Clinical efficacy of percutaneous vertebroplasty combined with intensity-modulated radiotherapy for spinal metastases in patients with NSCLC

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Objective: This study aimed to evaluate the safety and efficacy of percutaneous vertebroplasty (PVP) combined with intensity-modulated radiotherapy (IMRT) for metastatic lesions of patients with non-small-cell lung cancer (NSCLC) at centrum vertebrae.

Methods: A total of 39 patients with spinal metastatic NSCLC (stage IV) were treated with PVP followed by IMRT (30 Gy/10F/2 W) for metastatic lesion at centrum vertebrae under local anesthesia. Retrospective analysis was done with medical records and radiological data. The change of visual analog scale (VAS), activities of daily living, and kyphotic angle was measured preoperatively. The presence of complications was assessed preoperatively (baseline) at 24 hours, 1 week, and 1, 3, 6, 12, and 24 months postoperatively, or until the patient died or was lost to follow-up. Survival was assessed in the group.

Results: A total of 39 consecutive patients were successfully treated with PVP via a translational approach and IMRT. Their mean VAS score decreased from 7.93±1.09 preoperatively to 4.14±1.15 by the 24-hour postoperative time point and was 3.92±1.23 at 1 week, 4.27±1.93 at 1 month, 3.24±1.35 at 3 months, 2.27±0.96 at 6 months, and 2.59±1.55 at 12 months after the procedure. The mean VAS score at all of the postoperative time points was decreased significantly from the preoperative baseline score (P<0.05). Activities of daily living evaluation showed that the patients had a significantly high life quality after the combined approach (50.9±11.7 vs 82.3±9.9, P<0.05). No severe complications were observed. Mild complications included two cases (5.13%) of asymptomatic cement leakage into the epidural space and one case (2.56%) of paravertebral leakage. Median survival time was extended to 13 months.

Conclusion: The safety and efficacy of PVP combined with IMRT in patients with NSCLC with metastatic lesions at centrum vertebrae and the ability to prevent the diseased vertebrae from further deformation and tumor infiltration into the vertebral body were demonstrated. PVP combined with IMRT should be the optimal technique for treatment of vertebral compression pain resulting from spinal metastatic NSCLC.

Keywords: percutaneous vertebroplasty, IMRT, NSCLC, spinal metastases

Introduction

Patients of non-small-cell lung cancer (NSCLC) with metastatic lesions are often in advanced stages of the disease at the time of diagnosis. Approximately 10% of cancer patients will present with symptoms related to vertebral metastases, and of these 40%–70% will have multiple vertebral levels involved.1 The treatment purpose is, therefore, to palliate pain and prevent complications by reducing the length of hospital stay and by improving performance status. Standard treatments include systemic therapies, such as hormonal therapy, analgesics and bisphosphonates, and local, focused on the lesion, such as radiotherapy (RT) and surgery.2 RT has been used for spinal hemangiomases...
most of them underwent radionucleotide bone scanning and
ography and computed tomography (CT) scanning, while
between PVP combined with IMRT or not was decided by
explanation of therapeutic alternatives, treatment selection
September 2005 and June 2013 in our hospital. Following an
surgery, and are able to tolerate PVP and IMRT between
have technically unresectable cancer, choose to be free from
with spinal metastatic who are medically unfit for surgery,
multiple myeloma.\textsuperscript{7} Percutaneous vertebroplasty (PVP) can also
be performed as a complement to RT to provide immediate
vertebral stabilization. Also, it is a minimally invasive per
cutaneous procedure that is performed with the patient under
light sedation and local anesthesia.

Only a few studies report on the long-term outcome of
PVP combined with IMRT in the treatment of metastatic
lesions of the spine.\textsuperscript{8–10} In this study, we evaluated the fea
sibility, efficacy, safety, and clinical pathways of PVP com
bined with IMRT for the treatment of osteolytic metastasis
and compression fractures at centrum vertebrae in patients
with NSCLC.

Patients, materials, and methods

Ethics

The study protocol was in accordance with the ethical guide
lines of the 1995 Declaration of Helsinki and was approved
by independent ethics committees at Daping Hospital, Third
Military Medical University (Chongqing, People’s Republic
of China). Written informed consent was obtained from the
patients for the publication of this report and any accompa
nying images.

