The Efficacy and Safety of Percutaneous Kyphoplasty in the Management of Patients With Painful Spinal Osteoblastic Metastases

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Abstract

Background: The study aimed to evaluate the clinical efficacy and safety of minimally invasive approach for painful spinal osteoblastic metastases by percutaneous kyphoplasty (PKP).

Methods: A total of 30 patients (11 males and 19 females, average age, 58.9 ± 8.7 years) with 56 spinal osteoblastic lesions underwent PKP under conscious sedation were reviewed retrospectively. Visual analogue scale (VAS) score was employed to assess pain. Karnofsky performance score (KPS), quality of life (QOL) score (short form with 36 questions) and related complications were used to evaluate the clinical outcomes of the procedures.

Results: All patients underwent PKP successfully and the pain was significantly alleviated after PKP. Mean VAS scores decreased significantly from 6.07 ± 1.84 preoperatively to 2.70 ± 1.56 at 3 days after PKP (P<0.001), and remained largely immutable at 1 month (2.03 ± 0.72; 30 patients; P<0.001), 3 months (2.38 ± 1.24; 29 patients; P<0.001) and 1 year (3.04 ± 1.00; 26 patients; P<0.001). Mean KPS and QOL scores were 59.33 ± 19.11 and 91.20 ± 12.88 preoperatively and improved to 69.31 ± 19.81 (P < 0.001) and 99.61 ± 12.29 (P < 0.001) at 3 months after PKP, respectively. Two (6.7%) patients suffered from the leakage of bone cement.

Conclusions: As a minimally invasive surgery, PKP may not only effectively alleviated the pain, but also safely improved the QOL of spinal osteoblastic metastatic patients.

Introduction

The skeletal system is the most common location for metastasis of malignant tumor, of which spine is the most vulnerable site and the probability of spinal metastasis in patients with malignant tumor is about 5%-10%. Based on computerized tomography (CT) findings of the lesions, 78.3% of vertebral lesions are classified as osteolytic, 20.1% are mixed, and only 1.6% are osteoblastic. The predominant symptom for the patients suffering from spinal metastasis is intractable pain, including persistent localized, radicular and axial pain. Therapies for spinal metastasis in easement of pain include conservative and surgical treatments. Conservative treatments, including analgesics, chemotherapy, radiotherapy and bisphosphonates, were frequently used to achieve a relief of pain. However, effects were always transitory and unsatisfactory. As a consequence, for patients who have failed to conservative therapies, developed neurological deficits, or segmental instability, surgery is still required. Nevertheless, traditional open surgery is extensive trauma that generally not suitable for spinal metastatic patients with short life expectancy. Additionally, spinal metastasis always displayed terminal stage tumor, patients tend to have poor physical conditions, and they generally were not able to tolerate traditional open surgery. What is more, because spinal metastasis usually occurred in multiple segments, it was difficult for traditional open surgery to remove tumors completely. Therefore, traditional open surgical treatment accounted for only about 10% of spinal metastasis. In contrast, minimally invasive surgery, including percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP), represents a potential tool in the management of patients with painful spinal metastases. To our knowledge, PVP have been performed by some researchers as an effective treatment for spinal blastic metastatic lesions. However, the efficacy and safety of PKP for the treatment of osteoblastic metastases have not, as yet, been well investigated. Therefore, this study aims to evaluate the clinical efficacy and safety of PKP in the management of spinal osteoblastic metastases.

