Osteoporotic vertebral compression fractures with an intravertebral cleft treated by percutaneous balloon kyphoplasty

G. Wang, H. Yang, K. Chen

From The First Affiliated Hospital of Soochow University, Suzhou, China

We investigated the safety and efficacy of treating osteoporotic vertebral compression fractures with an intravertebral cleft by balloon kyphoplasty. Our study included 27 patients who were treated in this way. The mean follow-up was 38.2 months (24 to 54). The anterior and middle heights of the vertebral body and the kyphotic angle were measured on standing lateral radiographs before surgery, one day after surgery, and at final follow-up.

Leakage of cement was determined by CT scans. A visual analogue scale and the Oswestry disability index were chosen to evaluate pain and functional activity. Statistically significant improvements were found between the pre- and post-operative assessments (p < 0.05) but not between the post-operative and final follow-up assessments (p > 0.05). Asymptomatic leakage of cement into the paravertebral vein occurred in one patient, as did leakage into the intervertebral disc in another patient.

We suggest that balloon kyphoplasty is a safe and effective minimally invasive procedure for the treatment of osteoporotic vertebral compression fractures with an intravertebral cleft.
Two patients had been treated with steroids for more than three weeks. All the patients had severe back pain with no evidence of nerve damage. The symptoms, which had an insidious onset, had persisted for more than one month (one month to ten years) and were refractory to conservative therapy, such as bed rest and treatment with analgesics and anti-osteoporosis medication. All the patients had osteoporosis, identified before operation by dual-energy x-ray absorptiometry (DXA). The mean degree of osteoporosis was 0.591 g/cm. The mean T score was -4.75 (-6.87 to -2.79) as measured from the L-spine.

Diagnostic criteria of the intravertebral cleft. The intravertebral cleft was assessed by radiographs, MR and CT scans. It is a radiotranslucent zone on plain standing radiographs. There is a low signal intensity in the location of the cleft on T1-weighted images, a high signal intensity on T2-weighted MRI and short tau inversion recovery (STIR), and a cleft sign on CT scans (Figs 1 to 3). Table I shows the vertebral levels.

Surgical technique. The operation was undertaken under general or local anaesthesia with fluoroscopic guidance. Guide wires were initially inserted in order to obtain bilateral transpedicular access to the fractured vertebral body. The opening was gradually enlarged using successively larger cannulae. Kyphon balloon tamps (Kyphon Inc., Sunnyvale, California) were inserted through the cannulae and placed in the anterior three-quarters of the vertebral body on the lateral view, and covering both sides to the midline on the anteroposterior view. The balloons were then inflated slowly to reduce the fracture and to create a void for the injection of cement. The inflation was stopped when the pressure reached between 150 psi and 300 psi or if the balloon made contact with the endplate. At this time the volume of the balloons was noted. They were then deflated and removed. Polymethylmethacrylate (PMMA) cement was injected incrementally to fill the cavity. The bone cement introducer was then pulled back slightly but kept in until the cement hardened. The mean amount of PMMA injected was 5.88 ml (3.0 to 9.0). Patients were mobilised 12 to 24 hours after the procedure.

Efficacy assessments. Efficacy was assessed before operation, one day after operation and at final follow-up assessments following the balloon kyphoplasty. The anterior and middle heights of the vertebral and the kyphotic angle were measured on a standing lateral radiograph. Cement leakage was detected by post-operative CT scans. In addition, a visual analogue scale (VAS) from 1 to 10 (1, no pain; 10, worst possible pain) and the Oswestry Disability Index (ODI) were recorded.
Statistical analysis. Comparison of the pre- and post-operative assessments and the immediate post-operative and final follow-up assessments were analysed with SPSS 13.0 (SPSS Inc., Chicago, Illinois) using paired sample t-tests. A p-value of < 0.05 was considered to be statistically significant.

Ethical considerations. Ethical approval for the study was obtained and written informed consent was obtained from all patients.

