Because of an aging population, osteoporosis and its associated fractures have become an important health issue. Osteoporotic VCFs are associated with an increased incidence of death and morbidity, including back pain, loss of height, kyphotic deformity, and a reduction in quality of life. Since the introduction of PVP by Galibert et al. in 1987, this minimally invasive therapy that involves injection of bone cement in the fractured VB has gained popularity as a stabilizing treatment for osteoporotic VCFs, with resultant relief of associated local back pain. The PKP procedure is a modification of PVP, in which an inflatable instrument is inserted into the VB through the pedicle to restore the height of a collapsed VB and create a cavity inside before the cement is injected. Prospective and retrospective studies have shown that both procedures could give rise to excellent outcomes and significant improvements in pain, analgesic requirements, function, cost, and incidence of serious complications, although Kallmes et al. and Buchbinder et al. reported that improvements in pain and pain-related disability associated

Minimally invasive pedicle screw fixation combined with percutaneous vertebroplasty in the surgical treatment of thoracolumbar osteoporosis fracture

Clinical article

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Object. The purpose of this study was to evaluate the feasibility and safety of minimally invasive pedicle screw fixation combined with percutaneous vertebroplasty (PVP) for treating acute thoracolumbar osteoporotic vertebral compression fracture (VCF) and preventing secondary VCF after PVP.

Methods. Twenty patients with a mean age of 73.6 years (range 65–85 years) who sustained fresh thoracic or lumbar osteoporotic VCFs without neurological deficits underwent minimally invasive pedicle screw fixation combined with PVP. Visual analog scale pain scores were recorded, and the Cobb angles and the central and anterior vertebral body (VB) heights were measured on the lateral radiographs before surgery and immediately, 1 month, 2 months, 3 months, 6 months, 1 year, and 2 years after surgery.

Results. The patients were followed up for an average of 26 months (range 24–30 months) after surgery. The visual analog scale score was found to be significantly decreased; from 7.3 ± 1.3 before surgery to 1.2 ± 0.7 immediately after surgery and to 0.7 ± 0.7 (p < 0.001) at the end of follow-up. The Cobb angle was 17.0° ± 4.3° before surgery and 6.4° ± 3.6° immediately after surgery. The central VB height that was 44.5% ± 7.6% before surgery increased to 74.6% ± 6.4% of the estimated intact central height immediately after surgery (p < 0.001). The anterior VB height increased from 50.7% ± 7.4% before surgery to 82.5% ± 6.7% of the estimated intact anterior height immediately after surgery (p < 0.001). There were no significant changes in the results obtained over the follow-up time period. There was no occurrence of new fracture in surgically treated or adjacent vertebrae in these patients.

Conclusions. Minimally invasive pedicle screw fixation combined with PVP is a good choice for the treatment of acute thoracolumbar osteoporotic VCF and can prevent the occurrence of new VCFs after PVP.

Key Words • osteoporosis • thoracolumbar vertebral fracture • vertebroplasty • percutaneous surgery • pedicle screw fixation • minimally invasive spinal surgery • surgical technique

Abbreviations used in this paper: PKP = percutaneous kyphoplasty; PVP = percutaneous vertebroplasty; VAS = visual analog scale; VB = vertebral body; VCF = vertebral compression fracture.
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with osteoporotic VCFs in patients treated with PVP were similar to the improvements in a control group that underwent a sham procedure.

However, there have been some reports on further compression of previously treated vertebrae and newly developed fractures in adjacent vertebrae after PVP or PKP with no additional trauma. Heo et al. found recollapse of the same vertebra treated with PVP. Lavelle and Cheney reported a 10% incidence rate for recurrent fracture of the treated vertebra after PKP. The study of Kim and Rhyu showed that the incidence of re-compression in treated vertebrae was 12.5%. Jensen and Dion and Liebschner et al. reported that the percentage of polymethylmethacrylate to endplate, and intradiscal cement leakage, have been studied, but remain speculative. An effective strategy for avoiding new VCFs after PVP or PKP has not yet been found.

Clinical studies have shown that combining PKP and pedicle screw osteosynthesis to treat thoracic and lumbar burst fractures could achieve maintenance of sagittal curve and vertebral height correction in the injured vertebrae. In this report we introduce a technique of minimally invasive pedicle screw fixation combined with PVP for treatment of thoracolumbar osteoporotic VCFs. The feasibility and safety of this method for preventing the occurrence of new VCFs after PVP was evaluated.