Materials And Methods

Basic information

The study was approved by the ethics board committee of our hospital. All patients gave written informed consent. From February 2017 to April 2019, a total of 30 patients with 56 spinal osteoblastic lesions who underwent PKP under conscious sedation in our hospital were enrolled in this retrospective study. The diagnosis was based on medical history, clinical symptom, radiologic imaging and pathologic examination. All patients presented with a history of cancer and severe pain. Radiologic imaging included the identification of spinal vertebral destruction through plain radiographs, computed tomography (CT) or positron emission tomography-computed tomography (PET-CT), magnetic resonance imaging (MRI) and whole body skeletal imaging (WBS). Pathological examination was established based on biopsy of the diseased vertebrae and histologic examination of bone...
aspirates. The characteristics of 30 patients were shown in Table 1. Eleven (36.7%) males and 19 (63.3%) females were enrolled in the present study. There were 16 patients (53.3%) < 60 years old and 14 patients (46.7%) ≥ 60 years old, with an average age of 58.9 ± 8.7 years (range, 47-76 years). With regard to the number of affected vertebrae, involvements of 1 to 3 segments were noted in 18 cases, 6 cases, and 1 case respectively. While involvements of 4 to 6 segments were noted in 3 cases, 1 case, and 1 case respectively. There were 7 (23.3%) patients had alone thoracic vertebrae of involvement and 14 (46.7%) patients had alone lumbar vertebrae of involvement, while 9 (30.0%) patients had combined lumbar and thoracic vertebrae of involvement. The total numbers of affected thoracic and lumbar vertebrae were 18 and 38, respectively. The metastatic lesions of the spine were caused by secondary cancers of the lung cancer (n = 11), breast cancer (n = 7), kidney cancer (n = 3), rectal cancer (n = 3), prostate cancer (n = 2), esophagus cancer (n = 1), stomach cancer (n = 1), colon cancer (n = 1), and ovarian cancer (n = 1). All patients underwent clinical examination regularly by two of the authors. Visual analogue scale (VAS) score was recorded to evaluate pain in pre-procedure, three days, one month, three months and 1 year after PKP. Various parameters including Karnofsky performance score (KPS), quality of life (QOL) score (short form with 36 questions) were used to assess the clinical feasibility in pre-procedure and three months after PKP. Major and minor complications defined according to the Society of Interventional Radiology (SIR) reporting standards were employed to evaluate the clinical safety of the procedure.[9]

Operative procedures

The patients were initially positioned in a prone position with conscious sedation. Two puncture needles (STERYLAB, Italy) were placed into the appropriate position and angle at the diseased vertebra through the bilateral pedicle under C-arm fluoroscopic guidance. After obtaining a small cylindrical sample of diseased vertebral tissue and histologic examination of bone aspirates, polymethyl methacrylate (PMMA) cement (Weigao Medical GmbH, China) used as a filler, was injected into the diseased vertebra after intravertebral balloon inflation (Weigao Medical GmbH, China) performed. Injection was quitted when high resistance was felt obviously or leakage of PMMA was observed or the PMMA reached the posterior margin of the vertebra. When the PMMA had solidified, the injection needles were removed. The amount of PMMA used for PKP was recorded.

Postoperative management

Post-procedure, the patients were required to rest in bed for at least six hours, and the vital signs and sensory motor functions of the lower limbs were closely monitored during this period. If necessary, nonsteroidal anti-inflammatory drugs (NSAIDs) were used to alleviate pain at the puncture site after disappearance of the local anesthetic effect. And then the patients were allowed to stand or walk without weight-bearing. All patients were examined radiologically and clinically in three days, one month, three month and in twelve months after PKP and then, once a year thereafter until the patient's death. Postoperative CT examination was performed on the patients with the suspicion of bone cement leakage.

Statistical analysis

All continuous data were presented as mean ± standard deviation (SD). All data were statistically analyzed using SPSS 21.0 software (IBM Corp., Armonk, NY, USA). Pre and postoperative comparisons of the continuous parameters were carried out by a paired-sample t-test. A P value <0.05 was considered statistically significant.

Results

Clinical efficacy

All patients were technically successful and bone cement dispersion was uniform in all lesions. (Figure 1 and 2) The mean volume of bone cement injected into per vertebra was 2.63 ± 1.89 ml, with a mean of 2.35 ± 1.35 ml for per thoracic vertebra and 2.76 ± 2.10 ml for per lumbar vertebra. Pain was significantly relieved following the surgery in all patients. Mean VAS scores decreased significantly from 6.07 ± 1.84 preoperatively to 2.70 ± 1.56 at 3 days after PKP (P<0.001), and remained largely immutable at 1 month (2.03 ± 0.72; 30 patients; P<0.001), 3 months (2.38 ± 1.24; 29 patients; P<0.001) and 1 year (3.04 ± 1.00; 26 patients; P<0.001). (Table 2, Figure 3) The average KPS scores increased from 59.33 ± 19.11 preoperatively to 69.31 ± 19.81 at 3 months after PKP (P<0.001). While the mean QOL scores improved from 91.20 ± 12.88 preoperatively to 99.61 ± 12.29 at 3 months after the procedure (P<0.001). (Table 2)
Clinical safety

Due to conscious sedation, most patients complained transient local back pain during the progress of puncturing and injecting bone cement, however, no operation was stopped because of the patient's intolerance of the procedure. The only minor encountered complication was cement leakage, which was seen in the prevertebral space in 2 (6.7%) patients. Despite the leakage of PMMA, none of the patients developed any related clinical or neurologic symptoms. No surgical related complications such as cerebral fluid leakage, spinal cord compression, pulmonary embolism, leukopenia, and surgical site infection occurred in all patients. Four patients died due to the progression of primary disease at the final follow-up.

