Unieextrapedicular Kyphoplasty for the Treatment of Thoracic Osteoporotic Vertebral Fractures

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abstract

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Osteoporotic vertebral compression fractures are common and cause pain and disability. Most osteoporotic vertebral compression fractures occur in the lower thoracic and thoracolumbar spine. Percutaneous balloon kyphoplasty through a transpedicular approach is a classic procedure performed to treat osteoporotic vertebral compression fractures. However, due to the slender morphology of the pedicles, small pedicle size, and the angular severity of thoracic kyphosis, performing kyphoplasty in middle and high thoracic levels is technically challenging. The purpose of this retrospective study was to evaluate the clinical outcomes of single-balloon kyphoplasty for the treatment of thoracic osteoporotic vertebral compression fractures via an extrapedicular approach. Between July 2004 and May 2008, thirty-eight patients with thoracic osteoporotic vertebral compression fractures underwent percutaneous kyphoplasty via a unilateral extrapedicular approach. Average patient age was 60.3 years. Symptomatic levels ranged from T4 to T12. All affected vertebrae were identified via physical examination, magnetic resonance imaging, and radiographs. Pain relief, vertebral height restoration, and kyphosis correction were compared pre- and postoperatively using the visual analog scale and radiographs. The operation was successful in all patients. Average injected bone cement volume was 3.2±1.4 mL. Mean follow-up was 9.5 months. Visual analog scale pain score improved in 36 of 38 patients postoperatively. Mean visual analog scale pain score was 8.92±0.682 preoperatively and 2.40±0.31 postoperatively and remained at 2.80±0.34 until last follow-up. Mean middle body height correction ratio was 50.9%±34.6%. No lateral wedging was found in the coronal alignment of the treated vertebrae. Three (7.9%) patients sustained cement extravasation with no adverse events. Kyphoplasty through a unilateral extrapedicular approach can achieve convergent and proper cement filling in the affected vertebrae to effectively restore stiffness, relieve pain, and correct kyphosis in fractured vertebrae.

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Steeroporotic vertebral compression fractures are common and cause pain and disability. Most osteoporotic vertebral compression fractures occur in the lower thoracic and thoracolumbar spine. Percutaneous balloon kyphoplasty through a transpedicular approach is a classic procedure performed to treat osteoporotic vertebral compression fractures. However, due to the slender morphology of the pedicles, small pedicle size, and angular severity of thoracic kyphosis, kyphoplasty in the middle and high thoracic levels presents technical challenges. This article describes 38 consecutive patients who underwent single-balloon kyphoplasty through an extrapedicular approach and their early clinical outcomes.

**Materials and Methods**

Between July 2004 and May 2008, a total of 38 consecutive patients (52 vertebrae) with thoracic osteoporotic fractures underwent balloon kyphoplasty via a unilateral extrapedicular approach. Twelve patients were men and 26 were women with a mean age of 60.3 years (range, 55-72 years). All patients had persistent back pain related to fractured vertebrae. Symptom duration ranged from 3 days to 3 months. Symptomatic levels ranged from T4 to T12; 27 patients had fractures at 1 level, 10 at 2 levels, and 1 at 3 levels. The target vertebrae were identified via physical examination, magnetic resonance imaging (MRI) (lower signal on T1-weighted MRIs and high signal on T2-weighted MRIs), radiographs, and computed tomography (CT) scans showing that the posterior vertebral wall of all pathologic vertebrae were intact. Pain relief, restoration of vertebral height, and kyphosis correction were compared pre- and postoperatively using the visual analog scale (VAS) pain score and radiographs.

**Surgical Technique**

Patients were placed in the prone position on radiolucent operating tables. Preoperatively, 50 mg of pethidine was injected intravenously to alleviate pain. A C-arm fluoroscopic machine (OEC Flurostar Compact D; GE Medical Systems, Inc, Salt Lake City, Utah) was used to view simultaneous anteroposterior (AP) and lateral projections of the spines. After skin preparation and draping were performed, the operative vertebrae, including the pathologic vertebra and the pedicle of the operative side, were positioned on the fluoroscope. An incision was made via the unilateral approach in the thoracic spine approximately 1 cm lateral to the costotransverse joint of the affected vertebrae. Local anesthesia (lidocaine) was administered.