Methods

Patient Population

The clinical study proposal was approved by the medical ethics committee of our hospital. Between February 2009 and January 2010, 56 patients with osteoporotic VCFs (AO Classification A1) of the thoracic or lumbar spine without neurological deficits were treated with minimally invasive pedicle screw fixation combined with PVP in our hospital, and 20 patients with a recent (< 5 days) fracture were selected for this study. There were 5 men and 15 women with a mean age of 73.6 years (range 65–85 years). Preoperative clinical assessments, neurosurgical, and pain assessments performed using the VAS were obtained. The radiological tests performed prior to surgery included standard anteroposterior and lateral radiographs of the fractured vertebrae; CT scans with axial, sagittal, and coronal reconstruction; and MRI sequences to check that the spinal cord and the posterior ligamentous complex were intact.

Inclusion criteria were the presence of 1) more and more back pain or difficulty turning over in bed after conservative therapy; 2) a recent thoracolumbar osteoporotic VCF (defined as more than 15° of local kyphosis and/or 25% of vertebral height loss); and 3) edema, a fracture line, or both within the VB on MRI studies.

The exclusion criteria were the presence of more than 2 vertebral fractures, spinal cancer, neurological signs, spinal cord compromise, disc damage on MRI, medical conditions that would make the patient ineligible for emergency decompressive surgery if needed, previous vertebroplasty, inability to give informed consent, and a likelihood of noncompliance with follow-up.

The patients were surgically treated on a priority rather than an emergency basis within 1 week after trauma. Minimally invasive pedicle screw-and-rod reduction and fixation (EXPEDIUM, DePuy Spine, and XIA, Stryker Spine) and PVP (Shandong Longguan Co.) were performed in all cases after induction of general anesthesia and antibiotic prophylaxis (2 g cefazolin during surgery and 2 g twice in the following 24 hours). Patients were positioned prone on a radiolucent operating table, with surgical bolsters placed under the thorax and iliac crest to induce spinal lordosis and facilitate the reduction of the fracture. The involved vertebra was identified and the skin was marked under lateral fluoroscopic control before beginning the surgical procedure.

Surgical Procedure

In the first surgical stage, noncannulated pedicle screws were placed in the vertebra adjacent to the fractured one with minimally invasive technique (Fig. 1 left). The minimal access in a paraspinal sacrospinalis muscle-splitting (Wiltse) approach was performed to expose superior articular facet and the root of the transverse process. The entry site to the pedicle was located at the junction between the lateral border of the superior articular facet and the bisecting midline of the transverse process. Once the pedicle had been identified, either a pedicle probe or a handheld curette was used to enter the pedicle. Preoperative anteroposterior and lateral radiographs and CT scans obtained through the pedicles of the VB to be instrumented were studied to determine the correct angle of entry in both the coronal and sagittal planes. The pedicle integrity was verified in all 4 quadrants to be sure that a solid tube of bone existed and that violation into the spinal canal or inferiorly into the neuroforamen had not occurred.

Fig. 1. Left: Photograph showing placement of a pedicle screw into the vertebra adjacent to the fractured one by using a minimally invasive technique. Right: Fluoroscopic image showing injection of cement after minimally invasive pedicle screw-and-rod reduction and fixation.
pedicle screws of appropriate length were then introduced into the VB via the pedicle to engage at least 75% of the VB’s anterior-posterior width. Anteroposterior and lateral radiographs were taken to confirm the screws’ position, and 11- or 13-gauge needles were then passed into the anterior central aspect of the fractured VB through the pedicles under fluoroscopic guidance.

In the second surgical phase, 2 rods of the appropriate size were contoured to maintain normal lumbar lordosis and placed over the pedicle screws through subcutaneous soft tissues and muscles. The fracture was reduced by the combination of the method of installation and distraction applied between 2 screws as necessary. For the PVP procedure, bone cement (polymethylmethacrylate) was injected under constant fluoroscopy into the target VB through the previously placed needles until the cement approached the posterior aspect of the VB or leaked into an extraosseous space, such as the intervertebral disc or an epidural or paravertebral vein (Fig. 1 right).