Discussion

Approximately 85% of patients with the three most commonly malignant tumor (lung, breast, and prostate) suffered from skeletal metastatic lesions, of which spine is the most vulnerable site.[10] Spinal metastases, of which 70% are located in the thoracic spine, 20% in the lumbar spine and 10% in the cervical spine.[3] Based on CT findings of lesions, spinal metastases may be classified as purely osteolytic (78.3%) lesions, mixed osteolytic and osteoblastic lesions (20.1%), and purely osteoblastic (1.6%) lesions.[11] Nowadays, PKP has been safely employed in the management of vertebral collapse caused by lytic metastasis.[12-14] However, there have been few reports on the role of PKP in the management of spinal osteoblastic metastases.

Because spinal osteoblastic metastasis hardened the diseased vertebral body, it was difficult to penetrate diseased vertebra with kyphoplasty puncture needles and to inflate balloons, resulting in a possibility of smaller cavity created inside the diseased vertebral body and a relatively smaller quantity of bone cement compared with patients with osteolytic spinal metastasis. In our present study, mean mount of PMMA is 2.6 mL in per vertebra, which is less than that in PVP for osteoblastic lesion (3.3mL).[15] However, the analgesic effect of PKP in patients with spinal metastasis is not related to the quantity of bone cement injected, which supports the management of pure osteoblastic lesions as well as mixed and purely osteolytic lesions.[16,17]

The predominant symptom for the patients suffering from spinal metastatic lesions is intractable pain, including persistent localized, radicular and axial pain.[18,19] The mechanism of pain causing by spinal metastasis is currently unclear yet. Generally, the reasons include segmental instability, stimulation of neural endings and pathological fractures have been proposed. Some reports hold the opinion that the asymmetry of compressibility of the vertebral body might result in stress fractures, causing intractable pain for osteoblastic bone lesions.[8,20] Despite the technical challenge of the treatment of osteoblastic spinal metastasis, pain of relief was acheived immediately after PKP in all enrolled patients, which is consistent with previous study.[21] Some studies demonstrated that the mechanism of PKP treating spinal osteolytic and osteoblastic lesions is similar, though it still remains unclear.[3] And many studies have speculated that the relief of pain by PKP in patients with spinal metastasis was not only associated with enhancement of the vertebral body, but also related to chemical and exothermic reaction of the cement, which may have the capacity to destroy the sensory nerve endings and kill the tumor cells.[20,22,23]

Pain relief is vital to achieving a better KPS and QOL for patients with spinal metastasis in palliative treatment. In a result, KPS and QOL of enrolled patients also acheived substantial improvement in our present study. Generally speaking, patients with spinal metastasis always developed new painful metastasis, resulting in KPS and QOL deteriorated along with time. Nevertheless, in our present study, the significantly differences were observed at all study time points after PKP compared with preoperation, and there was improvement of KPS and QOL. The successful long-term pain relief in patients with spinal metastasis might be connected with the fact that the patients were treated regular treatments after PKP, such as chemotherapy or radiotherapy, which might have helped control the development of the cancer, although it may also be a study confounder.

The most commonly reported complication associated with PKP is extravasation of the bone cement.[24] Kyphoplasty has not been proven to be superior to vertebroplasty in treating painful spinal metastasis.[25] However, kyphoplasty has a significant advantage over vertebroplasty when comparing the incidence of cement leakage.[26] In our present study, the incidence rate of cement leakage is 6.7%, which is consistent with previous study.[27] Bone cement leakage was found by intraoperative fluoroscopy, and bone cement injection was stopped immediately. No obvious symptoms were observed after surgery. The dominant reason for cement leakage can be attributed to cortical damage.
Several limitations should not be ignored in our study. First of all, it was a single-center retrospective rather than a prospective study, leading the nature of data collection subjects the study to selection bias. Secondly, our study included a relatively small number of patients, and the follow-up time for evaluating patient outcome was relatively short. In addition, most patients had terminal-stage disease, resulting in precluded the follow-up time for evaluating patient outcome. A randomized controlled trial by different surgical approaches with a larger population and longer follow-up time is warranted to further confirm our findings.

In conclusion, PKP could serve as an effective and safe treatment in the management of spinal osteoblastic metastases. It may not only effectively alleviated the pain, but also safely improved the QOL of spinal osteoblastic metastatic patients.

Abbreviations

PKP: percutaneous kyphoplasty; KPS: Karnofsky performance score; QOL: Quality of life; PMMA: Polymethyl methacrylate; CT: Computerized tomography; PVP: Percutaneous vertebroplasty; PET-CT: Positron emission tomography-computed tomography; MRI: Magnetic resonance imaging; WBS: Whole body skeletal imaging; NSAIDs: Nonsteroidal anti-inflammatory drugs.