Results
All patients tolerated the procedure well (Fig. 4) and experienced partial or complete relief of their back pain and mobilised satisfactorily. The mean follow-up was 38.2 months (24 to 54). There were significant improvements in the mean kyphotic angle, VAS and ODI at the immediate post-operative and final follow-up assessments compared with the pre-operative values (Table II). There were no significant differences between the immediate post-operative and final follow-up assessments (Table III).

No major peri-operative complications were recorded, such as compression of the spinal cord, pulmonary embolism, or infection. Asymptomatic leakage of cement into the paravertebral vein occurred in one patient and leakage into the intervertebral disc in another patient.

Discussion
The incidence of osteoporotic VCFs with an intravertebral cleft has increased as imaging technology has improved. The condition develops in three stages: 1) The vertebra is intact or with a minor compression fracture, 2) the vertebral body collapses with dynamic mobility via the cleft, and 3) the posterior wall of the vertebral body collapses with ensuing cord compression, resulting in further back pain and/or paraparesis.3 Once osteoporotic VCFs with a cleft have progressed into serious collapse (> 75% of body height collapsed), there is an increased risk of nerve injury. Lafforgue et al13 reported that in 19 cases of VCF with a cleft there were five with nerve injury, including compression of a
lumbar nerve root, the cauda equina syndrome, and spastic paralysis. In addition, the patients in this study received long-term conservative management with pain control, bracing and bed rest but with no improvement in the symptoms. Thus an intravertebral cleft may not respond to conservative treatment and surgical intervention may be required to relieve symptoms and prevent further vertebral collapse.

We used balloon kyphoplasty to treat VCFs with intravertebral clefts. The intravertebral instability at the site of clefts can disappear after injection of the cement. Our patients all achieved partial or complete pain relief and an improvement in the level of daily activity. There was also some post-operative correction of the kyphosis and restoration of the vertebral height, which were not lost during follow-up. The results suggest that this procedure can be effective in the treatment of osteoporotic VCFs with a cleft. Peh et al\textsuperscript{10} reported that there was no pain relief in 4 (22.2\%) of 19 patients with VCFs with an intravertebral cleft treated by percutaneous vertebroplasty. Ha et al\textsuperscript{7} reported that patients with an intravertebral cleft had less reduction of pain and more inconvenience in daily life after percutaneous vertebroplasty than those without a cleft, and found that their correction of kyphosis and the restoration of height were partially lost at final follow-up. The results of Ha et al\textsuperscript{7} are similar to those of McKiernan, Jensen and Faciszewski.\textsuperscript{15} Thus it seems that balloon kyphoplasty might be more effective than vertebroplasty for VCFs with an intravertebral cleft. We believe that balloon kyphoplasty offers the additional advantages of restoring height of the vertebral body and correcting kyphosis with the use of sufficient volumes of cement. Garfin, Yuan and Reiley\textsuperscript{16} suggested that vertebroplasty leads to inadequate initial fixation of the cleft, resulting in clinical failure.

There was a high rate of cement leakage in VCFs with an intravertebral cleft treated by vertebroplasty. Ha et al\textsuperscript{7} reported an incidence of cement leakage of 75\% in VCFs with an intravertebral cleft treated by vertebroplasty. In the present study, cement leakage occurred in two cases (7.4\%), which is lower than the rates of 55\% to 79\% reported recently.\textsuperscript{7,10,12} The bone cement is injected under lower pressure in kyphoplasty than in vertebroplasty and can be more viscous when injected.\textsuperscript{8} Jung et al\textsuperscript{12} found that leakage of cement occurred mainly into the disc (65\%). This is almost always asymptomatic at short- or midterm follow-up.\textsuperscript{17} However, it may increase the risk of fracture of adjacent vertebral bodies due to increased mechanical pressure resulting from the cement.\textsuperscript{17,18} This higher rate, compared with that of VCFs without intravertebral clefts, may be attributed to the cleft as leakage into the disc almost always occurs at the site of the cleft.\textsuperscript{10} Thus, we believe that VCFs with an intravertebral cleft should be assessed on CT scans before operation, in order to determine where the cracks in the vertebral wall and the cleft itself are located. In the present study, for those patients with a defect of the anterior wall, cement was first injected when it was in the middle to later stages of viscosity in an effort to reduce the fracture of the vertebral body. After the defect was corrected with this higher viscosity cement, more cement (in the earlier stages of viscosity) was injected to stabilise the vertebra without leakage. In VCFs