No external braces were prescribed after the operation. The patients were mobilized as soon as feasible after surgery. After leaving the hospital, patients were encouraged to resume their daily routine and were followed up as outpatients at the hospital ward.

Clinical and Radiographic Evaluation

All the patients underwent clinical assessments to check for neurological deficits, and VAS pain assessments were also done immediately, 1 month, 2 months, 3 months, 6 months, 1 year, and 2 years after surgery. Anteroposterior and lateral radiographs (first supine, and then later standing) were obtained to evaluate the reduction of the fracture, the distribution of the cement, and the position of the implants. A CT scan was obtained to check that no cement leakage had occurred into the spinal canal immediately after operation. Cobb angles and central and anterior VB height were measured on the lateral radiographs. The fractured and restored heights were calculated as a percentage of the estimated, intact VB height immediately after surgery, and 6.7% before surgery to 74.6% ± 6.4% of the estimated intact central height immediately after surgery, and 69.8% ± 6.7% 2 years after surgery. The anterior VB height increased from 50.7% ± 7.4% before surgery to 82.5% ± 6.7% of the estimated intact anterior height immediately after surgery, and 78.8% ± 6.6% 2 years after surgery. Both the Cobb angle correction and the central and anterior VB height gains were significant (p < 0.001). There was no significant difference between the parameters of immediately and 2 years after surgery (Fig. 3). No significant changes in the results obtained were observed at the end of the follow-up period. The results of all the statistical tests performed are given in Table 2. There were no patients with a new fracture of the treated or adjacent vertebrae. No hardware failure was seen in any patient following the instrumentation and vertebroplasty.

Statistical Analysis

Comparison of pre- and postoperative measurements was performed using 1-way ANOVA for independent samples followed by Tukey posthoc analysis for multiple comparison procedures. Statistically significant differences were defined at a 95% confidence level. The values are given as the mean ± SD. The SPSS software (SPSS, Inc.) supported statistical evaluation.

Results

Twenty patients with osteoporotic VCFs (5 men and 15 women) were treated using the surgical method described above. The patients’ characteristics are summarized in Table 1. The lesions were located at the T-11 level in 1 case, T-12 in 5 cases, L-1 in 11 cases, and L-2 in 3 cases. The fractures were classified as type A1.2.1 in 13 cases (65%), A1.2.2 in 2 cases (10%), A1.2.3 in 2 cases (10%), and A1.3 in 3 cases (15%).

None of the patients were found to have postoperative neurological complications. The mean amount of cement injected was 6.1 ml (range 3.8–8.6 ml). The mean duration of the operation was 75 minutes (range 55–90 minutes). There was a mean blood loss of 70 ml (range 65–80 ml), and no blood transfusions were required. The mean stay in the hospital was 5.3 days (range 4–7 days). The patients were followed up for an average of 26 months (range 24–30 months).

The preoperative pain intensity level was 7.3 ± 1.3 on the VAS. The VAS score significantly dropped to 1.2 ± 0.7 (p < 0.001) immediately after the operation and to 0.7 ± 0.7 (p < 0.001) at final follow-up.

In all patients the postoperative radiographs and CT scans demonstrated good positioning of the pedicle screw construct and of the cement in the fractured VB (see examples in Fig. 2). The CT scans also showed that no cement leakage had occurred into the spinal canal, and 2 cases of lateral leakage were diagnosed without clinical consequences. On postoperative examinations, no signs of significant cement resorption or bridging of intervertebral segments were noticed.

The Cobb angle was 17° ± 4.3° before surgery, 6.4° ± 3.6° immediately after surgery, and 7.1° ± 3.6° 2 years after surgery. The central VB height increased from 44.5% ± 7.6% before surgery to 74.6% ± 6.4% of the estimated intact central height immediately after surgery, and 69.8% ± 6.7% 2 years after surgery. The anterior VB height increased from 50.7% ± 7.4% before surgery to 82.5% ± 6.7% of the estimated intact anterior height immediately after surgery, and 78.8% ± 6.6% 2 years after surgery. Both the Cobb angle correction and the central and anterior VB height gains were significant (p < 0.001). There was no significant difference between the parameters of immediately and 2 years after surgery (Fig. 3). No significant changes in the results obtained were observed at the end of the follow-up period. The results of all the statistical tests performed are given in Table 2. There were no patients with a new fracture of the treated or adjacent vertebrae. No hardware failure was seen in any patient following the instrumentation and vertebroplasty.