Patient characteristics

The retrospective study involved 39 patients with NSCLC
with spinal metastatic who are medically unfit for surgery,
have technically unresectable cancer, choose to be free from
surgery, and are able to tolerate PVP and IMRT between
September 2005 and June 2013 in our hospital. Following an
explanation of therapeutic alternatives, treatment selection
between PVP combined with IMRT or not was decided by
the patient with the oncologists.

The mean age of the study participants was 56 years
(range: 39–74 years). All patients underwent plain radi
ography and computed tomography (CT) scanning, while
most of them underwent radionucleotide bone scanning and
magnetic resonance imaging of the spine. The most com
monly involved spine levels are between T10 and L5. Table 1
summarizes the characteristics of the patients in this study.
The length of follow-up review was calculated from the date
of procedure to the most recent clinic visit or death.

Treatment procedure

PVP was performed as mentioned elsewhere.\textsuperscript{11} Briefly, PVP
was performed with a digital subtraction angiography unit
with a C-arm (Angiostar, Siemens) in the neurointerventional
angiography suite. Anatomic landmarks and structures differ
according to the vertebral level. Depending on the site of
the lesion in the thoracic and lumbar regions, four different
approaches were possible: the transpedicular approach, with
reliance on vertebral pedicles as landmarks; the postero
lateral approach, which was initiated at a point. Unilateral
transpedicular approach was used in most of patients. The
metastatic area was sterilized, and local anesthesia of the
skin and soft tissues was achieved by injecting 3 mL of 1%
lidocaine. The needle tip was positioned as near to anterior
margin of vertebral body as possible. The cement injection
process was continuously monitored under fluoroscopic
control in the lateral plane. Approximately 0.5 mL of pre
pared bone cement (approximately 20 g PMMA powder
mixed with 10 mL monomer until suitable for injection)
was then injected prior to scanning. Cement injection was
terminated when the PMMA reached the posterior margin
of the vertebral body. Immediately, a three-dimensional
CT scan was then performed to determine the distribution
of the cement after withdrawal of the needle and completion
of the PVP (Figures 1 and 2). Antibiotics were administered
1 day before and for 2 days after the procedure.

The IMRT was performed in the vertebroplasted vertebras
and others with osteolytic lesion after patients undergoing
PVP for approximately 3 days using an 8 MV linear (Precise
Treatment System\textsuperscript{TM}; ELEKTA, Stockholm, Sweden) at a
dose rate of 2 Gy/min with standard fractionation.\textsuperscript{12} Before
treatment, all plans underwent a quality assurance test that
included a film isodose curve comparison and absolute dose
check with an ion-chamber at the isocenter under a cylindrical
water phantom designed in-house. IMRT plans were prepared
using the Helio inverse planning system. The gross tumor
volume (GTV) of a tumor was defined as the volume of gross
visible tumor plus margins of approximately 2–4 mm. The
clinical tumor volume (CTV) was defined as the GTV plus a
margin. The planning target volume was defined as the CTV
plus 3 mm margins. To minimize the field-to-field junction
error, the upper and lower regions were irradiated using an
anterior–posterior portal with the same isocenter as IMRT.
### Table 1 Clinical characteristics of 39 patients with NSCLC with spinal metastasis

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**Abbreviations:** AD, adenocarcinoma; F, female; M, male; NSCLC, non-small-cell lung cancer; OS, overall survival; PVP, percutaneous vertebroplasty; RT, radiotherapy; SCC, squamous cell carcinoma.

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**Figure 1** X-ray image scan and serial radiographs of PVP to T10–T12 in a patient with NSCLC with multifocal metastases.  
**Notes:** (A) The location of metastasis before PVP. (B) The needle tip was positioned as near to anterior margin of vertebral body. (C) The PMMA reached the posterior margin of the vertebral body. (D) 3D computed tomography scan after withdrawal of the needle and completion of the PVP.  
**Abbreviations:** NSCLC, non-small-cell lung cancer; PMMA, polymethyl methacrylate; PVP, percutaneous vertebroplasty.
treatment. To design an inverse plan with the potential to provide both physical and biologic benefits, we assigned different doses to different targets, similar to the concept of simultaneous integrated boost. The dose regimen was designed to keep the CTV receiving conventional fractionation but to accelerate the dose to the GTV. Initially, 30 Gy were administered to the metastatic area in 10 fractions over 2 weeks. The goal was to deliver a minimum dose of 30 Gy to the metastatic area.