As confirmed on the AP fluoroscopic view, a disposable 11-gauge bone marrow needle (Manan Medical, Northbrook, Illinois) was directed at 40° to 45° related to the AP vertebral axis (Figure 1) and was advanced along the direction of the pedicle on the lateral view. When the needle tip arrived at the cortex of the costotransverse joint, it was adjusted to reach just anterior to the base and adjacent to the upper one-half of the pedicle. It was then advanced into the vertebral body, pointing toward the center of the vertebral body. Once the needle reached the posterior cortex of the vertebral body and before it transgressed the medial wall of the ipsilateral pedicle in the AP view, the needle tip was positioned anterior to the posterior wall of the vertebral body. A guidewire was then inserted through the needle and advanced to the anterior two-thirds of the vertebral body. Then, the needle stylus was withdrawn and the Osteo Introducer handle and cannula system (Kyphon, Inc, Sunnyvale, California) over the guidewire was advanced until a working cannula was in place. After the guidewire was removed, a hand drill was introduced through the working cannula and advanced to the center of the vertebral body to create a place for inserting the inflatable bone tamp (Kyphon, Inc). The tip of the drill should be positioned approximately 3 mm from the anterior cortex in the lateral view and should reach the medial outline of the contralateral pedicle in the AP view.

A 15- or 20-mm inflatable bone tamp was then inserted and placed in the middle of the vertebral body on the AP and lateral views. The balloon was slowly expanded until the pressures reached an average of 197 psi (with maximum pressures reaching 390 psi). The balloon was removed when the vertebral height achieved a relatively sufficient restoration. After the inflatable bone tamp was removed, the thick bone cement (Simplex-P; Tianjin, Inc, Tianjin City, China) was injected into the void created by the inflatable bone tamp by using the blunt bone filler under low pressure. Continuous monitoring was performed during injection to complete the filling of the void and to observe the bone cement extravasations.

Postoperatively, patients were placed in the supine position and remained flat.
for 3 hours in bed. Twenty-four hours postoperatively, patients were allowed to ambulate with a brace or orthosis.

Outcome Measures
Operative time, blood loss, and cement priming volume were recorded intraoperatively. Pre- and postoperative pain were measured using the VAS, with possible scores ranging from 0 (no pain) to 10 (worst possible pain). The preoperative scores were compared with the scores obtained 3 days and 6 months postoperatively and at last follow-up.

Radiographic Assessment
The vertical height (anterior and middle) of all fractured vertebrae and the kyphotic angle (Cobb’s method) of the affected vertebrae were measured pre- and postoperatively on standing lateral radiographs of the spine. To eliminate the measurement bias caused by the amplification ratio, the restoration percentage of the height deficit was estimated and compared with a nonfractured adjacent vertebral body [(restored vertebral height-initial fracture height)/(referent vertebral-initial fracture height)]×100%. In all patients, CT scans were obtained to find extravertebral cement leakage.

Statistical Analyses
Paired t tests were conducted to evaluate whether the baseline scores were significantly different from the follow-up scores for each outcome measure. Significance was set at a P value less than .05. All statistic analyses were performed with SPSS version 10 software (SPSS, UK, Ltd, Woking, United Kingdom).