Declarations

Acknowledgement

Not applicable.

No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

Authors’ Contribution

The authors’ contributions to this study were as follows: WCW, HML and XXZ contributed to the study design. WCW and SJY contributed to the data collection and statistical analysis. All authors wrote and approved the manuscript.

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Availability of data and materials

All data used by or generated in this study is available from the corresponding author upon reasonable request.

Ethics approval and consent to participate

The retrospective study was approved by the ethics board committee of National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College. Written informed consent was obtained from all the patients included in this study and the study protocol is performed in accordance with the relevant guidelines.

Consent to publication

All participants gave written informed consent for their personal or clinical details along with any identifying images to be published in this study.

Competing interests

The authors declare that they have no competing interests.
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**Tables**

**Table 1**: Characteristics of 30 patients
| Basic demographic data          | n (%)     |
|--------------------------------|-----------|
| Sex                           |           |
| Male                          | 11 (36.7) |
| Female                        | 19 (63.3) |
| Age (years), mean (range)     | 58.9 ± 8.7 (47-76) |
| < 60                          | 16 (53.3) |
| ≥ 60                          | 14 (46.7) |
| Number of affected vertebrae  |           |
| 1 segment                     | 18 (60.0) |
| 2 segments                    | 6 (20.0)  |
| 3 segments                    | 1 (3.4)   |
| 4 segments                    | 3 (10.0)  |
| 5 segments                    | 1 (3.3)   |
| 6 segments                    | 1 (3.3)   |
| Vertebrae of involvement      |           |
| Alone thoracic                | 7 (23.3)  |
| Alone lumbar                  | 14 (46.7) |
| Combined lumbar and thoracic  | 9 (30.0)  |
| Total involved vertebrae      | 56        |
| Thoracic                      | 18 (32.1) |
| Lumbar                        | 38 (67.9) |
| Primary malignancy            |           |
| Lung cancer                   | 11 (36.7) |
| Breast cancer                 | 7 (23.4)  |
| Kidney cancer                 | 3 (10.0)  |
| Rectal cancer                 | 3 (10.0)  |
| Prostate cancer               | 2 (6.7)   |
| Esophagus cancer              | 1 (3.3)   |
| Stomach cancer                | 1 (3.3)   |
| Colon cancer                  | 1 (3.3)   |
| Ovarian cancer                | 1 (3.3)   |

**Table 2: Clinical Outcomes of VAS, KPS and QOL after PKP**
| Parameter | Pre-op (n=30) | 3 days (n=30) | 1 month (n=30) | 3 months (n=29) | 1 year (n=26) |
|-----------|---------------|---------------|---------------|----------------|--------------|
|           |               |               |               | VAS (score)    |              |
|           |               |               |               | 6.07 ± 1.84    | 2.70 ± 1.56* |
|           |               |               |               | 2.03 ± 0.72*   | 2.38 ± 1.24* |
|           |               |               |               | 2.38 ± 1.24*   | 3.04 ± 1.00* |
| KPS       | 59.33 ± 19.11 | -             | -             | 69.31 ± 19.81* | -            |
| QOL(score) | 91.20 ± 12.88 | -             | -             | 99.61 ± 12.29* | -            |

PKP: Percutaneous kyphoplasty  
QOL: Quality of life  
KPS: Karnofsky performance score  
VAS: Visual analogue scale  

*Significant difference at P < 0.05 compared with preoperation at each follow-up point.

Figures
A 60 years old female patient with spinal metastasis from lung cancer underwent PKP. Preoperative radiography (a and b) and thoracic MRI including T1 and T2 sequences(c and d) showed an obvious metastasis of seventh thoracic vertebra body. CT (e and f) at different levels showed an obvious spinal osteoblastic lesion. Postoperative 3 days radiographs (d and e) showed bone cement dispersion was uniform.
Figure 2

A 58 years old male patient with spinal metastasis from lung cancer underwent PKP. Preoperative radiography (a and b) and lumbar MRI including T1 and T2 sequences(c and d) showed an obvious metastasis of third lumbar vertebra body. CT(e and f) at different levels showed an obvious spinal osteoblastic lesion. Postoperative 3 days radiographs (d and e) showed bone cement dispersion was uniform.
Figure 3

VAS scores were recorded to evaluate pain in pre-procedure (pre-op), three days (3d), one month (1m), three months (3m) and 1 year (1y) after PKP. Decrease in VAS was observed during the followup period.