in group A with prior pathologic fractures experienced a new adjacent vertebral fracture 5 months after PVP and was then referred for regional radiation therapy.

No major complications were reported during the follow-up period. Although pulmonary cement embolism was observed in one patient from group B (Fig. 1), the patient was asymptomatic during 6 months of follow-up, and no treatment was prescribed. No other complications were observed in either group.

Table 4 Changes in mobility scale scores during the 6-month follow-up period

Group	24 h before	24 h after	1 month after	3 months after	6 months after
A	1.1 ± 1.0	0.6 ± 0.9^a	0.7 ± 0.8^a	0.7 ± 0.8^a	0.8 ± 0.9^a
B	1.5 ± 1.0	0.7 ± 0.8^a	0.6 ± 0.7^a	0.8 ± 0.8^a	0.9 ± 0.8^a
<i>P</i> ^b	0.027	0.183	0.165	0.127	0.276

^a $P < 0.001$ compared with baseline value

^b P value for comparisons between A and B; bold value is statistically significant

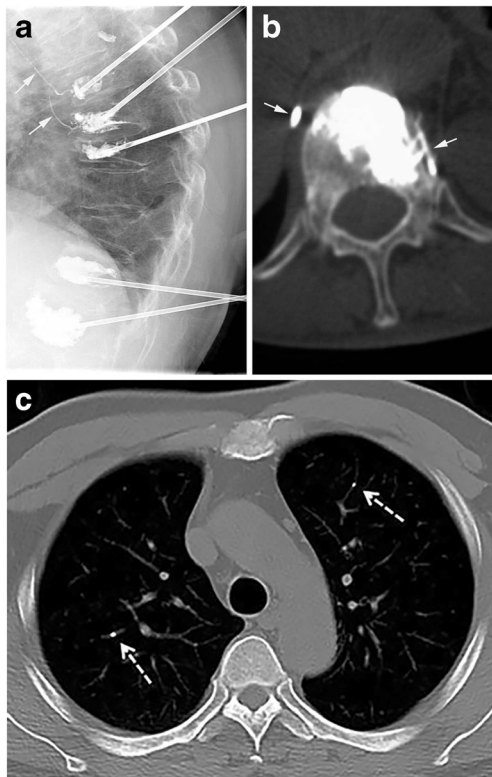


Fig. 1 A 65-year-old male with multiple osteolytic spinal metastases from gastric cancer underwent percutaneous vertebroplasty (PVP) at T5, T6, T7, T10, and T11. **a** During cement injection under fluoroscopic guidance, leakages into paravertebral veins were detected (*arrows*), the injection was stopped immediately, and the needle tips were repositioned by turning the handle bars in 90° steps. **b, c** Subsequent computed tomography (CT) scans of the treated vertebrae and the chest showed leakages into venous plexus (*solid arrows*) and small peripheral cement embolisms in arteries of the bilateral upper lobes (*dashed arrows*). However, the patient was asymptomatic during the 6-month follow-up

Discussion

It remains controversial whether it is most appropriate to perform single versus multiple level PVP treatments per session. A 2011 review of published data on PVP in malignancy reported that only two centres treated more than four vertebrae per session [21]. Other recent studies reported multilevel vertebroplasty, but often had a small sample size [14, 15]. The absolute safe number of lesions that can be treated per session is not yet known, and the safety and efficacy of multilevel vertebroplasty in malignancy warrant further investigation.

With regard to safety, cement leakages account for most of the complications resulting from PVP [22, 23]. A systematic review of 69 clinical studies reported that leakages occurred in 41% of treated vertebrae [24]. In the present study, the overall cement leakage rate per level was 25.1%, comparatively lower than previously published results. Subgroup analyses suggested that the leakage rate per level for vertebroplasty at more

than three vertebral levels was similar to that for vertebroplasty at up to three vertebral levels. Hence, the risk of cement leakage per session in a multilevel procedure should be higher than in a single level treatment because of the cumulative risk. However, all cement leakages in the present study were asymptomatic and well tolerated, so multilevel vertebroplasty was shown to be safe for multiple spinal metastases. This may be because appropriate cement opacification was accomplished with barium sulphate, which increased cement visibility and allowed early recognition of cement leakage while it was still minor. Moreover, the use of high-resolution biplanar fluoroscopy also contributed to early detection of small cement leakages, which then minimised symptomatic leakages.