### Table II. Efficacy outcomes (mean; range) at pre- and post-operative assessments (n = 27)

<table>
<thead>
<tr>
<th></th>
<th>Pre-operative</th>
<th>Post-operative</th>
<th>t</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertebral body height (%)\textsuperscript{1}</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>375 (20 to 50)</td>
<td>74.2 (55 to 90)</td>
<td>-14.96</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Middle</td>
<td>45.9 (34 to 60)</td>
<td>76.4 (65 to 85)</td>
<td>-11.69</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Kyphotic angle (*)</td>
<td>26.5 (15 to 55)</td>
<td>12.38 (8 to 20)</td>
<td>4.92</td>
<td>0.0004</td>
</tr>
<tr>
<td>Visual analogue scale for pain</td>
<td>8.7 (7 to 10)</td>
<td>2.7 (1 to 5)</td>
<td>23.70</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Oswestry Disability Index</td>
<td>81.8 (70 to 95)</td>
<td>32.7 (20 to 50)</td>
<td>19.36</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

\textsuperscript{1} vertebral body height (%) = Fracture vertebral body height [(upper vertebral body height + lower vertebral body height)/2]

### Table III. Efficacy outcomes (mean; range) at post-operative and final follow-up assessments (n = 27)

<table>
<thead>
<tr>
<th></th>
<th>Post-operative</th>
<th>Final follow-up</th>
<th>t</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertebral body height (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>74.2 (55 to 90)</td>
<td>72.5 (55 to 90)</td>
<td>2.06</td>
<td>0.0621</td>
</tr>
<tr>
<td>Middle</td>
<td>76.4 (65 to 85)</td>
<td>74.5 (60 to 82)</td>
<td>2.07</td>
<td>0.0603</td>
</tr>
<tr>
<td>Kyphotic angle (*)</td>
<td>12.38 (8 to 20)</td>
<td>13.5 (9 to 25)</td>
<td>-1.92</td>
<td>0.0785</td>
</tr>
<tr>
<td>Visual analogue scale for pain</td>
<td>2.7 (1 to 5)</td>
<td>1.7 (0 to 3)</td>
<td>1.80</td>
<td>0.0966</td>
</tr>
<tr>
<td>Oswestry Disability Index</td>
<td>32.7 (20 to 50)</td>
<td>26.9 (15 to 45)</td>
<td>2.00</td>
<td>0.0881</td>
</tr>
</tbody>
</table>

\textsuperscript{1} vertebral body height (%) = Fracture vertebral body height [(upper vertebral body height + lower vertebral body height)/2]
with rupture of the posterior or sidewall of the vertebra, fluoroscopy was used to monitor the injection of cement. Injection was stopped when the cement was near the wall of the vertebral body. In addition, VCFs with a cleft often have more severe compression of the vertebral body. Expansion of the balloon should be moderate to prevent excessive reduction of the fracture which may cause the defects of the vertebral body to enlarge, increasing the risk of leakage of cement.

Percutaneous balloon kyphoplasty is a minimally invasive, effective and safe procedure for treating osteoporotic VCFs with an intravertebral cleft, but the long-term efficacy needs further study.

This work was supported by the National Key Discipline of China and by the Natural Science Foundation of Jiangsu Province (BK2008008).

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

References