RESULTS
The authors treated 38 consecutive patients (52 vertebrae) between July 2004 and May 2008. Mean operative time was 30 minutes (range, 16-42 minutes) per level. Mean blood loss was 8.7 mL (range, 5-30 mL). Mean balloon pressure was 197±34.6 psi (range, 142-285 psi). Average volume of injected cement was 3.2±1.4 mL (range, 2.25-4.6 mL). No significant complications, such as segment vascular injury or spinal cord lesion, were found intraoperatively. No severe complication occurred related to pulmonary or vascular embolism. Three patients (5 vertebrae) sustained bone cement leakage in the epidural space (n=1) and into the paravertebral muscles (n=2). However, no cement leakage caused clinical symptoms and problems. All patients were ambulant with a brace 1 day postoperatively and were discharged 3 days postoperatively.

Mean follow-up was 9.5 months (range, 6-24 months). Postoperatively, VAS pain score improved in 36 of 38 patients. Mean VAS pain score was 8.92±0.68 preoperatively and 2.40±0.31 postoperatively and remained at 2.80±0.34 until last follow-up, which was statistically significant (P<.05). The clinical and radiographic results are shown in the Table. Pre- and postoperative height measurements were available for all 52 vertebrae. The preoperative anterior and middle body heights, which were 18.55±4.32 and 15.87±4.43 mm, respectively, were significantly restored to 21.54±4.32 and 21.52±3.41 mm, respectively, at last follow-up (P<.05). Mean correction ratio of the middle body height was 50.9%±34.6%. However, no statistical difference existed between the pre- and postoperative posterior body heights (P>.05). Mean kyphotic deformity was corrected from 19.52±4.79° to 10.70±6.44° at 3 days postoperatively (P<.05). Average correction was 8.9°. No lateral wedging or coronal alignment changes occurred in the treated vertebrae (Table; Figure 2).

DISCUSSION
Percutaneous balloon kyphoplasty, introduced by Garfin et al,1 is an effective procedure for the treatment of osteoporotic vertebral compression fractures. Classic kyphoplasty using 2 balloons has achieved excellent clinical results.2 However, the instrument is relatively expensive, and patients and surgeons must be exposed to

Table

<table>
<thead>
<tr>
<th>Score and Results</th>
<th>Preoperatively</th>
<th>3 d Postoperatively</th>
<th>6 mo Postoperatively</th>
<th>Last Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual analog scale pain score</td>
<td>8.92±0.68</td>
<td>2.40±0.31a</td>
<td>2.65±0.40b</td>
<td>2.80±0.34a</td>
</tr>
<tr>
<td>Anterior body height, mm</td>
<td>18.55±4.32</td>
<td>22.90±4.57a</td>
<td>22.85±4.34</td>
<td>21.54±4.32a</td>
</tr>
<tr>
<td>Middle vertebral body height, mm</td>
<td>15.87±4.43</td>
<td>21.62±3.64a</td>
<td>21.60±3.51</td>
<td>21.52±3.41a</td>
</tr>
<tr>
<td>Posterior vertebral body height, mm</td>
<td>26.40±4.52</td>
<td>27.36±5.08b</td>
<td>27.34±5.10</td>
<td>27.33±5.12b</td>
</tr>
<tr>
<td>Restoration ratio of middle body height, %</td>
<td>51.3±35.0</td>
<td>51.0±34.8</td>
<td>50.9±34.6</td>
<td></td>
</tr>
<tr>
<td>Kyphotic angle of pathologic vertebra, degrees</td>
<td>19.52±4.79</td>
<td>10.70±6.44a</td>
<td>10.96±7.10a</td>
<td>11.22±6.51a</td>
</tr>
</tbody>
</table>

aCompared with preoperatively: P<.05.
bCompared with preoperatively: P>.05.
In the current series, fluoroscopically guided percutaneous kyphoplasty was successful at all levels from T4 to T12 via a unilateral extrapedicular approach. No complication occurred related to the cannula and cement injection.