The incidence of epidural leakage in the present cohort was relatively high (about 6%). This may be because of the high number of vertebrae with posterior cortical destruction ($n = 115$, 24.2%). Epidural cement leakages occurred significantly more frequently in vertebrae with posterior cortical destruction ($n = 20$, 17.4%) versus vertebrae without posterior cortical destruction ($n = 8$, 2.2%; $p < 0.001$). It should be emphasised that the epidural leakages caused no severe consequences, and the incidence was similar in group A and group B.

Unlike cement leakage, fat embolism is a rare but serious complication following PVP, which is caused by the displacement of bone marrow fat from the cemented vertebrae. Fat embolism is usually deemed a major complication that precludes multilevel vertebroplasty during which a relatively large amount of bone marrow is displaced [25]. The risk of fat embolism after PVP may be increased in patients with poor cardiorespiratory function [10]. The maximal amount of cement that can be injected per session without risk of fat embolism is not exactly known. Hodler et al. [26] reported treating one to five vertebral levels (mean, two levels) per session with 1.25–20.25 ml (mean, 8.3 ml) of cement per vertebra, with no occurrence of fat embolism even with such a large filling volume [26]. In the present study, the total amount of PMMA injected per session in group A and group B was 8.2 ± 1.3 ml and 18.0 ± 1.1 ml, respectively, and no fat embolism was observed in any patient. Notably, the efficacy of PVP does not seem to correlate with the volume of injected cement [27, 28]. Good clinical results have reportedly been achieved with 1.5–3 ml of cement [29] and 3–5 ml of cement [30]. In our own experience with multilevel vertebroplasty, low-volume injection of approximately 4 ml of cement per vertebra with a total amount of no more than 20 ml per session appeared to minimise the risk of fat embolism.

The efficacy of multiple vertebroplasty for spinal metastases is controversial. Barr et al. [8] stated that better outcomes were achieved when treating only one vertebral

level compared with multiple levels, but they treated only eight patients with malignancies. In contrast, a study on 38 patients with malignancies found that pain relief and mobility improvement were similar in patients treated at up to three levels per session and patients treated at more than three levels per session [14]. In the present study, patients from both groups experienced substantial improvement in pain, QoL, and mobility after PVP, irrespective of the number of vertebrae treated per session. Furthermore, although group B had worse mobilisation status before PVP compared with group A, this difference was no longer significant after PVP. As a result of pain relief and reinforcement of the affected vertebrae, patients in the present study were able to return to normal daily and recreational activities after PVP.

Although preventive reinforcement of asymptomatic vertebrae was not performed in our cohort, the mean number of treated vertebrae per patient was higher in the present study compared with previous studies. This could be due to the characteristics of patients in our centre, who were mostly referred from other cancer centres because of severe spinal metastases refractory to conventional therapy. In cases of multiple painful spinal metastases at high risk of collapse, we preferred to perform multilevel vertebroplasty in a single session instead of multiple treatments in separate sessions; this resulted in satisfactory safety and efficacy and may also have contributed to the low rate of new fractures in our study population [only one patient (0.7%) developed a new vertebral fracture during the 6-month study period].

This study has several limitations. First, the retrospective study design meant that selection bias was unavoidable. Although two authors worked diligently to check the original data and collect missing data, a prospective study should be considered. Second, this study only focused on the traditional PVP technique. New techniques such as interventional tumour removal, ablation, or kyphoplasty may provide a relatively low rate of complication and high rate of effectiveness [29, 31, 32]; such techniques should be investigated in future studies.

In conclusion, the present study reported our experience of multilevel vertebroplasty for painful osteolytic spinal metastases. The findings indicated that treating a patient at more than three vertebral levels per session was as safe and effective as treating up to three levels. Patients with deteriorated mobility resulting from multiple spinal metastases could regain functional independence after single-session vertebroplasty.

Acknowledgements The scientific guarantor of this publication is Yang Yao. The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article. This study has received funding by the National Natural Science Foundation of China (81503396) and Shanghai Xinglinxing Program (ZY3-RCPY-2-2035). No complex statistical

methods were necessary for this paper. Institutional Review Board approval was obtained. Written informed consent was waived by the IRB. Methodology: retrospective, case-control study, performed at one institution.

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