Discussion

Osteoporotic VCFs can cause debilitating pain and functional decline necessitating prolonged bed rest and high-dose narcotics. Some patients with osteoporotic VCFs can get better without surgery when they lie in bed. However, in this study the patients had more and more back pain or difficulty turning over in bed after fracture. They could not endure bed rest, and came to the hospital for help after conservative therapy, including antipain medicine, had no effect. The PVP and PKP operations are cement augmentation procedures used to control pain and restore function in patients with osteoporotic VCFs that are refractory to conservative treatment.24,34,35,36,39,40,41,42,43,44,45,46,47,48,52,53. However, some studies have shown the recurrent fracture of a previously
Minimally invasive pedicle screw fixation

Verlaan et al.\textsuperscript{51} and Korovessis et al.\textsuperscript{32} performed balloon kyphoplasty in combination with pedicle screw instrumentation to treat thoracic and lumbar burst fractures. All patients recovered uneventfully, and the neurological examination revealed no deficits. The postoperative radiographs and CT or MRI studies demonstrated a good fracture reduction and filling of the bone defect without unwarranted bone displacement. There was no instrumentation failure or measurable loss of sagittal curve and vertebral height correction in the follow-up period. Fuentes et al.\textsuperscript{14} used PKP associated with percutaneous short-segment cannulated pedicle screw osteosynthesis in 18 patients with burst vertebral fractures without neurological deficits. The mean vertebral height was improved by 25\%, and a mean improvement of 11.28° in the local kyphotic angle was obtained. No significant changes in the results obtained were observed at the end of the follow-up period. Minimally invasive methods of treating burst vertebral fractures can be performed via the percutaneous pathway. This approach gives similar vertebral height recovery and kyphosis correction rates to those obtained with open surgery.

There are no reports on the use of pedicle screws and PVP to treat thoracolumbar osteoporotic VCF. We designed the minimally invasive pedicle screw fixation combined with PVP technique for osteoporotic VCF to prevent the occurrence of new VCF after PVP. The results of our study showed that a 17° ± 4.3° Cobb angle before surgery significantly decreased to 6.4° ± 3.6° immediately after surgery (p < 0.001). The central VB height significantly increased from 44.5% ± 7.6% before surgery to 74.6% ± 6.4% of the estimated intact central height immediately after surgery (p < 0.001). The anterior VB height significantly increased from 50.7% ± 7.4% before surgery to 82.5% ± 6.7% of the estimated intact anterior

**TABLE 1: Summary of clinical data in 20 patients with osteoporotic VCF**

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age (yrs), Sex</th>
<th>Fracture Type*</th>
<th>Vertebral Level</th>
<th>VAS Score</th>
<th>Preop</th>
<th>Postop</th>
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<tbody>
<tr>
<td>1</td>
<td>68, F</td>
<td>A1.2.1</td>
<td>T-12</td>
<td>8</td>
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<td></td>
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<tr>
<td>2</td>
<td>76, F</td>
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<td>L-2</td>
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<tr>
<td>3</td>
<td>80, M</td>
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<td>L-1</td>
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<tr>
<td>4</td>
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<tr>
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<td>79, F</td>
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<td>L-1</td>
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<tr>
<td>12</td>
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<td>L-1</td>
<td>8</td>
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<tr>
<td>13</td>
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<td>15</td>
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<tr>
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<td>A1.2.2</td>
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<tr>
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<td>20</td>
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* According to the AO classification system in Cresswell et al.\textsuperscript{10}.

Fig. 2. Axial CT scans obtained immediately after reconstruction, for verification of pedicle screw positioning and to search for cement leakage.
height immediately after surgery ($p < 0.001$). It is more important that the correction of both the Cobb angle and the VB height was stable over time, with a minimal loss of correction at final follow-up ($0.7^\circ$ of kyphosis, $4.8\%$ of central vertebral height, and $3.7\%$ of anterior vertebral height after 2 years), which seemed to occur during the 2 months after surgery. No fracture of the surgically treated or adjacent VB was found in our study.