Several biomechanical cadaveric studies⁴,⁶ have reported a positive correlation between the cement volumes injected and restoration of fractured vertebral stiffness. The effective and symmetrical cement filling of fractured vertebrae restored vertebral stiffness, avoided lateral wedging of the vertebrae, and corrected kyphosis. Belkoff et al.⁵ reported that using 5 to 10 mL of bone cement per level and 2 balloons achieved excellent pain relief and kyphotic correction in the treatment of osteoporotic vertebral fractures. The current authors questioned whether the single-balloon technique, which used a mean injected bone cement volume of 3.5 to 4.5 mL, could restore vertebral stiffness. Belkoff et al.⁵ and Tohmeh et al.¹³ reported that using 2 mL of cement for vertebral filling restored the stiffness of the affected vertebrae to approximately 50% of the stiffness of a normal thoracic vertebra and that using 6 mL of cement required the compression lumbar vertebrae to their normal rigidity. A retrospective study of 817 patients with osteoporotic vertebral fractures reported by Knavel et al.¹⁴ showed that no statistical differences existed in the VAS and Roland-Morris Disability Questionnaire between patients who underwent semi-vertebral bone cement filling and bilateral cement filling; this revealed that no direct correlation existed between the volume of bone cement injected and clinical pain relief. Papadopoulos et al.¹⁵ reported that 142 patients with osteoporotic vertebral fractures who underwent a unilateral transpedicular approach achieved satisfactory results in terms of VAS and Oswestry Disability Index scores and that mean bone cement volume and average middle vertebral body height restoration were 4.5 mL and 48.9%, respectively.
In the current series, bone cement filling of all vertebrae passed through the midline of the vertebral body. Mean amount of injected bone cement was $3.2 \pm 1.4$ mL per level. All patients had at least 1 year of follow-up. Visual analog scale pain scores improved in 36 (95%) of 38 patients postoperatively. Mean correction ratio of middle body height was $50.9\% \pm 34.6\%$, and average postoperative kyphosis correction was 8.9°. No lateral wedging or changes in coronal alignment were found at last follow-up. Compared with the 2-balloon techniques, the current technique showed similar clinical results with regard to back pain relief and kyphosis correction in the treatment of osteoporotic vertebral compression fractures.

Ledlie and Renfro reported that the incidence of adjacent vertebral fractures was approximately 4.5% per year. In the current series, 2 (5.26%) of 38 patients sustained adjacent vertebral fractures and underwent a second percutaneous kyphoplasty. Fractures secondary to the primary percutaneous kyphoplasty procedure occurred in the upper adjacent vertebrae and upper interval vertebrae of the treated vertebrae 40 days and 1 month postoperatively, respectively. The current incidence of cement leakage was 7.9%, which was close to that of 2-balloon percutaneous kyphoplasties. Among the current 38 patients, the 3 early patients sustained bone cement leakage in the intervertebral space ($n=1$) and into the paravertebral muscles ($n=2$). No cement leakage caused clinical symptoms and problems. With the improvement in the filling techniques, including keeping the tip of the cement filler seated just beneath the posterolateral wall of the vertebrae before cement cloting and sustaining proper augmentation of the fractured vertebrae and cement filling, the later 35 patients had good cement filling with no leakage.

**Conclusion**

Percutaneous kyphoplasty via a unilateral extrapedicular approach has advantages in treating osteoporotic vertebral compression fractures. It can achieve the convergent and proper filling of cement in the affected vertebrae to effectively restore stiffness, relieve pain, and correct kyphosis in fractured vertebrae. In addition, based on the procedure on 1 side, the procedure was easier to perform than 2-balloon techniques or percutaneous kyphoplasty through a transpedicular approach. It can reduce operative time, radiation exposure for patients and surgeons, costs, and the incidence of adjacent vertebral fractures, which are usually caused by overfilling the cement in the affected vertebrae. However, in severe kyphotic spines, pinning the pleura and dural sac and intervertebral disk is relatively easier by using the extrapedicular approach. If the path of the extrapedicular approach cannot be adjusted to insert and inflate a balloon, the authors usually stop the procedure and switch to a classic pedicular approach to avoid severe complications, including the injuries related to the pricking procedures and probable intraspinial cement leakage.  

**References**