Assessment indices
A visual analog scale (VAS), which was rated pain status of patients before and after the procedure, was performed according to standard procedures as previously described. VAS was classified as follows: a score of 0 indicated no pain and a score of 10 represented maximal pain. All enrolled patients were included in the intention-to-treat analysis of efficacy. The other assessment dates, including VAS, treatment response, mainly in terms of degree of pain et al were obtained by conducting clinical interviews in person, via telephone, or via mail at fixed intervals after their treatment sessions (at 1 week and 1, 3, 6, and 12 months) or until the patient died or was lost to follow-up. The analgesic efficacy of PVP was recorded, based on 50% or greater improvement in pain versus baseline.

The complications of the treatment, including severe complications (ie, tumor-related symptoms, pulmonary embolism, cardiogenic failure, septic shock, respiratory failure, or death) and mild complications (ie, infection, asymptomatic cement leakage) were recorded together with each patient’s clinical information. The activities of daily living (ADL) scale is frequently used in clinical trials for tumor and assesses patient functional ability. Changes in ADL scales were observed for patients. The ADL scale is as follows: very effective – the decrease of ADL score was >6 after treatment, effective – the decrease of ADL score was ≥3 and smaller than 6 after treatment, and invalid – the increase of ADL score was <3.

Statistical analysis
Statistical analysis was performed with SPSS 13.0 (SPSS Inc., Chicago, IL, USA). Survival rates were calculated from the date of the initiation of treatment until death or the last follow-up for surviving patients using the Kaplan–Meier method. Values are given as mean ± standard deviation. A P-value <0.05 was considered statistically significant.
Results
Thirty-nine consecutive patients were successfully treated with PVP via a translateral approach combined with IMRT. All the PVP procedures were completed within 40 minutes to 1 hour. The numbers of patients available for VAS evaluation at each follow-up interval were 39 (100%) at 24 hours and 1 week, 38 (97.44%) at 1 month, 27 (68.23%) at 3 months, 17 (43.59%) at 6 months, and 6 (15.38%) at 1 year. Their mean VAS score decreased from 7.93±1.09 preoperatively to 4.14±1.15 by the 24-hour postoperative time point and was 3.92±1.23 at 1 week, 4.27±1.93 at 1 month, 3.24±1.35 at 3 months, 2.27±0.96 at 6 months, and 2.59±1.55 at 12 months after the procedure. The mean VAS score at all of the postoperative time points differed significantly from the preoperative baseline score (P<0.05; Figure 3). ADL evaluation showed that the patients had a significantly high life quality after the operation for 6 months (50.9±11.7 vs 82.3±9.9, P<0.05; Table 2). No other severe complications were observed. Mild complications included two cases (4.86%) of asymptomatic cement leakage into the epidural space and one case (2.43%) of paravertebral leakage.

The length of follow-up review was calculated from the date of procedure to the most recent clinic visit or death. Median survival time was extended to 13 months in this group (Figure 4).

Discussion
Incidence of spine metastases is likely to increase as cancer patients live longer partly due to early detection and also because of improvements in medical care. Bone metastases are a frequent complication of cancer and bones are the third most common site for metastases following lung and liver.13 Of the various bones, the spine is the most common site of metastases. Within the spine, the incidence varies, thoracic (68%–70%), lumbosacral (16%–22%), and cervical (8%–15%).14 The treatment of painful vertebral metastases is a major therapeutic challenge. RT is efficacious in palliating painful uncomplicated bone metastases, especially for multifocal lesions and can reduce analgesic requirements for these patients. The RT overall response rates were approximately 60%.15 Tumor inhibition of the release of chemical pain mediators is the main mechanism by which RT probably acts. However, RT does not correct spinal instability, and its efficacy is delayed. Unlike the delayed effects of RT, PVP provides immediate strengthening of the anterior column, which may limit painful vertebral body fracture.