In this study the fracture was reduced by the combination of the method of installation and proper distraction applied between 2 screws as necessary before PVP. Short-segment pedicle screw instrumentation is a well-described technique to reduce and stabilize thoracic and lumbar spine fractures.\textsuperscript{10,44} It is a relatively easy procedure, but the means of augmenting the anterior column are limited. Hardware failure and a loss of reduction are recognized complications caused by insufficient anterior column support.\textsuperscript{31,39,50} Several studies showed that vertebroplasty with cement was able to restore the strength and stiffness of VCFs, even increase them, in osteoporotic specimens.\textsuperscript{3,5–7,21} In the cadaveric biomechanical study by Mermelstein et al.,\textsuperscript{42} it was found that the injection of cement in a burst fracture reduced the load on the pedicle screw construct that was inserted for fracture stabilization, and vertebroplasty with cement after posterior instrumentation might reduce hardware failure and anterior column collapse. Our study confirmed that there was no hardware failure in any patient following the instrumentation and PVP during follow-up.

In this series the minimally invasive access in the paraspinous sacrospinalis muscle-splitting (Wiltse) approach\textsuperscript{53} was performed to insert noncannulated pedicle screws into the vertebrae, and 2 rods of the appropriate size were placed over the pedicle screws through subcutaneous soft tissues and muscles. Unlike the traditional midline incision, the Wiltse approach protected the attachment of muscle to bone, avoided disruption of the supraspinous and interspinous ligaments, provided a more direct approach to the transverse processes and pedicles, and decreased bleeding and postoperative pain.\textsuperscript{1,27,43} In our study the mean duration of the operation was 82 minutes (range 67–91 minutes) and the mean blood loss was 77.2 ml (range 61.3–93.1 ml). The mean stay in the hospital was 5.3 days (range 4–7 days). The pain intensity level on the VAS dropped significantly, from $7.3 \pm 1.3$ preoperatively to $1.2 \pm 0.7$ ($p < 0.001$) immediately after the operation and $0.7 \pm 0.7$ ($p < 0.001$) at final follow-up. The results show that minimally invasive pedicle screw fixation results in only limited additional trauma in PVP (Fig. 4).

The feasibility and relative safety of minimally invasive pedicle screw fixation combined with PVP were confirmed by the fact that postoperative radiographs and CT scans showed that the screws and cement were all properly positioned in the present series of patients. None of the patients were found to have any postoperative neurological complications. Like all surgical interventions, pedicle screw stabilization is not devoid of risks—it can cause nerve injuries. The pedicle must be carefully probed in all 4 quadrants to be sure that a solid tube of bone exists and that violation into the spinal canal or inferiorly into the neuroforamen has not occurred before the pedicle screws are implanted into the vertebrae with minimally invasive technique under direct vision, as in our study. Cement instillation also involves risks of complications including cement leakage into the spinal canal, which is greater when the posterior wall has been damaged. During the PVP procedure, we injected bone cement into the target VB under constant fluoroscopy, which had to be

<table>
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<th>TABLE 2: Variations of each measured parameter from initial evaluation to last follow-up in 20 patients with osteoporotic VCF*</th>
</tr>
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<tbody>
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<td>Parameter</td>
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<tr>
<td>local kyphosis (°)</td>
</tr>
<tr>
<td>central height (%)</td>
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<td>anterior height (%)</td>
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</table>

* Values are expressed as the mean ± SD. There was a significant difference ($p < 0.001$) between pre- and postoperative values for all parameters.
stopped if the cement got close to the posterior aspect of the VB or leaked into an extraosseous space. All of these measures were taken to avoid the occurrence of neurological deficits and guarantee the safety of the operation.

Compared with percutaneous pedicle screws, minimally invasive noncannulated pedicle screw fixation has incisions of similar size, but easier manipulation and less fluoroscopic monitoring during the operation. The common pedicle screws used in this technique were much cheaper than the percutaneous cannulated ones.

We also realize the limitation of this report in that there is no control group. Further studies should be performed to compare this technique with PVP groups, PKP groups, and nonsurgically treated controls.

Conclusions

Minimally invasive pedicle screw fixation combined with PVP is a good choice for the treatment of acute thoracolumbar osteoporotic VCF and can prevent the occurrence of new VCFs after PVP.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following: Conception and design: Gu, Jiang. Acquisition of data: Gu, Jiang. Analysis and interpretation of data: Gu. Drafting the article: Gu. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Gu. Statistical analysis: Gu. Administrative/technical/material support: Gu, Jiang. Study supervision: Gu, Zhang, Jia, McGuire.

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