Results of other studies of PVP: in metastatic spinal disease, for example, Lim et al16 performed PVP in 185 vertebral body of 102 patients, 81% patients with metastases, and 19% with multiple myeloma. The reported mean follow-up period was 12.2 months. VAS score for back pain was 8.24 preoperatively, 3.59 at postoperative 1 day, 4.08 at postoperative 3 months, and 5.22 postoperative at 1 year; vertebral body compression ratio changed from 21.33% preoperatively to 13.82% (postoperative 1 day), 14.36% (3 months), and 16.04% (1 year). Cortet et al17 reported on the treatment of PVP in 37 patients, 29 with metastases, and eight with multiple myeloma. They found a decrease in pain within 48 hours of PVP in 97% of their 37 patients, complete pain relief in 13.5%, significantly reduced pain in 55%, and moderately reduced pain in 30%. Beneficial effects were seen in 89% at 3 months and 75% after 6 months. Fourney et al18 have performed PVP and kyphoplasty in patients undergoing 65 vertebroplasties and 32 balloon kyphoplasties; pain was completely absent in 84% and no change in 9%. The median

Figure 3 Visual analog scale (VAS) change of patients of at each pre- and postoperative follow-up time.

Notes: Data are expressed as mean ± standard deviation. The differences between the VAS scores prior to VP and at 1 day, 1 week, and 1, 3, 6, and 12 months, respectively, are statistically significant (P<0.05). *P<0.05 in comparison to preoperative.

Abbreviations: Preop, preoperative; VP, vertebroplasty; N, number of follow-up patients.
The mean VAS score at all of the postoperative time points differed significantly from the preoperative baseline score ($P<0.05$). No severe complications were observed. These results are in concordance with our result, which demonstrated significant change of VAS after PVP.

The majority of studies have found a reduction in pain after VP, with the improvement in pain ranging from 20% to 79% at 1 month in the literature. In this study, we first performed the treatment of PVP combined with IMRT for vertebral metastases of patients with NSCLC and evaluated the safety and efficacy of the treatment for these patients. Pain relief remained in 97.44% of the cases (38 of 39) at 1 month follow-up and in 43.59% of the cases at 6 months.

From our results, we can see that the mean VAS score decreased significantly by the 24-hour postoperative time point and was 2.59±1.55 at 12 months after the procedure. ADL evaluation has also showed that the patients had a significantly high life quality after the operation for 6 months. No other severe complications were observed. Mild complications included two cases (5.13%) of asymptomatic cement leakage into the epidural space and one case (2.56%) of paravertebral leakage. All these results have showed that the treatment is safe and effective on these patients.

The VP was performed prior to radiation therapy in our study, which corroborates the opinion from Zhao et al. The reason for this regimen includes that 1) the analgesic effects of the former are immediate and spinal stability is addressed; 2) the radiation therapy can lead to hardening of the bone, making the VP more difficult to perform; and 3) the malignant tissue is compressed and relocated to subcortical areas in VP, which support local control by radiation therapy later.

Median survival with spinal metastasis usually ranges from 3 to 18 months with RT. Median survival time in our group was extended to 13 months in the PVP combined with IMRT; there were no significant differences with other studies for patients with spine metastatic patients in overall survival. It also showed that PVP combined with IMRT was only local and incomplete therapy for advanced patients with NSCLC, and systemic therapies, including chemotherapy, and molecular targeted therapy should be considered.

Of course, there are some limitations to our study. First, this was a retrospective, nonrandomized study. The sample size was small, and reasons for this include slow recruitment and patients’ choice of other treatment regimes. Furthermore, there were a lack of references about randomized controlled trials for the assessment of VP as a therapeutic regime for lumbar scoliosis. Future extended studies with larger patient

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<td>Total</td>
<td>50.9±11.7</td>
<td>82.3±9.9</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

Abbreviations: ADL, activities of daily living; NSCLC, non-small-cell lung cancer; ns, not significant; N, number of patients.

Figure 4 Overall survival curves of each treatment modality for patients with NSCLC.

Note: Median survival time was extended to 13 months in PVP combined with IMRT.

Abbreviations: IMRT, intensity-modulated radiotherapy; NSCLC, non-small-cell lung cancer; PVP, percutaneous vertebroplasty.
sample are necessary to support and prove these preliminary results. In conclusion, PVP combinations with IMRT could be a safe and effective procedure as a treatment for painful bone metastatic cancer.

Disclosure
The authors report no conflicts of interest in this work.

References